

Impact of access to effective post-progression therapies on survival outcomes in first-line randomized oncology trials.

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Background: Effective anticancer systemic therapies are expected to improve overall survival (OS) or quality of life in randomized controlled trials (RCTs) for patients with cancer. However, access to effective post-progression therapies in control arms is inconsistent and may confound the observed OS benefits, especially for agents with known survival benefit in later lines. Here, we investigated whether control-arm post-progression access to effective therapies is associated with improved OS. **Methods:** This cross-sectional analysis included 52 phase II–III RCTs published between 2010 – 2025 in selected high impact journals. Eligible trials evaluated first line targeted therapies (TT), immune checkpoint blockers (ICB), or hormone therapy (HT) in the experimental arm for advanced lung, breast, or prostate cancer, where the investigational agent had proven OS benefit in later lines. Post-progression access to effective therapies was quantified as the proportion of patients in the control arm receiving the investigational agent (or similar class) relative to all pts randomized to control arm (Ratio_Effective/Control), and relative to patients receiving any subsequent treatment (Ratio_Effective/Therapy). Correlations between the ratio of post-progression access and OS HRs were assessed, with prespecified subgroup analyses by treatment class and tumor type. Geographic distribution was evaluated in trials reporting enrollment by region. **Results:** Across all trials, the mean proportion of patients in the control-arm receiving any post-progression therapy was 66% (SD 14%), of which 42% (SD 22%) received an effective therapy (or, 62.5%, considering relative numbers). Post-progression access differed significantly by tumor type ($p < 0.001$), with the lowest rate in breast cancer, followed by prostate and lung cancer. The median proportion of pts enrolled outside the United States and Europe (US/EU) was 36%. The overall median HR for OS was 0.78. No correlation was observed between rate of post-progression access to effective therapies and the HR for OS across studies. However, in TT trials, higher post-progression access to effective treatments was moderately associated with a less pronounced OS benefit ($r = 0.44$, $p = 0.056$, Ratio_Effective/Control and $r = 0.46$, $p = 0.046$, Ratio_Effective/Therapy). No association was observed in RCTs evaluating ICB. The difference in the correlation between the TT and ICB trials was statistically significant ($p = 0.032$). No correlation was observed between ratio of effective therapies and tumor type, and enrollment outside of US/EU. **Conclusions:** Post-progression access to effective therapies in control arms influenced OS benefits in TT trials but not ICB trials in this study. These results warrant caution interpreting TT survival benefits and underscore the need for RCTs to report and standardize post-progression therapy access. Research Sponsor: None.

Expert validation of an artificial intelligence-enabled trial matching solution using real-world data from patients with cancer.

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Background: Under-enrollment in cancer trials remains a major barrier for advancing cancer research in part because few patients are offered clinical trials and pre-screening is manual and laborious. One solution involves artificial intelligence (AI)-enabled centralized screening of patients, but this requires robust validation to facilitate trust and adoption. **Methods:** This is a retrospective study from a large community-academic hybrid cancer center comparing the performance of an AI system - Trial Recommendations using Intelligent Assessment to Guide Eligibility and Enrollment (TRIAGE) - to real-world enrollment using longitudinal electronic health records (EHRs), full versioned trial protocols, and expert clinical research coordinator (CRC) adjudication at the trial- and criterion-levels. The train set was composed of 629 patients and 4,094 patient-trial pairs. A large language model (LLM)-only solution was used to predict successful patient enrollment based only on answers to individual eligibility criteria. Next, a machine learning-based approach was used to train the model on top of LLM responses to yield robust, consistent decision rules across patients, with priorities set by the real-world behavior of CRCs. The test set was comprised of 198 patients with breast, lung, and pancreatic cancers and 793 patient-trial pairs. A stratified random sample of 100 patient-trial pairs (83 patients, 21 trials) underwent manual CRC adjudication. The primary outcomes were sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and Cohen’s κ for trial-level eligibility using a predefined trial match threshold of 0.40, and accuracy for criterion-level decisions. Performance evaluations were based on a binary classification: eligible or potentially eligible vs. ineligible. **Results:** In the training set, TRIAGE demonstrated 72% sensitivity and 90% specificity for trial enrollment. The table summarizes performance metrics in the test set for trial-level eligibility across 3 trial match thresholds. Criterion-level evaluation across 1,770 adjudications showed 93.1% raw agreement, improving to 94.2% after structured re-adjudication; 10/25 (40%) initial CRC discordances were overturned in favor of the AI decision. **Conclusions:** TRIAGE accurately determined trial-level eligibility from real-world EHR data with high performance and strong criterion-level agreement for oncology protocols. The system surfaced potential missed enrollment opportunities and supports adjustable trial-level decision thresholds. Prospective studies of TRIAGE implementation into research workflows are ongoing. Research Sponsor: None.

Trial Match Threshold	Sensitivity	Specificity	PPV	NPV	Cohen’s κ
0.13 (max Sensitivity)	98.7%	97.6%	91.2%	99.7%	0.84
0.40 (study threshold)	78.3%	98.5%	92.6%	94.8%	0.68
0.62 (max Specificity)	39.3%	100%	100%	87.0%	0.45

Development and external validation of a computational approach for accelerated read out of randomized clinical trials in metastatic prostate cancer.

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Background: While overall survival (OS) is the gold standard endpoint for clinical trials in metastatic prostate cancer (mPC), it requires years of follow-up. We sought to develop and externally validate a computational model for accelerated OS readout based on short term (4 months) PSA kinetic data. **Methods:** Longitudinal PSA data were obtained from 8 completed phase 3 mPC trials. Using data from the first 4 months on trial, 18 different PSA kinetic variables were developed, including 50% and 90% decline in PSA, PSA=0.1, and PSA=0.2 at 1, 2, 3, and 4 months, and slope and base of the exponential fit of PSA. TITAN, COU-AA-301, and ACIS comprised the training cohort. Data from those trials was used to model OS using a relaxed LASSO approach. The resulting model was applied to 5 validation trials (see Table 1) to simulate 1,000 potential outcomes for each trial (after Harden and Kropko). For the CHAARTED trial, a model using only PSA-kinetic data was used as most baseline variables were missing. The distribution of 1,000 simulated Hazard Ratios (HR) for each trial was compared against the reported HR. **Results:** Overall, > 100,000 PSA values were used with a total > 7,500 eligible study pts, with ~ 70,000 PSA values and ~5,000 patients comprised the validation cohort. The model identified baseline PSA at treatment, PSA50 at 4 months, and the PSA slope as the most informative PSA predictors of OS. Table 1 below compares the median predicted HR and 95%-interpercentile range from the 1,000 simulations with the reported HR for each validation trial. The model correctly predicted the OS point estimate and 95%-confidence interval using the first 4 months of PSA data in every validation trial. **Conclusions:** A computational simulation approach to predict the OS outcome of phase 3 mPC trials based on PSA kinetics from the first 4 months on trial was developed. This model correctly predicted OS outcomes in 5 completed validation phase 3 trials. This included phase 3 trials with both positive and negative outcomes for OS as well as in both hormone sensitive and resistant mPC, and involving AR signaling inhibitors, chemotherapy and a PARP inhibitor. This model is being further validated with additional completed phase 3 trials, and once prospectively validated, has the potential to significantly shorten the follow up required for OS readout from phase 3 trials in mPC. Research Sponsor: Prostate Cancer Foundation; 22CHAS02.

Predicted vs. reported HR of each trial.

Validation Trial	Predicted HR (median [95 th interpercentile range])	Actual HR [95%-CI]
LATITUDE	0.64 [0.54 – 0.74]	0.66 [0.56 – 0.78]
COU-AA-302	0.69 [0.60 – 0.80]	0.81 [0.70 – 0.93]
MAGNITUDE	1.06 [0.88 – 1.26]	0.97 [0.79 – 1.19]*
CALGB 90401	0.89 [0.78 – 1.01]	0.91 [0.78 – 1.05]
CHAARTED (Unselected)	0.79 [0.61 – 0.98]	0.72 [0.59 – 0.89]
CHAARTED (High Volume)	0.72 [0.53 – 0.92]	0.63 [0.50 – 0.79]
CHAARTED (Low Volume)	0.95 [0.61 – 1.52]	1.04 [0.70 – 1.55]

*Observed HR used as overall OS HR not reported in manuscript.

Impact of outpatient CAR T-cell therapy administration on healthcare utilization in patients with hematologic malignancies.

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Background: CAR T-cell therapy has revolutionized treatment outcomes in hematological malignancies, but has traditionally required inpatient post-infusion monitoring, which is associated with significant cost and time toxicity. Outpatient CAR T infusion and monitoring has been the standard approach at Mayo Clinic site in Rochester, MN, with demonstrated feasibility and safety (Bansal et al., ASCO 2023). We present data comparing healthcare utilization between CAR T recipients who underwent outpatient remote monitoring and those with traditional inpatient monitoring. **Methods:** Electronic medical records were retrospectively analyzed for 293 patients who received CAR T-cell therapy for a hematological malignancy at any of the 3 Mayo Clinic sites (MN, AZ, FL) between 2020 and 2024. Healthcare utilization was compared between patients who received outpatient CAR T with remote patient monitoring in Rochester, MN (N = 125) and those who received inpatient CAR T in the Arizona (n = 90) and Florida (n = 78) sites. Per protocol, patients in the inpatient group underwent mandatory inpatient monitoring for 7 days, with extension per provider discretion. Data was analyzed through Chi-Square and Wilcoxon tests. P values < 0.05 were considered statistically significant. **Results:** There was no significant difference in baseline sex, age, ethnicity, LDH, platelets, or neutrophils among the 293 patients. Diagnoses included lymphoma (n = 175), multiple myeloma (n = 106), and B-ALL (n = 12). The most common CAR T-cell products used were axicabtagene ciloleucel (n = 138) idecabtagene vicleucel (n = 56), and ciltacabtagene autoleucel (n = 50). Median hospital days were lower in the outpatient group vs the inpatient group at 30 days (4.4 vs 13.3, P < 0.001) and 90 days (4.6 vs 13.6, P < 0.001). ICU admission occurred in 1 outpatient patient (< 1%) vs 18 inpatient patients (11%) in the first 30 days (P < 0.001). In the first 30 days, 22% of patients in the outpatient group did not require hospitalization, while 56%, 15%, and 6% required 1, 2, and 3 hospitalizations, respectively. Similarly, only 11 (8.8%) patients in the outpatient group had ≥ 1 ED visit in the first 30 days compared with 32 (20%) pts in the inpatient group (P = 0.009). At 30 days, there was no difference in patient portal use, with 58% of patients using the portal at least once and a median of 1 message in both groups. Within the first 30 days, 53% and 2% of patients in the outpatient group required 1 and 2 outpatient visits, respectively, vs 29% and 2% in the inpatient group (P < 0.001). There was no difference in 30-day mortality (1.6% outpatient vs 2.4% in inpatient) between the 2 groups (P = 1.00). **Conclusions:** Outpatient CAR T-cell therapy monitoring was associated with significantly fewer hospital days without increased ED visits, ICU stays, portal use, or 30-day mortality. This demonstrates lower healthcare utilization for outpatient CAR-T therapy. Research Sponsor: None.

Outcomes of patients with cancer admitted to a dedicated oncology service within a multisite home hospital program.

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Background: Home hospital programs deliver acute, inpatient-level care in patients' homes, and many health systems have adopted these programs after CMS granted a waiver for acute hospital care at home in November 2020. These programs may offer advantages for patients with cancer, including reduced exposure to hospital-associated complications and increased time at home. However, evidence describing outcomes for patients with cancer admitted to home hospital programs remains limited. In March 2025, Mass General Brigham (MGB) launched an oncology service within the system's multisite home hospital program. Here we describe outcomes among patients with cancer admitted to this service and compared them with outcomes of patients admitted to a brick and mortar (B&M) oncology service. **Methods:** We conducted a retrospective cohort study of patients with cancer admitted to MGB's home hospital program between March 1, 2025 and December 31, 2025. Patient demographics, admission diagnosis, length of stay (LOS), the rate of escalations (patients requiring transfer back to a B&M hospital for increased acuity of care), and 30-day readmission rates were collected. Propensity score matching was used to construct a cohort of patients discharged from a B&M oncology service during the year prior to the launch of the home hospital oncology service. Total LOS and 30-day readmission rates were compared between the cohorts using multivariable regression models. **Results:** There were 137 patients admitted to the home hospital oncology service during the period of analysis. The mean age was 69.7, 53.3% of patients were male, 70.8% were non-Hispanic White, and 87.6% spoke English. The most common admission diagnoses were sepsis (16.1%), skin/soft tissue infections (13.9%), urinary tract infections (10.2%), and renal and electrolyte disorders (10.2%). Twenty patients (14.6%) were admitted directly from an Emergency Department and 85.4% of patients were transferred from inpatient services. The average LOS was 8.9 days, 4.5 days on a B&M service and 4.4 days admitted to home hospital, and the escalation rate was 10.2%. The 30-day readmission rate was 15.8%. When compared to a propensity score matched cohort of patients discharged from a B&M oncology service, the average LOS was not significantly different while the 30-day readmission rate was significantly lower among patients discharged from home hospital. **Conclusions:** These data show that patients with cancer can be successfully managed in a multisite home hospital program. This dedicated oncology service was able to care for patients with cancer with broad array of admission diagnoses, and the 30-day readmission rate was lower when compared to a cohort of matched patients discharged from a B&M oncology service. Home hospital is a promising model to provide acute care at home for patients with cancer and warrants further study. Research Sponsor: None.

Impact of remote symptom monitoring on acute care utilization in phase I cancer patients: Secondary analysis of a randomized clinical trial.

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Background: Patients with advanced cancer undergoing Phase I therapies often experience high symptom burden and complications, which may result in acute care encounters (i.e., emergency department [ED] visits and hospitalizations). Few studies have characterized these acute care encounters in Phase I patients. Furthermore, it is unclear if these encounters were avoidable and whether remote symptom monitoring (RSM) could reduce acute care utilization. We performed a secondary analysis of a randomized clinical trial to assess the impact of RSM on ED visits and hospitalizations in Phase I patients. **Methods:** This is a secondary analysis of a randomized clinical trial comparing specialist palliative care (SPC) alone and SPC+RSM in patients with advanced cancer enrolled in Phase I trials at MD Anderson Cancer Center. The key outcomes were the frequency of ED visits and hospitalizations over 6 months following enrollment. We documented the main presenting symptoms and reasons for acute care encounters. Additionally, two independent reviewers assessed whether these encounters were potentially avoidable, defined as whether timely outpatient involvement (e.g., nursing telephone call, clinic visit) could have prevented the encounter. We compared the outcomes between the two study groups using Fisher's exact test. **Results:** Among 100 enrolled patients (mean age 64, 63% female, 33% gastrointestinal cancers, median survival 221 [95% CI 171, 271] days), 43 were in the SPC group and 57 were in the SPC+RSM group. 22/43 (51%) SPC patients and 30/57 (53%) SPC+RSM patients had at least one ED visit over 6 m ($P=0.61$, Table). 15/43 (35%) SPC patients and 21/57 (37%) had at least one hospitalization over 6 m ($P=0.63$, Table). Only 4/84 (5%) ED visits and 0/100 (0%) of the admissions were deemed avoidable. The most common presenting symptoms were pain (ED 27%, hospitalizations 30%) and respiratory distress (ED 23%, hospitalization 23%). The main reasons for acute care encounters were disease progression (ED 49%, hospitalizations 58%), acute complications (ED 26%, hospitalizations 28%) and treatment-related complications (ED 13%, admissions 11%). **Conclusions:** Phase I patients had high rates of ED visits and hospitalizations even when they were followed by SPC. The addition of RSM did not reduce the rates of these encounters. A vast majority of these visits were deemed unavoidable, attributed to disease progression and acute complications. These findings underscore the need for novel interventions to support Phase I patients as they navigate the acute care system near the end of life. Clinical trial information: NCT04989556. Research Sponsor: American Cancer Society; CSDG-19-153-01.

Frequency of acute care utilization over 6 months in phase I patients.

# of visits	ED Visits	ED Visits	Hospitalizations	Hospitalizations
	SPC n=43 (%)	SPC+RSM n=57 (%)	SPC n=43 (%)	SPC+RSM n=57 (%)
0	21 (49)	27 (47)	25 (58)	36 (63)
1	16 (37)	16 (28)	14 (33)	12 (21)
2	4 (9)	8 (14)	3 (7)	7 (12)
3	1 (2)	5 (9)	1 (2)	1 (2)
4	0	0	0	0
5	1 (2)	1 (2)	0	1 (2)

Analysis of an oral anticancer repository program and the impact on access to care.

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Background: Patients with cancer face many barriers to timely access of oral anticancer agents, including financial toxicity and delays in insurance and patient assistance program (PAP) approval. The Ohio State University Comprehensive Cancer Center (OSUCCC) launched a pharmacist-led Oral Oncology Drug Donation Repository (OODDR) program in 2020 to allow patients to donate unused oral anticancer medications with the intent to re-dispense to other patients in need. The goal of this study was to describe our OODDR experience and its impact on access to anticancer care. **Methods:** A retrospective chart review was conducted for OSUCCC patients who received at least one dispense of oral anticancer medication from the start of the program in February 2020 through August 2025. Data were collected on patient characteristics, anticancer therapy, barriers to access, and long-term medication access outcomes. **Results:** A total of 392 medication access encounters were identified for 376 patients through OODDR dispense reports. Four encounters were excluded for missing data or not starting treatment, leaving 388 encounters for analysis. The median age of patients was 65 years, majority were female (51%), white (83%), and had commercial insurance (38%), Medicare (39%), or were uninsured (18%). The most common treatment indications included breast (23%), leukemia (17%), lymphoma (15%), and gastrointestinal (13%) malignancies. The OODDR dispensed 53 unique medications, mostly for on-label indications (76%), with 91% of encounters dispensing one treatment cycle/month or less (median 14 days [IQR 10–28]). Patients accessed long-term drug supply primarily via manufacturer PAP (42%) or insurance approval (31%), while 28 patients (7%) received the full course of treatment with OODDR supply. Reasons that repository supply was utilized included (multiple may apply): delay in prior authorization or appeal process (25%), delay in drug delivery from pharmacy (22%), delay in PAP approval and/or supply delivery (30%), and loss or change of insurance/assistance (19%). The OODDR notably improved the time from treatment decision to initiation with a median start of 6 days (IQR 1–13 days) compared to 14.5 days (IQR 6–30 days) to non-repository drug access. The average retail cost of drug dispensed per encounter was \$10,789.28. Utilizing repository supply when patients required inpatient treatment (19%) resulted in hospital savings of \$207,654.78. In total, the OODDR provided more than \$4.1 million worth of anticancer treatment at no charge. **Conclusions:** The OSUCCC OODDR is an instrumental resource for patients and care teams to remove barriers and improve access to anticancer medications. Patients were able to initiate therapy sooner using the OODDR than would have otherwise been possible using routine insurance and assistance programs. Future efforts to improve medication access and awareness of medication assistance platforms are vital. Research Sponsor: None.

Follow-up of outpatients taking oral anticancer drugs in the multidisciplinary community hospital ONCORAL care plan.

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Background: The increasing use of oral anticancer drugs (OADs) has shifted cancer care toward outpatient and home-based management, raising major challenges related to treatment adherence, drug-related problems (DRPs), and coordination between hospital and community healthcare professionals. ONCORAL is a structured multidisciplinary community-hospital care plan designed to secure OAD use through coordinated personalised pharmacist-nurse-oncologist follow-up, by face-to-face consultations and phone-calls. The present study aims to assess the impact of ONCORAL over the course of treatment. **Methods:** This prospective real-life cohort study included adult outpatients treated by OADs and followed within ONCORAL between October 2021 and April 2024 in a tertiary referral hospital within the Hospices Civils de Lyon (Lyon, France). The 6-months follow-up was structured in two sequential phases from initiation, with hospital-led consultations, to community monitoring. The primary outcome was the number and nature of nurse and pharmacist interventions (NPIs), classified between DRPs and coordination issues. The secondary outcome was relative dose intensity (RDI), defined as the ratio of prescribed to theoretically approved dose, assessed at months 1 (M1), 3 (M3), and 6 (M6). Based on the literature, a RDI target range of 80–85% is associated with OAD efficacy. Descriptive analyses were performed at both patient and treatment follow-up levels. **Results:** Five hundred and thirty-six patients were included: mean age 69 ± 13 years; M/F ratio 0.8; 52.4% women; 55.8% with solid tumours. Targeted therapies accounted for 55.2% of treatments. Overall, 71.3% of patients received OADs for ≥ 6 months. Mean RDI was above 80% throughout follow-up for 86.1% at M1, 84.3% at M3, 83.5% at M6. Four hundred and eighty-one patients (90.0%) had at least 1 NPI during follow-up, for a mean of 4.8 NPIs per patient. DRPs (88.5%) were identified in 426 patients (79.5%): patient-reported symptoms and adverse effects (37.5%), drug-drug interactions (DDIs) (30.1%), and adherence issues (20.4%). Clinically relevant DDIs were identified in almost more than 1 in 3 patients ($n = 145$; 27%), with respectively 26.2% and 43.4% of DDIs potentially reducing OAD efficacy or increasing toxicity. Most NPIs concerned information relay to community healthcare professionals (64.2% of patients), and pharmaceutical counselling on side-effects management and treatment schedules (58.4%). **Conclusions:** This longitudinal evaluation demonstrates that the ONCORAL multidisciplinary community-hospital program enables safe outpatient management of OADs, with sustained dose intensity and early detection of DRPs. Pharmacist-nurse collaboration plays a crucial role in securing treatment pathways and optimising the use of anticancer therapies in a real-world setting. Research Sponsor: None.

Essential but unaffordable: Real-world costs of WHO essential cancer medicines in a low-income setting.

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Background: The World Health Organization (WHO) Essential Medicines List (EML) defines priority anticancer medicines. In many low-and-middle-income countries (LMICs), EML inclusion may not translate into financial accessibility. Using Nepal as a case study, we mapped availability pathways and real-world prices to quantify affordability of WHO EML regimens. **Methods:** We conducted a cross-sectional audit of WHO EML anticancer medicines in Nepal. Regimens were selected for high-incidence and high-curability cancers and to reflect commonly used standard-of-care regimens. Patient prices were abstracted from Nepal distributor and manufacturer price lists (2024–2026), using the lowest listed patient price when multiple listings existed. Regimen costs were estimated using standard dosing and typical cycle numbers. Metastatic regimens were excluded because treatment duration is open-ended. Fixed-duration curative-intent regimens were analyzed. The primary outcome was affordability, expressed as regimen cost divided by annual GDP per capita (Y), used as a proxy for yearly income. **Results:** WHO EML drugs were broadly identifiable, but free access to high-cost agents via NGO programs was confined to three city hospitals, creating a geographic lottery. Using Y = US\$1,447/year, estimated total costs for standard regimens were substantial: dd AC-T for breast cancer US\$552 (0.38Y); FOLFOX for colon cancer US\$1,226 (0.85Y); CAPOX US\$1,090 (0.75Y); FLOT for gastric cancer US\$1,063 (0.73Y); and R-CHOP for lymphoma US\$1,144 (0.79Y). Add-on biologics were far higher: trastuzumab for HER2-positive therapy (17 cycles) was US\$3,998 (2.76Y). Pembrolizumab (9 cycles) was US\$27,246 (18.83Y). One year of oral targeted therapy was osimertinib US\$4,448 (3.07Y) and olaparib US\$10,716 (7.41Y). **Conclusions:** In this LMIC case study, most WHO EML curative regimens approached/exceeded one year of average income, while add-on components approached two decades. EML prioritization alone was insufficient to ensure financial access at the point of care. The findings support targeted national procurement with financial-risk protection for a small set of high-impact medicines, complemented by high income countries (HIC)–LMIC access partnerships, like said NGO-programs, to extend reach beyond a geographically advantaged catchment. Research Sponsor: this work was carried out with the aid of a grant from Royal College Canada International, a charity affiliated with the Royal College of Physicians and Surgeons of Canada.

Nepal oncology regimen costs.

Regimen	Cost/cycle (USD)	Total treatment cost (USD)	Cycles/duration
Breast			
dd AC-T	68	551	8
dd AC-TH	235	3,998	17
TNBC-pembro	3,027	27,246	9
Colon			
FOLFOX	102	1,226	12
CAPOX	136	1,089	8
NSCLC			
Paclitaxel + carboplatin	119	715	6
Pemetrexed + carboplatin	78	470	6
SCLC			
Carboplatin + etoposide	40	245	6
EGFR TKI in NSCLC			
Osimertinib		4,393	1
BRCA+ breast/ovarian			
Olaparib (300 mg BID assumption)		10,716	1
Gall bladder			
Gemcitabine + carboplatin	108	653	6
Gemcitabine + capecitabine	145	874	6
Stomach			
FLOT	177	1,062	6
NHL			
CHOP	13	81	6
R-CHOP	190	1,144	6
HL			
ABVD	27	108	4

Implementation science insights from a community-embedded cervical cancer screening program integrating high-risk human papillomavirus DNA testing with non-communicable disease screening in rural South India.

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Background: The WHO Cervical Cancer Elimination Initiative recommends screening $\geq 70\%$ of eligible women and linking $\geq 90\%$ of those with identified disease to treatment. However, in most low- and middle-income countries (LMICs), screening rate remains around 30–40%, and only 40–60% of high-risk human papillomavirus (HR-HPV)–positive women complete colposcopy thereby precluding identification of disease and linking to treatment. To address this gap across the screening–diagnosis–treatment pathway, we implemented a multi-pronged community-based program integrating community participation, self-swab HR-HPV DNA screening at doorsteps, with non-communicable disease (NCD) screening and patient centric treatment linkage. **Methods:** This longitudinal implementation study was conducted within the Rural Effective Affordable Comprehensive Health (REACH) cohort in Medchal district, Telangana, India. Trained non-physician health workers conducted door-to-door outreach among women aged 25–65 years. Community engagement was supported by a local Community Advisory Board and village influencers, who guided outreach strategies and timing. Counseling and self-collection of vaginal samples were carried out at participants' homes. Educational content was developed based on prior formative research using the Health Belief Model to address fears, stigma, and misconceptions. Screening for HR-HPV DNA was offered as part of a bundled women's health package that included blood pressure and diabetes testing. Appointments for both swab collection and colposcopy/biopsy were coordinated and scheduled at the convenience of the community. HR-HPV testing was done using a chip-based PCR platform. Women who tested positive were referred for colposcopy, biopsy, and treatment at an affiliated teaching hospital. **Results:** Of 1,869 women approached, 1,747 (93.5%) completed HR-HPV self-sampling, surpassing the WHO's 70% screening target. HR-HPV was detected in 89 women (5.1%). Of these, 64 (71.9%) underwent colposcopy, higher than LMIC averages. All with abnormal findings had biopsies. Four women were diagnosed with high-grade lesions or early invasive cancer, all successfully linked to definitive care or referral, meeting the WHO $\geq 90\%$ treatment linkage benchmark. **Conclusions:** Integrating HR-HPV screening with NCD services, enabled by community leadership, doorstep access, and logistical support, achieved high coverage, improved follow-up, and complete linkage to care. This model offers practical, scalable insights for cervical cancer screening programs in rural, resource-limited settings. Research Sponsor: None.

Low-dose pembrolizumab with chemotherapy in advanced NSCLC: A phase 3 randomized trial.

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The full, final text of this abstract will be available at meetings.asco.org on the day of presentation and in the online supplement to the June 10, 2026, issue of the *Journal of Clinical Oncology*.

Immunotherapy access disruptions in Mexico: Real-world delivery irregularities at a public cancer referral center.

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Background: Immunotherapy improves outcomes in selected cancers, but access in middle-income countries may be limited by cost and supply instability. We quantified eligibility, initiation, and delivery disruptions attributable to drug unavailability at a public cancer referral center in Mexico. **Methods:** Retrospective cohort of adults with a first oncology consultation at Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán (Mexico City) between January 2023 and March 2025. Records were reviewed to identify standard indications for immunotherapy per NCCN/ESMO/ASCO guidelines current at evaluation. Among eligible patients, we assessed initiation and delivery fidelity. Deviations were defined as delay to initiation >30 days, regimen modification, or temporary/permanent suspension due to drug shortages. **Results:** Among 1,201 first-time consultations, 228 (18.9%) had an immunotherapy indication; 114/228 (50.0%) initiated immunotherapy. Among eligible patients who did not initiate (n=114), medication unavailability was the most frequent reason (48, 42.1%). Among treated patients (n=114), delivery disruptions were common: 42 (36.8%) had treatment suspensions due to shortages, 9 (7.9%) received regimens deviating from approved protocols, and 8 (7.0%) started with >30-day delay. Overall, only 55/228 (24.1%) immunotherapy-eligible patients received treatment as recommended by international guidelines. **Conclusions:** In this public Mexican referral center, only half of immunotherapy-eligible patients initiated treatment, and over half of treated patients experienced delivery disruptions linked to drug unavailability. These findings support urgent procurement and supply-chain strategies to ensure timely, uninterrupted access to high-impact cancer therapies in publicly funded systems. Research Sponsor: None.

Extent of immunotherapy eligibility, initiation, and delivery disruptions attributable to drug unavailability.	
Measure	Value
First-time oncology consultations	1201
Immunotherapy indication	228 (18.9%)
Initiated immunotherapy	114/228 (50.0%)
Non-initiation due to medication unavailability	48/114 (42.1%)
Any delivery irregularity among treated patients	59/114 (51.8%)
Suspension due to drug shortages	42/114 (36.8%)
Regimen deviation due to unavailability	9/114 (7.9%)
Initiation delay >30 days	8/114 (7.0%)
Guideline-concordant immunotherapy among eligible patients	55/228 (24.1%)

Values are n (%) unless otherwise indicated. Delivery irregularities include initiation delay >30 days, regimen modification, or temporary/permanent treatment suspension due to drug shortages. Percentages are calculated using the denominators specified in each row.

Sustaining oncology clinical trials under wartime conditions: Strategic lessons from Ukraine.

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Background: On February 24, 2022, when Russia launched its full-scale invasion of Ukraine, our center had already treated more than 5,000 patients across 410 oncology clinical trials (CTs) since 2002. At the onset of the war, 125 active CT contracts across 18 cancer types (64 sponsors) were ongoing, with 413 patients enrolled or under follow-up, including 210 in active treatment (57 CTs), 203 in follow-up (53 CTs), and 15 CTs pending initiation. The sudden transition to wartime conditions posed unprecedented challenges to patient safety, continuity of care, trial operations, regulatory compliance, and data integrity, requiring rapid adaptation of clinical, logistical, and digital infrastructures. **Methods:** We conducted statistical analyses to evaluate the feasibility of sustaining CTs over 35 consecutive months of martial law. Key domains included personnel retention, trial activity, protocol adherence, supply chain continuity for a research center located 80 miles from the frontline, and digital infrastructure performance, including utilization of the Medical Control Records (MCR) management system. Our goal was to identify factors applicable to clinical research in armed conflict, natural disasters, and other protracted crises. **Results:** Despite ongoing air raids, missile attacks, power outages, and mass displacement, 99% of scheduled patient visits and data transfers were completed. Of the 413 patients at the start of the war, 150 (36.3%) remain in active treatment (n = 42) or follow-up (n = 108) across 55 trials, representing 44% of the pre-war portfolio. Since February 2022, 7,891 patient visits, 16,155 blood tests, 1,762 tumor response assessments, 3,525 intravenous infusions, and 3,272 oral drug distributions have been completed, with 176 deaths recorded as protocol endpoints. Rapid restoration of supply chains, communications, patient logistics, and secure data management enabled uninterrupted trial activity. A key facilitator was the adaptive MCR digital platform, developed during the COVID-19 pandemic, enabling real-time monitoring, centralized, high-quality electronic medical records, timely e-CRF entry, and remote oversight of CT processes under extreme conditions. The system's AI-assisted planning and multilingual tools are now being tested as a new paradigm for global CT continuity and effective performance. **Conclusions:** Armed conflict disrupts clinical research at every level, threatening patient safety, data integrity, and national research infrastructure. Our experience shows that rapid digital adaptation, operational flexibility, and collaborative governance can sustain oncology trials under extreme geopolitical conditions. These lessons offer a scalable framework for research continuity, regulatory alignment, and patient protection in conflict zones and disaster settings, reinforcing global oncology's role in health system resilience and recovery. Research Sponsor: None.

Randomized controlled trial of a psychosocial digital application (THRIVE-MM) for patients living with multiple myeloma.

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Background: Patients living with multiple myeloma (MM) struggle with considerable quality of life (QOL) impairments, fatigue, and psychological distress throughout their illness course. However, few accessible and scalable interventions address the supportive care needs of these patients. We assessed the efficacy of a self-guided psychosocial digital application, THRIVE-MM, for improving QOL, fatigue, and psychological distress in patients living with MM. **Methods:** We conducted a single-center randomized controlled trial of THRIVE-MM vs. usual care for adults living with MM. Eligibility criteria included patients newly diagnosed with MM receiving first line therapy, those with relapsed MM receiving second- or third-line therapy, or those with MM on maintenance therapy. Participants were randomly assigned 1:1 to THRIVE-MM or usual care, stratified by line of therapy (first line vs. second/third line vs. maintenance) and were given access to the THRIVE-MM digital app up to 8 weeks after enrollment. THRIVE-MM comprises five modules designed to improve patients' physical and psychological symptoms via psychoeducation and evidenced-based self-management skills training for behavioral change and coping, delivered through interactive activities, educational games, and videos. Participants completed self-report measures at baseline and at week-8 after enrollment. The primary endpoint was QOL at week-8 assessed by the Functional Assessment of Cancer Therapy (FACT)-MM. Secondary outcomes were fatigue (FACT-Fatigue), depression and anxiety symptoms (Hospital Anxiety and Depression Scale), and symptoms of posttraumatic stress disorder (PTSD Checklist). We used analysis of covariance controlling for baseline criterion value to assess the effect of THRIVE-MM on outcomes. **Results:** From 12/2023-6/2025, we enrolled 59.1% (120/203) of eligible patients (mean (SD) age = 68.2 (10.0) years; 49.2% women). Mean (SD) use time for THRIVE-MM in the intervention group was 221.9 (197.1) minutes. At week-8, QOL did not differ significantly between the two groups (THRIVE-MM; 125.2 vs. usual care; 125.1, $p = 0.977$). THRIVE-MM participants reported lower fatigue (40.6 v. 37.6, $p = 0.012$) and lower depression symptoms (2.5 vs. 3.4, $p = 0.044$) at week-8. Anxiety or PTSD symptoms did not differ significantly between the two groups at week-8. **Conclusions:** THRIVE-MM, a psychosocial digital health intervention, decreased fatigue and depression symptoms but not QOL among patients living with MM. Clinical trial information: NCT06073353. Research Sponsor: None.

Use of a patient-facing digital tool for glioblastoma outside scheduled clinic visits.

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Background: Care for patients with glioblastoma is largely organized around scheduled clinic encounters, yet symptom management, decision-making, and caregiver responsibility extend beyond office visits. While patient portals, phone triage, and after-hours call coverage exist, these pathways are often resource-intensive, variably available, and insufficient to meet ongoing informational and emotional needs. Scalable, low-cost tools that extend access to vetted support outside clinic hours without increasing clinician workload may help address gaps in care delivery. We evaluated real-world use of a freely accessible, patient- and caregiver-facing digital support tool in glioblastoma. **Methods:** A freely accessible AI chatbot supporting informational, emotional, and care-navigation needs was deployed online without registration or recruitment. The tool excluded medical decision-making and clinical recommendations. De-identified conversation logs generated during routine use were retrospectively analyzed over a 4-month period (Sep 15, 2025 – Jan 14, 2026). Analyses included descriptive characterization of conversation volume, geographic distribution, timing of use, engagement depth, user-reported feedback, and primary topics addressed. All analyses used aggregate, de-identified data with no interaction or intervention involving human subjects. The protocol is IRB exempt per 45 CFR 46.104(d)(4) (WCG IRB 20260304). **Results:** During the study period, the chatbot supported 1,661 conversation threads comprising 15,197 messages across 54 countries. Most conversations originated from the United States (59.9%), followed by the United Kingdom (7.3%), Australia (5.2%), Canada (4.1%), and Greece (3.8%). Conversations were predominantly multi-turn and included use outside clinic hours. The tool was used primarily in English; however, ~12% of messages occurred in other languages, most commonly Spanish and French with additional use of Arabic, German, Italian, Portuguese, Hebrew, Hindi, and several Central and Eastern European languages. Conversations most frequently addressed imaging interpretation and scan-related uncertainty, treatment decision-making, symptom management and treatment-related side effects, and caregiver concerns. Additional topics included clinical trial exploration and prognosis clarification. When clinical trial-related questions arose, users were directed to a brain tumor trial finder. Across the study period, 374 users engaged in trial searches across 22 countries; among respondents to a trial-interest query (n = 251), 92% expressed interest. Voluntary user feedback (n = 97) demonstrated high perceived usefulness and trust (net promoter score, 80). **Conclusions:** A freely accessible AI chatbot demonstrated feasibility as a scalable approach to extending access to care for patients with glioblastoma and their caregivers outside office hours. Research Sponsor: None.

Telehealth visits to support extended dosing of pembrolizumab and reduce health care visits: A pragmatic trial.

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Background: Single agent pembrolizumab is standardly administered every 3 weeks (q3wk). Although extended interval dosing every 6 weeks (q6wk) was approved during the pandemic, most oncologists (65%) prefer q3-week dosing to monitor and mitigate immune-related adverse events (irAEs). We hypothesized that telehealth (TH)-enabled safety monitoring may facilitate broader adoption of q6 week dosing with reduced in-person health care visits while maintaining safety and patient experience. **Methods:** MAKING Telehealth Delivery of Cancer Care at Home Effective and Safe for Immunotherapy (MATCHES-IO) is a single-arm pragmatic trial among patients with solid tumors receiving single-agent pembrolizumab. The intervention consisted of q6-week in-person pembrolizumab infusions with interim (eg, weeks 3,9,15) telehealth toxicity assessments during the first 6 months of therapy. Intervention components included a TH clinician visit, home phlebotomy, and biometric monitoring. The primary outcome was the number of days with an in-person health care facility visit, ascertained from the electronic health record. Participants were compared to a contemporaneous matched cohort receiving standard q3-week pembrolizumab, matched 1:1 on cancer type, stage (I–III vs IV), and age (15-year bands). Safety was evaluated by comparing irAEs requiring steroid use. Patient experience was assessed using a survey that included likelihood to recommend the intervention. **Results:** Between May 2023 and February 2025, 60 patients were enrolled (median age 69.5 [range: 25–85], 38% female, 78% white). Cancer diagnoses included thoracic (52%), genitourinary (30%), and melanoma (18%) in cases and controls. In matched analyses, there was a 3.5-day difference in total healthcare facility contact days between cases and controls (median 8.5 vs. 12.0, $p = 0.14$) that did not achieve statistical significance. Rates of irAEs requiring steroids were similar between groups (25.0% vs. 27.1%, $p = 0.84$). Fifty-two patients (87%) in the intervention group completed a patient experience survey. The median likelihood to recommend score was 10 (Q1,Q3: 8.0, 10.0). Most respondents (96%) perceived a benefit from the telehealth platform, including saved time (85%), increased convenience for patients (75%) and caregivers (44%), and cost savings (52%). **Conclusions:** Extended interval pembrolizumab supported by TH-enabled toxicity monitoring with remote phlebotomy and biometric assessments was associated with reduced in-person health care facility days but did not achieve the significance threshold. The intervention was associated with high patient satisfaction and no increase in irAEs. These results may address clinicians' concerns about the safety of q6 week immunotherapy dosing and inform future care-delivery strategies integrating telehealth with immunotherapy treatment. Research Sponsor: National Cancer Institute; P50 CA271357; National Institutes of Health and National Cancer Institute; P30 CA008748.

Addressing geographic disparities in cancer care: An examination of the contributions of international medical graduates (IMGs).

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Background: IMGs comprise 38% of the US hematology and medical oncology workforce according to the Association of American Medical Colleges. We examined the geographic distribution of oncologists by IMG status to quantify and contextualize the role of IMGs in providing cancer care across the United States, particularly in rural and underserved areas. **Methods:** We used Medicare Care Compare to identify and locate physicians practicing in the U.S. as hematology and medical oncology specialists. IMG status, defined as graduation from a medical school outside of the US, Puerto Rico, and Canada, was assigned from Care Compare where information was available (51%), then from AMA Masterfile data (43%). For the 6% missing IMG data, Google Gemini was used for imputation. We cross-tabulated oncologist IMG status with whether they practiced in a rural county, a county with high cancer incidence (in top 25% of counties for age-adjusted cancer incidence from the National Cancer Institute), and a primary care Health Provider Shortage Area (HPSA). Across counties, we assessed the distribution of new cancer cases by oncologist availability according to IMG status. Proportions and odds ratios with 95% confidence intervals are reported to demonstrate associations. **Results:** There were 14,946 oncologists practicing in the US as of March 2025, of which 5,840 (39%) were IMGs. IMG status was associated with locations that are rural, have high cancer incidence, and have provider shortages (Table). In county-level analysis, among 1,395 counties with oncologists, 1,105 (80%) had IMG oncologist presence. In 662 (47%), IMGs comprised ≥50% of the oncology workforce, corresponding to areas where 32% of patients with newly diagnosed cancer live (549K/1.72M). In 250 counties (18%), only IMG oncologists provided care; 191 (76%) of those were rural and/or had high cancer incidence. **Conclusions:** IMG oncologists play a pivotal role in the geographic availability of cancer care in the United States. They are more likely to practice in rural areas and in areas with increased cancer burden and provider shortages. Any reductions in the IMG oncologist workforce could impede patient access to cancer care on a broad scale and further aggravate shortages in rural and underserved areas. Research Sponsor: None.

Oncologist practice site characteristics by IMG status.				
Site Characteristic	All Oncologists, N (%)	IMG Oncologists, n (%)	Non-IMG Oncologists, n (%)	Odds Ratio for IMG vs. Non-IMG (95% CI)
Overall	14,946	5,840	9,106	
Rural				1.34 (1.20, 1.50)
Yes	1,488 (10)	677 (12)	811 (9)	
No	13,458 (90)	5,163 (88)	8,295 (91)	
High Cancer Incidence*				1.54 (1.41, 1.68)
Yes	2,346 (16)	1,116 (20)	1,230 (14)	
No	12,264 (82)	4,554 (80)	7,710 (86)	
HPSA				1.38 (1.29, 1.49)
Yes	3,923 (26)	1,760 (30)	2,163 (24)	
No	11,023 (74)	4,080 (70)	6,943 (76)	

*County incidence data unavailable for 336 (2%) oncologists.

Evaluation and appraisal of quality indicators for end-of-life cancer care in an African context.

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Background: Population-based quality indicators (QIs) for end-of-life (EoL) cancer care are used to monitor and improve care delivery. Most QIs measure overuse of anticancer therapy or acute care near death and underuse of palliative care. This enables optimization of patient-centered care and healthcare resource utilization, which is especially critical in low-resource settings. Yet, QIs developed in U.S. may not be directly transferable in Africa. We evaluated EoL cancer care in Rwanda using existing QIs and appraised their relevance and feasibility in Rwanda. **Methods:** We conducted a retrospective chart review of all patients who died or were referred for EoL care (i.e., hospice) in 2022 in a Rwandan cancer center. Missing death dates were sought from family and community health workers. Relevance and feasibility of established QIs were appraised by the study team. QI performance was compared with published U.S. benchmarks. **Results:** Of 297 patients (median age 43; 16% pediatric; 61% female), the most common cancers were breast (19%), cervical (9%), acute lymphoid leukemia (9%), gastric (8%), lymphoma (7%), rectal (5%). Nearly half (46%) were stage IV at diagnosis. Most (72%) received treatment; 61% had chemotherapy. After outreach, death dates were available for 95%. Of 18 QIs validated in U.S., 5 were retained or adapted for Rwanda and 13 excluded due to contextual irrelevance or inadequate documentation. Length of stay in EoL care achieved its benchmark, while performance on other QIs was suboptimal (see Table). **Conclusions:** This study is among the first to evaluate and appraise established EoL cancer care QIs in Africa and highlights opportunities to reduce overuse of non-beneficial chemotherapy near death, increase use of palliative care and hospice, and adapt or develop novel EoL QIs to best fit African contexts. Research Sponsor: UCSF Society of Hellman Fellows award; National Cancer Institute; K08CA279874.

Comparison of EoL Care in Rwanda with published benchmarks.

	Rwanda	Benchmark
% referred for EoL care before death (n=297)	45%	>55%
% with length of stay in EoL care 3 days (n=114)	5%	<8%
% who died in a hospital (n=281)	48%	<17%
% starting new chemo within 30 days of death (n=297)	12%	<2%
% receiving chemo within 14 days of death (n=297)	17%	<10%
% receiving chemo within 30 days of death (n=297)	24%	N/A*

*Not a published benchmark; 45% in a published report from Uganda.

Timing of telepalliative care and end-of-life outcomes in advanced cancer: A multicenter retrospective cohort study.

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Background: Telemedicine has become an integral component of palliative care delivery; however, its impact on end-of-life outcomes in oncology remains insufficiently explored, particularly in low- and middle-income countries (LMICs). Place of death is a key quality indicator in palliative oncology and reflects goal-concordant care. This study evaluated whether the timing of palliative care teleconsultations was associated with a higher likelihood of home death among patients with advanced cancer receiving care in a Brazilian multicenter setting. **Methods:** We conducted a multicenter retrospective cohort study in Brazil including adults with advanced cancer who received interdisciplinary palliative care and died due to disease progression between January 1, 2024, and December 31, 2025. Exposure to telepalliative care was defined according to the timing of teleconsultations relative to death (any teleconsultation, ≤ 7 days, ≤ 30 days, or exclusively in-person care). The primary outcome was place of death (home vs other). Secondary outcomes included intensive care unit (ICU) admission and receipt of disease-modifying therapy in the last 30 days of life. Given the sample size, associations were evaluated using univariate logistic regression. **Results:** Among 116 patients (median age 65 years; 55% female), 63 (54.3%) received telepalliative care. Exposure to telepalliative care overall, irrespective of timing, was not associated with home death. In contrast, telepalliative care delivered closer to death was significantly associated with a higher likelihood of home death, particularly when performed within the last 7 days of life (OR 5.93; 95% CI 1.75–20.15; $p = 0.004$) and within the last 30 days (OR 3.08; 95% CI 1.04–9.10; $p = 0.042$). Telepalliative care was also associated with lower odds of ICU admission in the last 30 days of life (OR 0.34; 95% CI 0.16–0.73; $p = 0.006$) and reduced odds of receiving disease-modifying therapy in the final month of life (OR 0.35; 95% CI 0.15–0.79; $p = 0.012$). **Conclusions:** In this Brazilian multicenter retrospective cohort, the timing of telepalliative care, rather than teleconsultation exposure alone, was a key determinant of end-of-life outcomes. Telepalliative care delivered closer to death was associated with a higher likelihood of home death and reduced use of high-intensity end-of-life care. These findings highlight the importance of timely integration of telepalliative care to maintain continuity of interdisciplinary care and support goal-concordant end-of-life care, particularly in resource-constrained and geographically diverse settings. Research Sponsor: None.

LLM-generated serious illness conversation summaries to improve care for hospitalized patients: A pilot clinical trial.

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Background: Patients with cancer often receive intensive care near the end of life that does not align with their goals and preferences. Hospitalization is a critical opportunity to engage in serious illness conversations (SICs) that can align care with preferences, but SICs rarely occur. Large language model (LLM)-generated SIC summaries may help busy inpatient clinicians by identifying patient preferences in fragmented SIC documentation in voluminous electronic health record (EHR) notes. **Methods:** This randomized pilot clinical trial enrolled adults with solid tumors admitted to an academic hospital with a 90-day predicted mortality > 40%. Patients were randomized 3:1 (intervention:control) to usual care or to an intervention consisting of an LLM-generated summary of SIC documentation in EHR notes from the last 6 months emailed to their inpatient and outpatient oncology and palliative care teams within 16 hours of admission. Summaries included 8 SIC topics and up to 18 bullet points, and emails included a message encouraging SICs and incorporation of patients' preferences into care plans. The primary outcome was SIC summary accuracy: manual review determined whether each summary bullet point accurately reflected the source note, and the proportion of accurate bullet points were calculated. Other outcomes included user perspectives from day 3 patient interviews and day 7 clinician surveys and 90-day care delivery outcomes (days in the hospital, number of hospitalizations, hospital re-admission). **Results:** 58 enrolled patients were 55% female, 76% White, 91% non-Hispanic and had a mean 90-day predicted mortality of 57.7%. 902 of 936 (96.4%) summary bullet points accurately reflected underlying documentation. Inaccuracies were typically not clinically significant and related to overstating the strength of preferences (e.g., documentation stating a plan to start treatment to improve symptoms might be summarized to state the patient is "focused on improving symptoms") and misattribution of clinician concerns to the patient. 32 patients participated in interviews. They were generally supportive of the intervention and felt it would improve patient-clinician understanding and communication around preferences. 31 clinicians completed surveys and evaluated SIC summaries as "moderately" to "extremely accurate." 90-day outcomes were mature for 24 patients. In 90 days after enrollment, preliminary mean hospital days (20.9 vs 13.2), mean number of hospitalizations including index admission (2.3 vs 1.5) and re-admission (42.9% vs 23.5%) were all lower in the intervention arm. Full trial data will be available in March. **Conclusions:** LLM-generated SIC summaries can be accurately generated, delivered within 16 hours of hospital admission, are received favorably by patients and clinicians, and may reduce care utilization. An effectiveness clinical trial starts May 2026. Clinical trial information: NCT07147023. Research Sponsor: The Fund for Innovation in Cancer Informatics.

Effect of a financial navigation intervention on financial toxicity among patients with breast cancer: A randomized controlled trial in China.

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Background: Financial toxicity (FT) is a common and burdensome consequence of breast cancer treatment, adversely affecting patients' psychological well-being, treatment adherence, and quality of life. Financial navigation (FN) has been proposed as an effective strategy to mitigate FT; however, high-quality randomized evidence evaluating its impact on patient-centered outcomes remains limited. **Methods:** This assessor-blinded, parallel-group randomized controlled trial enrolled adult female patients with breast cancer who had undergone surgery and were receiving or scheduled for adjuvant therapy. Participants were randomized to an FN intervention or usual care ($n = 41$ per group). The FN intervention included individualized needs assessment, cost-related health education, referral to financial and social resources, and personalized counseling. Outcomes were assessed at baseline (T_0), 1 month (T_1), and 3 months (T_2) post-discharge. Primary outcome was FT, with secondary outcomes including cost-related health literacy (CRHL), shared decision-making (SDM) ability, and perceived stress. Intention-to-treat analysis using generalized estimating equations was applied. **Results:** Of 311 patients screened, 82 were enrolled. Compared with controls, the FN group demonstrated significantly lower subjective FT at T_1 (mean difference = 4.76, 95% CI 0.75–8.76, $P = 0.020$) and T_2 (mean difference = 4.66, 95% CI 0.94–8.37, $P = 0.014$). CRHL significantly improved at T_1 (mean difference = 3.15, 95% CI 0.91–5.38, $P = 0.006$) and further increased at T_2 (mean difference = 5.56, 95% CI 3.53–7.59, $P < 0.001$). SDM ability was also higher in the FN group at T_2 (mean difference = 3.24, 95% CI 0.47–6.00, $P = 0.022$). No significant effects were observed in material or behavioral FT domains. Perceived stress was higher in the FN group at T_2 ($P = 0.032$). **Conclusions:** This randomized controlled trial demonstrates that financial navigation is an effective intervention for alleviating subjective financial toxicity and improving cost-related health literacy and shared decision-making among patients with breast cancer. By providing rigorous randomized evidence, this study advances the field beyond descriptive and observational research and offers high-level evidence supporting financial navigation as a clinically actionable strategy to address cancer-related financial toxicity. These findings contribute to the global effort to mitigate financial toxicity and support the integration of structured financial navigation programs into survivorship care models across diverse healthcare settings. Clinical trial information: NCT06484140. Research Sponsor: National Natural Science Foundation of China.

Effect of group community health worker–led advance care planning education on advance care planning documentation, satisfaction, palliative care, and hospice: Results from a randomized clinical trial.

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Background: Advance Care Planning (ACP) is recommended for all patients with cancer yet engagement remains low due to multilevel barriers including limited clinician time, lack of adequate reimbursement, and workforce shortages. Our team demonstrated that one-on-one community health worker (CHW)-led education interventions can improve ACP documentation, satisfaction, and hospice use. Group CHW-led interventions may improve scale and spread, however, the effectiveness of such approaches compared to usual cancer care remains unknown. **Methods:** This prospective randomized clinical trial compared a 1-month CHW-led group ACP education intervention plus usual cancer care (intervention group) with usual cancer care alone (control group). Veterans newly diagnosed with solid tumor malignancies, 18 years of age or older, and planned to receive cancer care at one VA facility were eligible. All who verbally consented were randomized 1:1 to the intervention group or the control group. The intervention consisted of two 90-minute group sessions over 1-month post-randomization with 8-10 participants per group led by trained CHWs. The sessions included tailored education regarding ACP, surrogate decision-maker designation, and communication strategies with cancer clinical teams. Usual care included access to nurse navigators, social workers, palliative care and hospice teams, and ancillary support services. The primary outcome was ACP documentation (comprised of the VA Life Sustaining Treatment, VA Advance Directive, and Goals of Care documentation by the oncology clinician) in the electronic health record within 6-months after randomization. Secondary outcomes included satisfaction with care decision, palliative care use, and hospice use. **Results:** 65 patients were screened with 60 (92.3%) eligible of whom all 60 (100%) participated with 30 in each group. There were no withdrawals or participants lost to followup; 55 (91%) were male; 5 (8.3%) were female; median age was 79 years (IQR 67-86); 53 (88.3%) had stage 3 or 4 cancer; 9 (15%) reported ethnicity as Hispanic or Latino; 39 (65%) reported race as White; 12 (20%) Black; 3 (5%) American Indian; and 6 (10%) multiple races. At 6-months followup, intervention group participants had greater ACP documentation (30 (100%) versus 12 (40%)), strongly agreed that they were satisfied that care matched their preferences (27 (90%) versus 18 (66.7%)); no differences in palliative care use (3 (10%) versus 3 (10%)) and greater hospice use (15 (55.6%) versus 3 (10.0%)) than control group participants. **Conclusions:** This group CHW-led ACP education intervention improved ACP documentation, satisfaction, and hospice use at one VA. Group CHW-led ACP approaches may be a potentially scalable approach to address workforce shortages and effectively improve ACP. Clinical trial information: NCT06646614. Research Sponsor: VA Health Services Research & Development.

Association of socioeconomic and clinical factors with overall survival in immunotherapy-eligible stage III non-small cell lung cancer following definitive chemoradiation.

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Background: Use of consolidative immunotherapy (IO) for stage III non-small cell lung cancer (NSCLC) has increased since FDA approval in 2018, yet disparities in access persist. Few studies have examined survival in the IO era accounting for both socioeconomic and clinical factors. We evaluated determinants of overall survival (OS) in IO-eligible patients (pts) after definitive chemoradiation (CRT). **Methods:** Retrospective National Cancer Database analysis was performed, of adults ≥ 18 years with stage III NSCLC (2018-2020) receiving ≥ 60 Gray in ≥ 30 fractions of RT with known IO status, defined as receipt 50-150 days from CRT start. Surgical cases were excluded. Variables included race/ethnicity (R/E), insurance, facility type, Charlson-Deyo comorbidity index (CCI), high school graduation rate (HSGR), household income, sex, age, NSCLC primary site, and histology. OS was assessed using the Kaplan-Meier method, followed by multivariable Cox regression models adjusting for aforementioned variables, including IO receipt. **Results:** Among 19,418 pts, 54.4% received IO. Median age was 68 years; 44% were female; 85% White, 12.5% Black, 2% Asian, and 2% Hispanic. Median OS was higher with IO (42.1 vs 22.3 months [mo], $P < .001$) and in females (38.8 vs 28.1 mo, $P < .001$). OS differed by R/E: Asian (52 mo), Black (40.3 mo), Hispanic (37.2 mo), American Indian/Alaska Native (24 mo) vs White pts (31.1 mo), $P < .001$. Privately insured pts (41.7 mo) and those treated at academic/research (A/R) centers (36.5 mo) had higher OS ($P < .001$). On multivariable analysis, IO receipt was associated with lower all-cause mortality (HR 0.53; 95% CI, 0.51-0.56). Reduced mortality was seen in Asian (HR 0.82; 95% CI, 0.68-0.99) and Black pts (HR 0.83; 95% CI, 0.77-0.89) vs White pts. Higher mortality was associated with male sex (HR 1.28; 95% CI, 1.22-1.34), urban (non-metropolitan) vs metropolitan residence (HR 1.14; 95% CI, 1.07-1.22), Medicare (HR 1.10; 95% CI, 1.03-1.18) or no insurance (HR 1.36; 95% CI, 1.14-1.63) vs private insurance, non-academic facilities (comprehensive: HR 1.09; 95% CI, 1.03-1.16; integrated network: HR 1.15; 95% CI, 1.07-1.23), and CCI of 2 (HR 1.13; 95% CI, 1.04-1.21) or ≥ 3 (HR 1.29; 95% CI, 1.19-1.40). Income and HSGR showed marginal association with OS. Upper-lobe vs main bronchus sites were associated with better OS ($P < .02$), while squamous histology was associated with worse OS ($P < .001$). **Conclusions:** Approximately half of IO-eligible stage III NSCLC pts received IO, which was independently associated with improved OS, adjusting for socioeconomic and clinical factors. Asian and Black race, and treatment at A/R centers, were associated with lower mortality. Insurance and facility type significantly influenced OS, highlighting persistent access-related disparities and the need for targeted interventions to promote equitable care. Research Sponsor: National Institute on Aging; T32AG000243.

Intersecting rural, racial, and Medicaid disparities in cervical cancer outcomes across North Carolina, 2019–2023.

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Background: Although national cervical cancer incidence has declined, mortality disparities persist, particularly among rural and racially diverse populations. North Carolina—marked by heterogeneous access to care and recent Medicaid expansion—offers a unique setting to examine geographic and socioeconomic inequities in cervical cancer outcomes. **Methods:** County-level *Cervix Uteri* incidence and mortality data (2019–2023) were obtained from the North Carolina Central Cancer Registry via State Cancer Profiles. Counties were categorized by USDA Rural–Urban Continuum Codes (2023) (urban = 1–3; rural = 4–9). Rates per 100,000 women were calculated using 2020 county populations; 95 % CIs were derived by Poisson approximation. Race-specific rates were determined from State Cancer Profiles (2017–2021 incidence; 2018–2022 mortality). Medicaid enrollment was derived from NC DHHS (SFY 2024) and merged by county rurality. **Results:** Between 2019–2023, 1,624 new cervical cancer cases and 541 deaths occurred. Rural counties comprised 36 % of the female population but 42% of deaths. Incidence was similar between rural and urban counties (18.1 vs 18.9 per 100 000; 95 % CI 14.9–21.2 vs 17.4–20.6), whereas mortality remained higher in rural areas (7.0 vs 5.9; 95 % CI 5.0–8.9 vs 5.1–6.8). Medicaid enrollment was 33.7 % in rural vs 27.1 % in urban counties. High-mortality counties (Robeson, Halifax, Bladen) also had > 45 % Medicaid coverage and higher proportions of Black and Native American residents. Race-specific analyses showed Black women had the highest burden (incidence 8.0; mortality 2.6 per 100 000) compared with White (6.2; 2.0) and Hispanic (7.1; 1.9) women, highlighting overlapping racial and geographic disadvantage. **Conclusions:** In North Carolina, 1) rural residence, 2) race, and 3) Medicaid dependence intersect to drive cervical cancer mortality disparities. Despite comparable incidence, rural and racially diverse counties experience 20–30% higher mortality. Elevated Medicaid enrollment in these regions suggests that insurance expansion alone cannot offset structural barriers in access to gynecologic oncology care. Sustained Medicaid funding, equitable provider reimbursement, and targeted investments in rural cancer infrastructure are essential to improve survival and equity. Research Sponsor: None.

Lost in translation? Evaluating associations between English proficiency and next generation sequencing completion, and comparing understandability across different translation modalities among Spanish speakers with metastatic breast cancer.

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Background: Disparities in next-generation sequencing (NGS) utilization persist among patients with metastatic breast cancer (MBC), disproportionately affecting Hispanic/Latino populations. We hypothesized that the challenges in explaining NGS, particularly when mediated through translation, could be contributing to this observed discrepancy in NGS testing rates within the Hispanic/Latino populations. We evaluated the associations between limited English proficiency and NGS testing by comparing the understandability between English, certified Spanish translations, and artificial intelligence (AI)-generated Spanish translations of provider explanations of NGS testing. **Methods:** We analyzed 191 patients with recurrent MBC from the Dallas Metastatic Breast Cancer Study. Ethnicity was categorized as Hispanic vs non-Hispanic. NGS completion between 2014–2022 was assessed. Three versions of NGS explanations (original English, certified Spanish translation, and AI-generated Spanish translation) were evaluated using the Flesch–Kincaid Readability Score (English) and the Fernández–Huerta Index (Spanish) using 10 provider–patient interactions. Scores range from 0–100, with higher scores indicating greater understandability; CDC/NIH-recommended patient materials target scores of 60–70. Readability discordance < 10 points was considered acceptable. **Results:** 81.7% (156) of patients were proficient in English and were 3.2 times more likely to complete NGS testing than Spanish speakers (95% CI 1.35–7.73, $p < 0.01$). Mean readability score between the English, certified Spanish, and AI Spanish were 47.9, 51.4, and 54.1, respectively. The mean discordance was 6.1 points between English and certified Spanish, 5.9 points between certified Spanish and AI Spanish, and 8.6 points between English and AI Spanish. All ten original English explanations fell below CDC/NIH readability targets, and only 4 of 10 certified Spanish translations met the recommended standards. When refining the prompts to maximize patient understanding, AI-generated text generated perfect understandability scores. **Conclusions:** Although translation fidelity was preserved, most provider-generated explanations failed to meet recommended readability standards, suggesting that communication quality, not translation alone, may limit patient understanding. AI-generated explanations may serve as a tool to mitigate language-related barriers when certified interpreters or optimized explanations are unavailable and enhance informed decision-making across varied clinical discussions, not limited to NGS testing. Research Sponsor: None.

Mapping access to retinoblastoma care: Geographic disparities and service availability across Africa, and West and Central Asia.

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Background: Retinoblastoma, the most common childhood eye cancer, is highly manageable with prompt diagnosis and appropriate care. Access to specialist services is, however, unequal in low- and middle-income countries (LMICs), leading to unnecessary morbidity and death. This study assesses the geographic reach of retinoblastoma treatment centers, estimates the burden of cases relative to available services, and analyzes referral barriers—in terms of distance and cost of travel—across Africa, West and Central Asia. **Methods:** We used the One Retinoblastoma World Map to categorize African, West and Central Asian (excluding India, China, and Mongolia eastern countries) specialized treatment centers. The centers were classified as Tier 1 (comprehensive care with focal therapy and radiotherapy) or Tier 2 (lacking at least one essential treatment modality). The availability of genetic testing was also recorded. Country-specific incidence of retinoblastoma was estimated at 1 case per 18,000 live births, using UN population and birth rate data. For countries without Tier 1 or Tier 2 centers, we calculated minimum travel distances and estimated one-way costs for a child and guardian to reach the nearest facility. **Results:** Among 71 countries analyzed, there were just 28 (39%) countries with Tier 1 or Tier 2 retinoblastoma centers and 43 (61%) countries without such centers. Tier 1 centers were available in just 16 countries (22.5%), predominantly middle- and high-income countries: only 2 of 25 low-income countries (Uganda, Mali) had access to Tier 1 versus 11 of 39 middle-income and 3 of 7 high-income countries (Saudi Arabia, Israel, Russia). Notably, 64% of low-income and 59% of middle-income countries did not have any retinoblastoma center. Twenty-two high-burden nations (≥ 10 cases/year) had no Tier 1 or Tier 2 center, including the Democratic Republic of Congo (242 cases/year), Mozambique (65), and Yemen (63). Average one-way travel distance in these environments exceeded 1,000 km at a cost of nearly \$1,000 per referral trip. While some nations (e.g., Nigeria, Egypt, Pakistan) had acceptable case-to-center ratios (50–80 cases/center), others (e.g., Uganda, Tanzania) had possible overcapacity with single-center systems. Genetic testing was accessible in just 24% of nations. **Conclusions:** Despite potential underreporting of more recently established centers, this study reveals profound inequalities in the availability of retinoblastoma care, with most LMICs lacking sufficient essential services. Excessive case volumes within underserved regions overwhelm existing infrastructure and necessitate prompt interventions: (1) focused expansion of Tier 1 hubs within regions of greatest need, (2) streamlining of regional referral chains, and (3) integration of genetic and focal treatments to reduce disparities in survival. Research Sponsor: None.

Financial toxicity in early-phase cancer clinical trials: A review of sponsor-supplied information at a large trials unit.

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Background: Financial toxicity (FT), the objective financial burden and resulting subjective distress experienced by oncology patients, adversely impacts clinical outcomes and access to care. Reimbursement practices between studies vary, possibly exacerbating the lack of representation of people from socioeconomically deprived areas and marginalized groups in early phase cancer clinical trials (EPCCTs). An ASCO roundtable in 2018 emphasized the need for clear details on out-of-pocket costs for trials. Studies in EPCCTs show FT is a recognized problem; however, management of this remains inconsistent. **Methods:** A retrospective portfolio review of open EPCCTs at a large UK cancer centre (Jan-Dec 2025) was conducted to assess reimbursement practices. Sources included informed consent forms (ICFs), contract trial agreements (CTAs) and sponsor provided patient materials. Reimbursement details (including amounts and timelines) were also assessed. **Results:** 64 studies were reviewed, encompassing 41 sponsors (38 industry and 3 academic). Reimbursement was mentioned in ICFs for 62 studies (96.8%) and by 39 sponsors (95.1%). The 2 studies lacking information were academic studies. Specific reimbursable activities were described in 15 studies (23.4%) across 11 sponsors (26.8%). No sponsor included a defined reimbursement timeline in any provided materials. Only 1 sponsor (2.4%) provided additional reimbursement information for patients. Third party vendors for reimbursement were used for 18.8% of studies, with 8 different vendors across 10 sponsors. Reimbursement processes were often detailed in CTAs, with 55 studies (85.9%) outlining specific reimbursable activities. Of 8 academic studies reviewed, 75% listed a maximum budget for each patient to cover the whole study duration (median £350; range £300-£500). Among studies reporting mileage repayment (53; 82.8%), the median rate was £0.45/mile (range £0-£0.45). Median patient travel expense entitlement per visit, where mentioned (55; 85.9%), was £150 (range £40-£700), while refreshment reimbursement was noted in 26 studies (40.6%) with a median value of £15/visit (range £5-£80). The total reimbursement offered per patient per visit was reported in 55 studies (85.9%), with a median of £152.50 (range £40-£1,145). Additional costs covered included reimbursement for carers (9 studies; 14.1%) and unforeseen/inconvenience payments (2 studies; 3.1%). **Conclusions:** Reimbursement terms are regularly specified in CTAs but there is limited inclusion in patient-facing trial documents and lack of flexibility for additional costs. Academic studies restrict reimbursement. Patients may decline clinical studies due to fear of financial toxicity, compounding health inequity. We are partnering with patients to co-develop clearer communication about reimbursement, supporting informed decision-making prior to study enrollment. Research Sponsor: NIHR Manchester Biomedical Research Centre; Roche.

Geographic migration patterns of practicing medical oncologists in the United States, 2020-2025.

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Background: The regional provision of cancer care in the United States (US) remains plagued by disparities along the continuum of screening, diagnosis, and treatment. The geospatial accessibility and migration patterns of medical oncologists may contribute to these disparities. We aimed to assess urban-rural and state-level migration patterns of practicing medical oncologists in the US using national datasets. **Methods:** The Doctors and Clinicians national downloadable file was used as the primary dataset for these analyses. Physician data from August 2020 and August 2025 was used to identify changes in geographic location. The specialties “Hematology/Oncology” and “Medical Oncology” were used to identify oncologists. We utilized Rural-Urban Continuum Codes (RUCC) to classify counties as urban (RUCC 1-3) or rural (RUCC 4-9). If oncologists practiced in multiple states, they were included in all relevant states for these analyses. For categorical variables, the chi-squared test was used for statistical significance. For continuous variables, the two-sample t-test was used for statistical significance. **Results:** There were 12,222 oncologists in 2020 and 13,420 oncologists in 2025. Our final cohort for analysis comprised 10,172 oncologists present in both datasets. 1,233 oncologists (12.1%) began practicing in a new state during this time period. The five states with the largest percentage of oncologists gained from net migration were: Hawaii (10.8%), Montana (6.7%), Vermont (5.5%), Idaho (5.0%), and Nebraska (4.1%). The five states with the largest percentage of oncologists lost from net migration were: Wyoming (-8.7%), West Virginia (-6.2%), Delaware (-6.2%), Alaska (-4.2%), and Arkansas (-4.1%). Female oncologists were more likely to migrate to a new state (12.6%) than male oncologists (11.8%); however, the difference was not statistically significant (p-value = 0.25). The mean number of years since medical school graduation was 25.1 years for oncologists who began practicing in a new state and 28.4 years for oncologists who did not (p-value <0.001). Oncologists in rural areas were more likely to migrate to urban areas (N = 492; 48.7%) than oncologists in urban areas were to migrate to rural areas (N = 380; 4.1%; p-value <0.001). **Conclusions:** Oncologists in the US exhibit distinct regional and urban-rural migration patterns. Targeted interventions to ensure adequate geospatial supply of physicians should focus on rural areas and states such as Wyoming and West Virginia. Improving understanding of the underlying factors driving oncologist migration patterns is crucial to ensuring a distributed oncology workforce. Research Sponsor: None.

Scaling digital patient navigation to improve access to multidisciplinary melanoma care.

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Background: Multidisciplinary (multiD) melanoma care is associated with improved patient (pt) outcomes, yet access is variable due to geographic, informational, and system-level barriers. We previously reported preliminary single-center feasibility of engaging pts using a digital patient navigation platform (DPNP) that provides information about melanoma, cutaneous oncology subspecialists, and clinical trials. We now report results from a multi-site expansion evaluating engagement across academic (Johns Hopkins; JH) and regional health systems (RHS). **Methods:** In this IRB-approved study, adult pts recently diagnosed with melanoma at JH or at a participating RHS were identified monthly using ICD-10 codes. Pts who were not already receiving multiD melanoma care at JH were sent DPNP invitations via their electronic medical record (EMR)-based pt portal. The primary endpoint was clickthrough rate (CTR; % of eligible pts who clicked the link in the invitation), benchmarked against web-based healthcare messaging standards (7%); invitation of ≥ 183 pts per setting was targeted (one-sided 90% CI exceeding benchmark if $CTR \geq 7.5\%$). Secondary endpoints included conversion rate (registration after clickthrough; benchmark 10%) and subsequent pursuit of multiD melanoma care. **Results:** From Nov 2023 - Dec 2025, 194 eligible pts were identified at JH; from Dec 2024 - Dec 2025, 356 at RHS; all were sent DPNP invitations. CTR: 41% at JH (80/194, 95% CI 34.2%-48.5%), 30% at RHS (106/356, 95% CI 25.1%-34.8%). Conversion rates were 23% (18/80, 95% CI 13.9%-33.2%) and 25% (27/106, 95% CI 17.5%-34.9%), respectively. Of 45 total registrants, 42 (93%) provided demographic data: mean age 59.7 yrs (range 25-83), 55% female, melanoma stage 0-IV. Among 16 JH and 26 RHS registrants, 2 (13%) and 6 (23%), respectively, had high-risk (stage $\geq$ II) melanoma warranting a multiD consultation. After registering, 2/2 (100%) and 0/6 (0%) high-risk pts sought multiD care. Median distance to JH was 45 miles and 100 miles for JH and RHS registrants, respectively. **Conclusions:** In this multi-site study, melanoma pt engagement with a DPNP significantly exceeded established benchmarks across academic and RHS, demonstrating scalability of EMR-integrated outreach. However, among pts with high-risk melanoma, transition to multiD care occurred more frequently at the academic center than in RHS, revealing setting-specific barriers to converting engagement into subspecialty care. These findings indicate that while digital navigation can effectively identify unmet need across care environments, patient-initiated pathways alone may be insufficient to close access gaps. In response, we are developing a clinician-facing platform designed to overcome informational and geographic barriers by enabling collaboration between community clinicians and multiD oncology teams, thereby facilitating delivery of subspecialty cancer care closer to home. Research Sponsor: Blackbird Laboratories; 1104Health; Maryland Cigarette Restitution Fund.

Trends in biosimilar bevacizumab adoption and Medicare spending by socioeconomic deprivation and rurality, 2019-2023.

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Background: Biosimilar bevacizumab has the potential to reduce oncology drug spending, but the equity of its real-world adoption across socioeconomic and geographic contexts remains uncertain. **Methods:** We analyzed Medicare Part B provider-year claims from 2019–2023 for bevacizumab administrations. Biosimilar adoption was defined as the proportion of total bevacizumab services delivered as biosimilars. Neighborhood socioeconomic deprivation was measured using Area Deprivation Index (ADI) quintiles (Q1=least deprived; Q5=most deprived). Rurality was classified using provider-level Rural-Urban Commuting Area (RUCA) codes available in Medicare Part B, with urban defined as RUCA 1–3 and non-urban as RUCA ≥4. Adoption patterns were compared using chi-square tests for categorical outcomes and independent t-tests for spending measures. Temporal trends in adoption by ADI quintile were compared using logistic regression with Year × ADI interaction terms to test whether adoption trajectories diverged over time. Statistical significance was defined as $p<0.05$. **Results:** The study included 11,803 provider-year observations. Biosimilar market share increased from 0.5% of services in 2019 to 61.3% in 2023. In 2023, biosimilar adoption differed significantly by ADI quintile ($p=0.0004$), ranging from 55.7% in ADI Q4 to 81.3% in the most deprived quintile (Q5), patterns that may reflect institutional purchasing or practice-level factors rather than patient-level access alone. Adoption was higher in urban compared with non-urban areas (62.0% vs 33.6%, $p=0.002$), despite no baseline differences in 2019. Biosimilars were less expensive than originator bevacizumab in all years (all $p<0.001$). Mean per-administration savings increased from \$8.03 (10.3%) in 2019 to \$36.4 (52.2%) in 2023 ($p=0.001$). Originator prices did not differ by ADI in 2023 ($p=0.58$). **Conclusions:** Biosimilar bevacizumab adoption expanded rapidly and generated increasing Medicare savings, but uptake varied by socioeconomic deprivation and rurality. Differences in adoption, rather than pricing, appear to drive inequities in realized savings. Targeted policy strategies may be needed to promote equitable biosimilar diffusion in oncology care. Research Sponsor: None.

Biosimilar bevacizumab adoption in 2023 by socioeconomic deprivation and rurality.	
Category	Biosimilar share of services (%)
ADI Q1 (least deprived)	58.1
ADI Q2	61.1
ADI Q3	61.7
ADI Q4	55.7
ADI Q5 (most deprived)	81.3
Urban	62.0
Non-urban	33.6

Patient characteristics, treatment patterns, social determinants of health, and safety in patients prescribed nivolumab and hyaluronidase-nvhy by early adopters.

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Background: Subcutaneous (SC) nivolumab and hyaluronidase-nvhy (nivo + hyal) is approved for administration across most adult solid tumor indications previously treated with intravenous (IV) nivolumab (nivo) and offers substantially shorter administration time (3–5 minutes). While clinical trial data demonstrate comparable efficacy and safety, real-world evidence on early adoption, patient selection, access-to-care considerations, and safety in community oncology settings remains limited. This study provides early real-world insight into the use of SC nivo + hyal in routine clinical practice. **Methods:** This non-interventional, retrospective medical chart review collected routine-care data from Florida Cancer Specialists & Research Institute LLC. Adults receiving ≥ 1 dose of nivo + hyal SC or nivo IV in 2025 were included. Follow-up extended from index (first receipt of SC or IV) through last available record, disenrollment, death, or database cutoff. Patient demographics, disease characteristics, treatment patterns, social determinants of health (SDOH; including proximity-to-care measures), and safety outcomes were summarized descriptively. **Results:** Ninety-eight patients were included (SC n=49; IV n=49). Baseline demographic and disease characteristics were comparable between cohorts, include age, sex, performance status, and metastatic disease prevalence. A greater proportion of SC-treated patients resided in suburban settings (45% SC, 37% IV). Mean travel distance to care was greater among SC recipients, with similar median distances and overlapping interquartile ranges; the longest observed travel distance occurred in a patient receiving SC therapy (110 miles vs 33 miles for IV). Treatment patterns were similar between groups; all patients receiving concurrent therapy were treated with oral anti-cancer agents. SC administration was primarily abdominal (90%). Among SC-treated patients, 54% initiated therapy in the first line setting, while remaining use reflected conversion from IV therapy, most commonly following nivo IV + ipilimumab induction, where SC administration is not currently indicated. No new or unexpected safety signals were observed with SC administration compared with IV nivo. **Conclusions:** In this early real-world community oncology analysis, nivo + hyal SC use demonstrated patient characteristics, treatment patterns, and safety comparable to nivo IV. Difference in proximity-to-care measures, including greater variability and longer travel distances among SC recipients, suggest SC administration may support treatment delivery for patients with higher geographic burden. Findings should be interpreted cautiously given the limited sample size but offer early insight into real-world adoption and access considerations for subcutaneous immunotherapy. Research Sponsor: Bristol Myers Squibb.

Impact of advanced practice provider–led new consults in community oncology: Expanding access and volume in benign hematology.

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Background: Community oncology practices face rising patient volumes and workforce shortages, leading to delays in access to care. Although Advanced Practice Providers (APPs) are increasingly utilized to expand capacity, the structure and impact of APP-led new consult models, particularly in benign hematology, remains unclear. This analysis evaluated the operational and clinical impact of APP-led benign hematology consult programs to determine whether this model improves timely access and supports high-quality, patient-centered care.

Methods: A retrospective, multi-site analysis was conducted in four community oncology practices within The US Oncology Network that implemented APP-led new consult models in benign hematology. Key performance indicators included total new consult volume, time to first appointment (T2F), percentage of APP visits, and APP engagement. Data were obtained from internal scheduling platforms, productivity dashboards, and operational reports. Pre- and post- implementation comparisons assess changes in access and throughput. **Results:** Across all sites, APP-led consults significantly enhanced access and capacity. In a four-year period at Practice A, median T2F decreased by 50% (24 to 14 days; 36 to 18 days across two regions). During the same timeframe, monthly new consults increased from 208 to 1,045, and total new patient volume rose 403% (2,495 to 12,544). APP participation expanded from 93 to 162 clinicians. In Practice B, APP-led consults increased from 55 (2024) to 406 (2025; 638% YOY growth), with daily new visits rising from 0 to 3 per day and APP share of total practice visits increasing from 0% to 23%. The model generated 295 physician hours saved and reduced T2F for new cancer patients from 8 to 4 days. Physicians and patients expressed confidence and satisfaction with APP new visit care. Practice C grew APP-led consults from 171 (2024) to 235 (2025; 37% YOY growth), increasing APP share of total practice visits from 5% to 23%. Practice D expanded from 2 to 7 visits/day (September 2024 to Oct 2025) with consults rising from 81 to 1,221 (1,407% YOY). APP visit share grew from 6% to 59%, and T2F decreased from 15 days to 7 days. **Conclusions:** APP-led new consult models in benign hematology improved access, operational efficiency, and growth within community oncology settings. By optimizing APP utilization, the model addressed workforce shortages, accelerated time to care, and enabled early triage of patients. Broad APP engagement and sustained growth across diverse settings demonstrates its scalability and impact. Together, these findings support the integration of APP-led new consults as a practical and transformative approach to addressing critical gaps in oncologic care delivery. Ongoing prospective evaluation will further define the model's impact and inform broader adoption of this approach and best practices across the oncology landscape. Research Sponsor: None.

Transportation insecurity and RBC transfusion burden in multiple myeloma and related plasma cell disorders in New Mexico: A CRIIS statewide analysis (2013-2019).

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Background: Multiple myeloma (MM) and related plasma cell disorders are commonly complicated by anemia requiring red blood cell (RBC) transfusion. In geographically large and predominantly rural states such as New Mexico, transportation insecurity may contribute to fragmented outpatient access and downstream supportive care burden. Using statewide oncology informatics data, we characterized RBC transfusion utilization patterns and their association with county-level vehicle access. **Methods:** Using the Cancer Research Integrated Informatics System (CRIIS), a novel statewide oncology informatics platform, we identified patients with MM and related plasma cell disorders (including Waldenström macroglobulinemia and plasma cell leukemia) receiving care from 2013–2019. We performed a repeated cross-sectional county-level analysis, using county-year as the analytic unit. Transportation insecurity was defined as the percent of households without vehicle access and summarized using the median county value across 2013–2019 due to minimal year-to-year variability. Counties were categorized as higher versus lower transportation insecurity using a median split. The primary outcome was receipt of ≥ 1 RBC transfusion within a calendar year, summarized at the county level. **Results:** Among 2,436 patients statewide, 614 (25.2%) received ≥ 1 RBC transfusion. Annual transfusion utilization increased from 15.0% in 2013 and stabilized at ~25–30% thereafter. Median county transportation insecurity ranged from 0% to 12.8%. Across multiple years, counties with higher transportation insecurity accounted for a disproportionate share of statewide transfusion burden relative to patient volume (~1.3–1.5-fold higher absolute transfusion burden). Transfusion burden was concentrated in a subset of counties, with Bernalillo contributing the largest share, while several smaller counties demonstrated high transfusion rates despite low total patient volume. Transfusion delivery remained concentrated in access-rich counties, consistent with regional centralization of oncology supportive care. **Conclusions:** In this statewide real-world analysis, RBC transfusion burden in MM and related plasma cell disorders clustered disproportionately among residents of transportation-insecure counties. Transportation insecurity may serve as a pragmatic structural marker to identify regions bearing elevated supportive care burden and supports collaborative evaluation of transportation-focused care delivery strategies to improve equity across rural and underserved communities. Research Sponsor: None.

Statewide cohort size and RBC transfusion utilization by year.

Year	Total Patients	Transfused Patients	Transfusion Rate (%)
2013	240	36	15.0
2014	238	49	20.6
2015	301	67	22.3
2016	373	109	29.2
2017	411	118	28.7
2018	427	107	25.1
2019	446	128	28.7
Total	2,436	614	25.2

Neighborhood social vulnerability and clinical trial enrollment in colon cancer: Does age matter?

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Background: Colorectal cancer is now the leading cause of cancer-related death in people under 50, and young adults living in poverty have increased mortality. Despite younger age being associated with higher clinical trial enrollment, young adults face distinct social and structural barriers that may impede participation. This study examines how neighborhood social vulnerability is associated with clinical trial participation for colon cancer in young and older adults. **Methods:** Patients diagnosed with colon cancer were identified in the nationally representative Vizient Clinical Database from January 2022 – June 2025 and stratified into young adult (age 18–49) and older adult (50 and above) cohorts. The outcome of interest was clinical trial enrollment, identified by billing codes. Social vulnerability was defined by the Vizient Vulnerability Index in quartiles at the census tract level. Multivariable analyses were performed in both cohorts. An interaction analysis was performed between age and social vulnerability. **Results:** Of 234,047 patients, 15% were young adults, of which 5.1% enrolled in a clinical trial. Eighty-five percent were older adults, of which 3.0% enrolled in clinical trials. Most young adults had private insurance (73.1%) while most (56.6%) of the older patients were enrolled in Medicare. Non-Hispanic (NH) Black patients were less likely to enroll than NH White patients in both the young adult (OR 0.72, $p=0.0001$) and older adult cohorts (OR 0.79, $p<.0001$), as were young and older patients with Medicaid vs. private insurance (OR 0.75, $p=0.0001$ and OR 0.71, $p<.0001$, respectively). Diagnosis at an academic medical center vs. community hospital increased the odds of enrollment for both groups: young (OR 2.79, $p<.0001$) and older (OR 2.04, $p<.0001$), as did being married vs. single: OR 2.31, $p=0.0016$ for younger and OR 1.85, $p<.0001$ for older adults. Among older adults only, Hispanic patients (OR 0.87, $p=0.0056$; ref NH White) and female patients (OR 0.91, $p=0.0002$; ref male) were less likely to enroll. Living in the most vs. least socially vulnerable neighborhoods impacted trial enrollment more for young adults (OR 0.75, $p<.001$) than for older adults (OR 0.91, $p<.0001$), $p=0.0042$ for interaction. **Conclusions:** Many factors that influence trial enrollment, including insurance, social support, diagnosis at an academic center, and race/ethnicity, are similar among young and older adults with colon cancer. However, the negative impact of neighborhood disadvantage on trial enrollment is more pronounced among young adults, highlighting the need for practical trial design, targeted navigation, and strategic recruitment of young adults living in socially vulnerable areas. Research Sponsor: None.

Accessibility of study contact information in ClinicalTrials.gov: A comprehensive analysis.

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Background: While the official purpose of ClinicalTrials.gov is to satisfy regulatory requirements from the U.S. Food and Drug Administration meant to safeguard human subjects, the database also serves as the most comprehensive record of ongoing clinical trials for patient and provider use. Previous studies have focused on compliance with results reporting and completeness of information within restricted subsets of the database. Taking the perspective of a potential participant or their provider, the purpose of this study was to assess the accessibility of ClinicalTrials.gov contact information across actively recruiting oncology and non-oncology studies. **Methods:** This study included all actively recruiting interventional studies listed in the ClinicalTrials.gov database as of June 11, 2025. We assessed the completeness of location and contact information by multiple factors including oncology versus non-oncology study, sponsor type, trial phase, study start date, and date of last posted update. Within oncology studies, we further analyzed information availability by disease subsite. **Results:** We identified 47,703 actively recruiting interventional trials, among which 12,400 (26.0%) pertained to oncology. Within these oncology studies, 3178 (25.6%) had an industry sponsor, 9729 (78.5%) had a study phase listed (among which 59.4% were Phase 2 studies), and 4311 (34.8%) involved an FDA-regulated drug. Across both oncology and non-oncology studies, 2678 (5.6%) were missing any central contact information. While all trials had at least one study location listed, 3492 (7.3%) did not include a location-specific contact name and 9994 (21.0%) had neither a location-specific contact phone nor email address (24.1% for oncology, 19.8% for non-oncology). Within oncology trials, 50.9% of studies with an industry sponsor lacked any location-specific contact phone or email, compared to 11.3% for NIH sponsors and 14.9% for other (including academic) sponsors. Completeness of location-specific contact information was similar across trial phases. By oncology disease subsite, thoracic trials (29.8%) or those including multiple disease subsites (33.8%) most often lacked location-specific contact phone and email, whereas head and neck (15.4%) and neuro-oncology (16.3%) trials were least likely to do so. **Conclusions:** Location remains a primary means by which many potential trial participants filter clinical trial opportunities. Missing location-specific contact information, particularly among trials with industry sponsors, is an area of potential improvement that could be addressed by increased attention or more stringent registration requirements. While emerging strategies to improve clinical trial accessibility include artificial intelligence-powered platforms, these are only as good as the primary data on which they are built. Research Sponsor: None.

Hospital designation and survival disparities in young-onset gastrointestinal cancer.

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Background: Early-onset gastrointestinal (GI) cancers (<50 years) are increasing in incidence. We examined the impact of National Cancer Institute (NCI) designation and academic affiliation on mortality and care delivery for young-onset GI cancer patients in New York State. **Methods:** We performed a retrospective analysis using the Statewide Planning and Research Cooperative System (SPARCS) database from 2009 to 2024. Patients were stratified by admission type (emergency vs elective) and hospital site (NCI vs non-NCI; academic vs community). GI cancers included anal, biliary, colorectal, esophageal, gallbladder, liver, pancreatic, peritoneal, small intestine, and gastric cancers. Clinical characteristics were defined using the All Patient Refined grading system. Academic hospitals were classified via the Association of American Medical Colleges Database. Wilcoxon rank-sum tests compared continuous variables; Chi-squared or Fisher's exact tests for categorical variables. Linear regression was performed for continuous outcomes, and multinomial logistic regression for categorical outcomes, with significance at $P \leq 0.05$. **Results:** A total of 29,753 young-onset GI cancer patients were included, of which 48.7% were emergency admissions. For emergency admissions, NCI sites treated patients with higher illness severity, and most had private insurance ($P < 0.001$). There was no significant difference in length of stay (LOS) between NCI and non-NCI sites. Cost of treatment was significantly higher at NCI sites ($P < 0.001$), which also performed more procedures ($P = 0.002$). NCI sites were associated with 36% lower odds of in-hospital mortality ($OR = 0.64 [0.55-0.75]$, $P < 0.001$) despite higher illness severity. For elective admissions, in-hospital mortality was 0.5% at NCI sites vs 7.3% at non-NCI sites ($OR = 0.04 [0.03-0.05]$, $P < 0.001$). For emergency admissions, academic sites treated patients with higher illness severity, and most patients had private insurance ($P < 0.001$). Admission to an academic site was associated with increased LOS ($\beta = 0.03 [0.02-0.05]$, $P < 0.001$). Cost of treatment was significantly higher at academic sites ($P < 0.001$), which performed more procedures ($P < 0.001$). No significant difference in mortality was seen between academic and community sites. For elective admissions, in-hospital mortality was 0.5% at academic sites vs 5.8% at community sites ($OR = 0.08 [0.06-0.11]$, $P < 0.001$). Across all hospitals and admission types, private insurance was independently associated with shorter length of stay ($P < 0.001$). **Conclusions:** Treatment at NCI-designated centers for both emergent and elective admissions was associated with significantly lower in-hospital mortality among young-onset GI cancer patients despite higher illness severity. Insurance-based disparities highlight the need for interventions to ensure equitable access to high-quality cancer care for this vulnerable population. Research Sponsor: Roswell Park Cancer Institute; National Cancer Institute (NCI) grant; P30CA016056.

Transportation access as a structural determinant of quality of life and symptom burden among cancer patients.

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Background: Growing evidence links the built environment to cancer outcomes, with NCCN recommendations emphasizing the importance of transit access in cancer care. Cancer patients, especially at advanced ages, are vulnerable to inadequate transit access due to frequent medical appointments and treatment-related physical and financial toxicity. This study examined the relationship between public transit access, quality of life (QoL), pain, and fatigue among adults with cancer. **Methods:** We analyzed data from 31,126 adults with cancer enrolled in the NIH All of Us cohort, which is designed to include populations historically underrepresented in biomedical research. Cancer cases were identified using ICD and SNOMED codes. Multivariable ordinal logistic regression was used to assess associations between distance to public transit and self-reported QoL, pain, and fatigue adjusted for age, sex, race/ethnicity, income, education, and insurance. Similar models examined sociodemographic predictors of transportation-related healthcare delays. **Results:** Decreased public transit access was associated with worse QoL, pain, and fatigue (Table 1). Transportation-related delays in care were more likely among older adults aged 65+ (aOR=0.30, $p=0.02$) compared to 18-25 year olds; women (aOR=1.13, $p=0.03$); unemployed individuals (aOR=1.13, $p<0.001$); and those with lower income (aOR=7.60, $p<0.001$). Participants identifying as Black (aOR=1.65, $p<0.01$), Hispanic (aOR=1.27, $p<0.01$), or multiracial (aOR=1.73, $p<0.01$) also reported higher odds of transportation-related delays. **Conclusions:** Reduced public transit access is associated with worse quality of life, symptom burden, and care delays among adults with cancer. Providers can utilize transportation coordination as a tool for improving patient outcomes, particularly in the functional domains of pain and fatigue and among underserved populations. Further, policy-makers should identify and address gaps in public transit access, yielding downstream benefits for population health, quality of life, and survivorship among cancer patients. Consideration for transportation should be integrated into treatment plans for all cancer patients to reduce financial toxicity and treatment costs while improving outcomes. Research Sponsor: National Institutes of Health, Office of the Director.

Adjusted odds of worse health outcomes by decreased transit access: Adjusted association between public transit access and pain, fatigue, and quality of life among adults with cancer.^a

Outcome	aOR (95% CI) ^b	P-value
Low Quality of Life	1.09 (1.00, 1.19)	0.04*
Moderate/High Pain	1.12 (1.06, 1.18)	<0.001****
Moderate/High Fatigue	1.14 (1.08, 1.20)	<0.001****

^aAdjusted for age group, sex, race/ethnicity, employment, income, insurance.

^bPublic transit stop >15 minutes away.

* $p < 0.05$, **** $p \leq 0.001$.

Travel time to cancer care as it relates to care access, transportation distress, and financial toxicity: Findings from the Cancer Experience Registry.

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Background: Longer travel time to cancer care has been linked to worse prognosis and quality of life for patients. This study aims to examine how travel time to cancer care is associated with access to care, transportation-related distress, and financial toxicity. **Methods:** Participants in Cancer Support Community's Cancer Experience Registry (CER) from Oct 2021-Dec 2025 reported sociodemographic and clinical information, financial toxicity (11-item FACIT-COST), travel time to cancer care (min/hr), transportation-related distress (1=*not at all* to 5=*very seriously concerned*), and delays/barriers to accessing cancer care (yes/no). Descriptive findings and between-groups analyses (Chi-square) are presented. **Results:** 3,590 U.S. adults (75% women; 82% non-Hispanic (NH) White, 7% NH Black, 5% Hispanic/Latino, 5% multiple or other races; 18-95 years old [Mean=62.2, SD=13.1]) reported various cancer diagnoses (34% breast, 25% blood, 10% colorectal, 7% gynecologic, 25% other), with 54% in remission/NED, 18% localized, and 15% metastatic (time since diagnosis Median=3yrs). FACIT-COST indicates 52% with no financial toxicity, 26% mild, 20% moderate, and 2% severe financial toxicity (M=24.9, SD=12.0). For travel time, 67% of participants reported < 1hr, 23% 1-2hrs, 7% 3-4hrs, and 4% 5+hrs. 79% reported no transportation distress, while 10% were slightly concerned and 12% moderately to very seriously concerned. Over one-quarter (29%) reported ever experiencing a delay in cancer care. Among patients traveling <1hr to their care center, 24% reported experiencing delays/barriers, compared with 46% of those traveling 5+hrs ($\chi^2=84.3$, $p<.001$). Similarly, transportation-related distress increased with travel time: 84% of patients traveling <1hr reported no concern, whereas only 60% of those traveling 5+hrs reported no concern, with 29% reporting moderate to very serious concern ($\chi^2=167.9$, $p<.001$). Lastly, financial toxicity increased with travel burden: 43% of patients traveling <1hr reported mild-to-severe financial toxicity versus 64% of those traveling 5+hrs ($\chi^2=63.7$, $p<0.001$), and 85% of those reporting moderate to severe transportation distress also reported at least mild financial toxicity ($\chi^2=388.4$, $p<0.001$). **Conclusions:** Most patients surveyed reported living within 1hr of their care site and experienced little transportation distress; however, those who travel longer distances for care report higher rates of delays/barriers, greater transportation-related distress, and more financial toxicity. Collectively, these findings underscore that longer travel times are linked to both objective barriers and subjective distress, highlighting that travel burden may limit timely cancer care and worsen patient outcomes. Policy solutions that bring quality care closer to patients are essential to reduce travel burdens and distress. Research Sponsor: Genentech; Bristol Myers Squibb.

Exploring transportation insecurity among cancer patients in urban cancer clinics in Ontario, Canada.

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Background: Advancements in cancer therapeutics have led to increasing care complexity, higher visit frequency, and increased economic burdens for many patients undergoing cancer treatment. Emerging data suggests that transportation challenges may have an important, and uneven impact on the delivery of cancer care. We completed a cross-sectional survey to better understand the prevalence and impact of transportation insecurity in cancer clinics serving a diverse urban and inner-city patient population in a public-payor system. **Objectives:** The Care for All Health Equity Pilot aims to explore the barriers that patients experience when engaging with cancer treatment. In a pilot exploratory analysis we identified transportation insecurity as associated with missed oncology appointments. The objectives of this study were to explore factors associated with higher level of transportation insecurity amongst our patient population. **Methods:** A cross-sectional survey on patient demographics, financial toxicity (COST tool), transportation challenges, housing and food insecurity was delivered to all adult patients attending cancer clinics at two major urban centres in Toronto, Ontario from July – August 2025. We conducted an exploratory, descriptive, and bivariate analysis of factors correlated with higher levels of transportation insecurity amongst survey respondents. **Results:** 576 patients completed the survey, 48.6% of whom identified as female. 44.8% and 25.0% of respondents had solid tumour or malignant hematologic diagnoses respectively. The most common diagnoses were breast cancer (18.8%), and lymphoma (10.8). Nearly a third (28.8%) of survey respondents endorsed stress related to accessing and paying for transportation to and from their medical appointments. The most common transportation-related stressors preventing patients from attending appointments were parking/travel expenses (26.7%), and the ability to locate accessible parking (13.9%). In an exploratory bivariate analysis patient age, non-English preferred language, access to a personal vehicle, self-identifying with a disability, and living alone emerged as correlates for transportation insecurity. **Conclusions:** Health-related transportation insecurity is common, impacting nearly a third of adult cancer patients receiving care at major urban cancer clinics in a public-payor system. Transportation related costs, and lack of accessible parking, are key contributors to transportation related stress. A multivariate analysis exploring the impact of transportation insecurity on missed oncology appointments, and healthcare utilization, is underway and further information will be available at the meeting. Research Sponsor: Academic Health Sciences Center (AHSC) Alternate Funding Plan (AFP) Innovation Fund.

Access to trastuzumab deruxtecan for HER2-low metastatic breast cancer in Brazil's Unified Public Health System: A population-impact model.

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Background: HER2-low disease has recently emerged as a distinct, targetable category in metastatic breast cancer (MBC), with trastuzumab deruxtecan (T-DXd) demonstrating a clinically meaningful overall survival (OS) benefit. In Brazil, however, access to innovative oncology therapies within the Unified Health System (SUS) is frequently delayed. We quantified the population-level consequences of delayed access to T-DXd for patients with HER2-low MBC. **Methods:** We conducted a nationwide population-impact analysis from the public-payer perspective, combining Brazilian epidemiologic data with survival benefit estimates derived from randomized clinical trials, using an exponential approximation to model long-term outcomes under delayed-access scenarios. An annual eligible cohort was constructed stepwise from incident MBC (21,133/year), applying: SUS dependence (proxy: 1 - private coverage, $p=0.759$), HER2-low prevalence ($p=0.320$), HR+ proportion among HER2-low (proxy using luminal status, $p=0.747$), and probability of reaching the eligible line of therapy ($p_{line}=0.50$). Treatment effect inputs were taken from the DESTINY-Breast04 HR+ subgroup (median OS 23.9 vs 17.5 months. OS HR=0.64 [95% CI 0.48–0.86]). Primary outcome was preventable deaths/year, computed as $\text{treated/year} \times (1 - \text{HR})$, where treated/year equals the annual eligible cohort multiplied by uptake (95%, 75%, 50%). A sensitivity range for preventable deaths was generated by varying HR across its trial-reported 95% CI. Life-years gained over 10 years were estimated as $\text{treated/year} \times 10 \times \Delta \text{median OS (years)}$. One-way sensitivity varied p (HER2-low) from 0.25 - 0.46 (uptake fixed at 95%). **Results:** The modeled annual eligible cohort was 1,917 patients/year, treated/year was 1,821 (95% uptake), 1,438 (75%), and 959 (50%). Estimated preventable deaths/year were 656 (range 255–947), 518 (201–748), and 345 (134–498), corresponding to 6,560, 5,180, and 3,450 deaths avoided over 10 years, respectively. Life-years gained over 10 years were 9,713, 7,668, and 5,112 across the three uptake scenarios. Varying $p(\text{HER2-low})$ from 0.25–0.46 yielded 513–943 preventable deaths/year and 7,588–13,962 life-years gained (10 years) at 95% uptake. **Conclusions:** Delayed access to T-DXd within Brazil's public health system may result in substantial, avoidable mortality among patients with HER2-low MBC. These findings highlight the urgent need for accelerated incorporation pathways, consistent HER2-low testing, and operational readiness to translate proven survival gains into real-world benefit. Research Sponsor: None.

Scenario	Uptake	Treated/ year	Preventable deaths/year	Range (HR 95% CI)	Life-years gained (10 years)
Base-case (95%)	95.0%	1,821	656	255 – 947	9,713
Moderate (75%)	75.0%	1,438	518	201 – 748	7,668
Conservative (50%)	50.0%	959	345	134 – 498	5,112

Geographic accessibility of recruiting clinical trials for rare and common gastrointestinal malignancies in the United States.

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Background: Gastrointestinal (GI) cancers account for substantial cancer mortality, with rare GI malignancies experiencing particularly poor outcomes and limited therapeutic options. Clinical trials are essential for treatment development; however, the geographic accessibility of disease-specific trials for rare GI cancers remains insufficiently characterized. **Methods:** We queried ClinicalTrials.gov to identify actively recruiting interventional disease-specific trials for GI cancers in the United States (accessed Jan 2026). Trials were classified as common (colorectal, pancreatic, hepatocellular, gastroesophageal) or rare (anal, appendiceal, small bowel adenocarcinoma, biliary tract) GI cancers. Trial sites were geocoded by ZIP code. Geographic accessibility was defined as the proportion of the U.S. population residing within 30 miles of a recruiting trial site; areas without a site within 30 miles were defined as clinical trial deserts. Urban-rural status and income quartiles were derived from census-based classifications. A 60-mile access definition was evaluated as a sensitivity analysis. **Results:** A total of 283 disease-specific GI cancer trials encompassing 1,322 unique U.S. trial site ZIP codes were included. More than 80% trials were early-phase (Phase I-II). Using a 30-mile access definition, overall population coverage was 83.6%, with lower coverage in rural versus urban populations (47.5% vs 90.9%) and in the lowest vs highest income quartiles (65.8% vs 98.0%). Common GI cancers had broad access, including colorectal cancer (80.2% population coverage) and pancreatic cancer (75.3%). In contrast, more than half of the population resided in a clinical trial desert for rare GI cancers (biliary tract = 55.2%, small bowel = 56.4, anal cancer= 80.8%, appendiceal 99.5%). Over 75% of rural residents resided in trial deserts for any rare GI cancer. Findings were consistent using a 60-mile access definition. **Conclusions:** Geographic accessibility remains a major barrier for disease-specific clinical trials of rare GI malignancies. This results in extensive clinical trial deserts and perpetuates existing disparities for rural and lower-income populations. These findings highlight structural gaps in trial availability and support the need for more geographically inclusive trial designs. Research Sponsor: None.

Geographic access to disease-specific gastrointestinal cancer clinical trials.

Cancer type	Trials(N)	Trial site ZIP (N)	% Pop ≤30 mi	%Pop in trial desert	%Rural Pop in trial desert	%Lowest income quartile in trial desert
Common						
Colorectal	82	1,026	80.2	19.8	59.2	38.5
Pancreas	75	730	75.3	24.7	67.1	45.1
Gastroesophageal	46	684	71.9	28.1	69.1	49.8
Hepatocellular cancer	45	210	54.7	45.3	93.2	64.5
Rare						
Biliary tract cancer	28	109	44.8	55.2	95.1	70.3
Small bowel adenocarcinoma	2	419	43.6	56.4	77.5	67.2
Anal	5	19	19.2	80.8	99.1	86.6
Appendicular	1	1	0.5	99.5	99.9	99.7

Validation of prognostic scores in Hispanic patients with advanced solid tumors enrolled in a single-center phase I clinical trial program.

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Background: Prognostic scores are commonly used to guide enrollment in early-phase oncology trials. Despite their widespread use, these models have not been specifically evaluated in Hispanic patients, to the best of our knowledge — a population historically underrepresented in clinical trials. We evaluated the predictive performance of the Royal Marsden Hospital (RMH) score, the Princess Margaret Hospital Index (PMHI), and the MD Anderson Cancer Center (MDACC) score in a cohort of Hispanic patients with advanced solid tumors enrolled in phase I clinical trials. **Methods:** We performed a retrospective chart review of Hispanic patients with advanced solid tumors enrolled in phase I clinical trials at USC Norris Comprehensive Cancer Center and its affiliated safety-net institution, Los Angeles General Medical Center, between 2015 and 2022. Prognostic scores were calculated using the established criteria: RMH score (albumin <3.5 g/dL, LDH > ULN, >2 metastatic sites), PMHI (albumin <3.5 g/dL, ECOG >0, >2 metastatic sites), and MDACC score (albumin <3.5 g/dL, LDH > ULN, ECOG >0, >2 metastatic sites, gastrointestinal tumor type). RMH and PMHI risk groups were categorized as low (0–1 points) or high (2–3 points), while MDACC risk groups were defined as low (0–1 points), intermediate (2–3 points), or high (4–5 points). Overall survival (OS) was analyzed using Kaplan–Meier methods. **Results:** A total of 191 Hispanic patients were included (109 gastrointestinal, 36 lung/head and neck, 20 other, 16 gynecologic, 6 genitourinary, 4 breast). Median age was 59 years (25–86). The median OS for this cohort was 13.1 months (95% CI, 8.8–18.3). Significant differences in OS were observed across prognostic risk groups for all three prognostic scores. Median OS for RMH high- versus low-risk patients was 5.1 versus 18.3 months ($p=0.004$); for PMHI high- versus low-risk patients, 6.5 versus 20.0 months ($p=0.002$); and for MDACC high-, intermediate-, and low-risk patients, 4.1, 15.7, and 32.7 months, respectively ($p=0.007$). **Conclusions:** In this Hispanic solid tumor phase I trial population, higher RMH, PMHI, and MDACC scores were associated with poorer overall survival. These findings support the use of established prognostic scores in Hispanic patients for identifying candidates with poor prognosis and informing early-phase trial enrollment. Prospective studies are warranted to further validate prognostic scores in the Hispanic population. Research Sponsor: None.

RMH	Median OS (Months)	PMH	Median OS (Months)	MDACC	Median OS (Months)
Low (0-1)	5.1	Low (0-1)	6.5	Low (0-1)	4.1
High (2-3)	18.3	High (2-3)	20.0	Intermediate (2-3)	15.7
				High (4-5)	32.7
	$p=0.004$		$p=0.002$		$p=0.007$

Breaking barriers: Evaluation of a low-threshold community-based HPV vaccination model for gender minorities and sex workers in Milan.

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Background: Human Papillomavirus (HPV) is the primary etiological factor for anogenital and oropharyngeal cancers. Sexual and gender minorities (SGM) and sex workers (SW) face an increased risk of HPV-related diseases but encounter significant barriers to vaccination, including stigma, discrimination in healthcare settings, and low risk perception. "VaccinaMI-LAN*" is a community-based initiative designed to enhance vaccine accessibility by offering the first dose of the 9-valent vaccine in safe and inclusive environments, such as Milan's "rainbow" districts during weekend evening hours. This study assessed the demographic characteristics, risk factors, and barriers within this hard-to-reach population. **Methods:** An anonymous paper-based questionnaire was administered to participants vaccinated during the May and October 2024 editions of VaccinaMILAN*. The survey evaluated demographics, gender identity, sexual behaviors, HPV knowledge, vaccination barriers, and satisfaction with the community approach. Categorical variables were described using frequencies and percentages; data were analyzed using Chi-square tests (two-tailed p-value < 0.05). **Results:** 320 questionnaires were collected (response rate: 76.2%). Most respondents were under 35 years old (68.7%) and held a university degree (65.9%). The sample primarily consisted of cisgender MSM (76.9%), followed by cisgender female SWs (13.4%) and gender minorities (9.8%). Despite a high prevalence of receptive anal intercourse (61.7%), 95.4% had never undergone anal cancer screening. HPV knowledge was significantly higher among younger participants ($p = 0.0063$) and university graduates ($p = 0.0169$). Reported barriers included: 45.7% did not know how to access vaccination; 25.4% did not perceive themselves at risk; approximately 20% had previously experienced vaccination refusal in traditional healthcare settings. Overall, 99.7% expressed satisfaction with the initiative. **Conclusions:** The VaccinaMILAN* project demonstrates the effectiveness of a multidisciplinary community-based approach in improving vaccine equity for marginalized populations. The findings highlight the urgent need for targeted awareness campaigns and specific training for healthcare providers regarding HPV vaccination and anal cancer screening recommendations for these populations. Research Sponsor: None.

Participation of older adults (aged ≥ 65 years) in SWOG cancer clinical trials.

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Background: Cancer disproportionately affects older adults. Approximately 60% of cancer diagnoses occur in adults aged 65 and older in the United States. However, disparities persist in participation of older adults in cancer clinical trials. **Methods:** Using 38 years of data from phase III trials of the SWOG Cancer Research Network between 1985 to 2022, this study examined clinical, socio-demographic, and trial factors associated with participation of older adults (≥ 65 Years) in cancer clinical trials. Summary statistics were used to describe patient and trial characteristics. To examine factors associated with enrollment of older adults, mixed-effects multivariate logistic regression was performed with the odds of being an older adult (≥ 65 years) as the dependent variable. **Results:** A total of 45,670 patients accrued to 64 SWOG phase III trials were included in the analysis. Across all trials, 30.6% participants were aged 65 and older, and 57.8% were female. Participants were predominantly non-Hispanic (96.2%) White (87.4%) and most resided in urban areas (82.4%). Regression analysis results showed that adjusted odds of enrollment as an older adult did not differ statistically significantly by cancer stage or intervention type (targeted therapy, immunotherapy, hormonal therapy, chemotherapy, radiation, or surgery). Compared with breast cancer trials (reference group with the lowest proportion of older adult enrollment), the odds of enrolled participants being older adults were higher in gastrointestinal cancer trials (OR=3.39), lung/thoracic cancer trials (OR=3.24), and genitourinary/prostate cancer trials (OR=6.77). Compared with White participants, Black participants (OR=0.64) and Asian/Pacific Islander (OR=0.64) had lower adjusted odds of being older adults. The odds of being aged ≥ 65 years were nearly twice as high among non-Hispanic participants compared with Hispanic participants (OR=1.85). Participants from rural areas had higher adjusted odds of being aged ≥ 65 years than those from urban areas (OR=1.10). No statistically significant differences were observed across Area Deprivation Index (ADI) quartiles. **Conclusions:** Although some progress has been made in the participation of older adults in cancer clinical trials in the past decades, more work needs to be done to enhance their participation (especially those belonging to underrepresented groups) in cancer clinical trials. Tailored and targeted recruitment efforts are needed to improve participation of diverse older adults in cancer clinical trials. Research Sponsor: Hope Foundation for Cancer Research.

Time to treatment initiation for triple-negative breast cancer in Brazil: A call for public health action.

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Background: Timely initiation of treatment is a critical determinant of outcomes in breast cancer. In Brazil, national legislation mandates treatment beginning within 60 days of histopathological diagnosis. Adherence to this interval may be particularly relevant in triple-negative breast cancer (TNBC), an aggressive subtype associated with rapid disease progression and poor prognosis. **Methods:** Data were collected from patients (pts) diagnosed with primary TNBC, stages I–III, treated at two large public cancer centers in Brazil between 2010–2016 and in 2022 and one private oncology network in Brazil between 2020–2023. Treatment delay was defined as an interval ≥ 60 days. Data were compared between public and private settings. Logistic regression models were used to identify factors associated with treatment delay. **Results:** A total of 1,644 pts were included, 1,347 (82%) in the public and 297 (18%) in the private setting. Pts aged < 50 years accounted for 40.3% of those in the public healthcare system and 67.7% of those in the private sector. Patients in the private setting presented with earlier-stage disease (49.5% diagnosed at stage I–IIA vs. 28.1% in the public setting), whereas a higher proportion of stage IIB–III disease was observed in the public setting (71.9% vs. 50.5%; $P < 0.001$). Treatment initiation beyond 60 days occurred in 75.4% of pts in the public setting, compared with 14.1% in the private setting ($P < 0.001$). In multivariable logistic regression analysis, factors independently associated with treatment delay included public healthcare service (OR 19.26, 95% CI 13.3–27.9; $P < 0.001$), older age compared to ≤ 30 ys, ranging from OR = 2.06 among patients aged 31–39 years (95% CI 1.02–4.16; $p = 0.045$) to OR = 5.48 among those aged ≥ 70 years (95% CI: 2.55–11.81; $p < 0.001$) and earlier stage (I–IIA vs. IIB–III OR = 1.45, 95% CI 1.10–1.91; $p = 0.008$). **Conclusions:** Rates of treatment initiation beyond 60 days after diagnosis are alarmingly high in the Brazilian public health system, indicating that the 60-day law implementation remains suboptimal. Lower odds of treatment delay among younger patients and those with more advanced disease likely reflect clinical prioritization of individuals with more aggressive or symptomatic presentations. These findings underscore the urgent need for health policy interventions aimed at reducing delays in cancer care, particularly for high-risk subtypes such as TNBC. Research Sponsor: None.

Impact of neighborhood socioeconomic deprivation and diet quality on immune checkpoint blockade outcomes.

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Background: Immune checkpoint blockade (ICB) has significantly improved survival across multiple advanced malignancies; however, outcomes remain heterogeneous. While socioeconomic disadvantage (SED) is known to adversely affect cancer outcomes through delayed diagnosis and access to care, impact of SED upon ICB efficacy remains incompletely characterized. The Area Deprivation Index (ADI) is a validated, neighborhood-level measure of SED. We evaluated the association between ADI and clinical outcomes to ICB across a large, multi-state integrated cancer network. **Methods:** We identified 1,699 adult patients with advanced cutaneous melanoma (CM), renal cell carcinoma (RCC), or urothelial carcinoma (UC) treated with first-line ICB (monotherapy or combination) between 2013–2025 within the UPMC Hillman Cancer Center network (>70 sites across four states). ADI scores were derived from 9-digit ZIP codes at ICB initiation using the Neighborhood Atlas and categorized into quartiles, with higher quartiles indicating greater SED. Primary endpoints were time-to-next therapy (TTNT) and overall survival (OS), measured from ICB initiation to initiation of subsequent systemic therapy or death, respectively. Outcomes were analyzed by ADI quartile using Kaplan–Meier methods and Cox proportional hazards models adjusted for relevant clinical covariates. Analyses were limited to first ICB exposure. **Results:** Across 2,156.3 person-years follow-up, patients in highest ADI quartile experienced a significantly higher incidence of TTNT events compared with lowest quartile (31.1% vs 22.8%; χ^2 $p=0.008$), without a corresponding increase in deaths (39.2% vs 38.4%; χ^2 $p=0.86$). Highest ADI status was independently associated with inferior TTNT after first-line ICB in CM (HR 1.51; 95% CI 1.01–2.27; $p=0.04$), RCC (HR 1.58; 95% CI 1.02–2.45; $p=0.04$), and UC (HR 2.02; 95% CI 1.11–3.68; $p=0.01$). Association between ADI status and OS were not statistically significant after adjustment for confounding variables. Univariate and multivariate analyses were performed to control for confounding variables, and confirmed independent prognostic impact of highest ADI quartile upon inferior TTNT. Within a subset of ICB-treated CM patients with available dietary intake data, highest ADI quartile had lowest Healthy Eating Index (HEI) scores (Wilcoxon $p=0.01$). **Conclusions:** Neighborhood-level SED is associated with inferior durability of response to first-line ICB across multiple solid tumors. These findings suggest that SED may influence ICB effectiveness beyond treatment access alone and underscore the need to identify biologic and care-delivery mechanisms—potentially including diet, comorbidities, and the gut microbiome—through which deprivation impacts ICB outcomes. Prospective, pan-cancer studies integrating social, clinical, and biological variables are warranted. Research Sponsor: None.

CancerTrialsBR: An open-access, collaborative platform to improve visibility and access to cancer clinical trials in Brazil.

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Background: Lack of timely and understandable information is a major barrier for cancer trials recruitment, particularly outside high-income countries. ClinicalTrials.gov (CTGov) has been widely used to address this need, but language barriers and inconsistent identification of research facilities limit its use. Large language models (LLMs) now offer opportunities to address these limitations. We describe CancerTrialsBR, a pilot platform that integrates CTGov, Google Maps (GMaps), and LLMs to provide Portuguese-language geographically contextualized cancer trial information in Brazil. **Methods:** Clinical trials data and listed research sites are retrieved from CTGov on a daily basis with condition as “cancer”, location as “Brazil”, and status as “recruiting”. Using prompt engineering techniques (CoT and few-shot), trial information is processed by LLM to generate a Portuguese brief summary, ideal patient profile, and trial descriptors according to primary site (N=39), treatment settings (N=8, i.e. first-line), and biomarkers (N=18, i.e. PDL1). For each site, its address components (i.e. name, city) are queried through the GMaps API for standardized facility identification. A LLM performs facility-matching validation, and invalid cases are manually reviewed. This enriched database is made available as an open-access clinical research platform of the Brazilian Society of Clinical Oncology since November 4th, 2025 (<https://pesquisaclinica.sboc.org.br>), where users can suggest real-time status updates. We report facility identification metrics, database statistics, and site interactions since launch. **Results:** Of 2,873 unique CTGov addresses, 654 (22.76%) retrieved zero results from GMaps, of which 612 (93.57%) were subsequently identified by zip code. For the 2,219 GMaps retrieved locations, LLM validation demonstrated an accuracy of 85.78%, with positive and negative predictive values of 96.9% and 59.0%. Overall, only 93 (3.2%) addresses remained unidentifiable after human review. As of January 19th, 2026, the database comprised 272 trials conducted across 191 research facilities, encompassing 22 of 27 Brazilian states and 76 cities. The median (IQR) of clinical trials per facility was 2 (1-9) with 8 facilities hosting 40 trials or more. São Paulo (260/272, 95.6%), Rio Grande do Sul (195/272, 71.6%), and Rio de Janeiro (108/272, 39.7%) had the largest availability of trials. The platform had 2,320 visits from 220 cities within 76 days, and the leading searched cancer was breast. Users feedback resulted in 34 of 57 (59.6%) suggested status updates incorporated in the database. **Conclusions:** CancerTrialsBR demonstrates the feasibility of integrating LLMs and GMaps to deliver accessible, real-time cancer trial information in Brazil, with early adoption highlighting unmet need and offering insights into the country's cancer research infrastructure. Research Sponsor: None.

Breast cancer patient navigation to identify individual needs and offer medical and supportive care referrals.

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Background: Despite evidence that patient navigation (PN) improves access to comprehensive care for patients with breast cancer (BC), its adoption in Mexico remains limited, likely due to multifactorial barriers. To address this gap, our center implemented one of the country's first PN programs to systematically identify and document patients' medical and support needs and provide referrals to appropriate services. This study describes patient needs and referral attendance up to 6 months (m) post-diagnosis. **Methods:** Patients newly diagnosed with BC are identified after their first medical oncology consultation at Hospital Zambrano Hellion TecSalud and are consecutively invited to the PN program, which consists of assessments at baseline, 3m, and 6m. At each timepoint, patients answer validated surveys and target questions to explore their needs. The navigator then shares the results with each patient and refers them to the required specialty or support services. Attendance to baseline and 3m referrals is assessed at 3m and 6m, respectively. This analysis includes patients navigated from 2020–2025. **Results:** 421 patients had reached 6m of follow-up: 357 (85%) and 261 (62%) completed their 3m and 6m navigation, respectively. Median age at diagnosis was 48 years (IQR 41–58). Most were married (76%), and had ≥ 1 child (84%), higher education (75%), and private healthcare (76%). The most common baseline referrals were to nutrition (86%), psychology (68%), support groups (47%), and wig providers (42%). At follow-up, patients mainly required referral to sexology counseling (3m: 82%, 6m: 79%), nutrition (3m: 78%, 6m: 77%), psychology (3m: 51%, 6m: 39%), and lymphedema counseling/therapy (3m: 40%, 6m: 66%). Attendance was highest to support groups (90–95%), wig providers (64–87%), and geriatric assessment (67–80%). Despite high need, attendance was notably lower for nutrition (47–52%), psychology (58%), and sexology counseling (0%). Main reasons for nonattendance were lack of interest (48%), time constraints (38%), and financial issues (10%). **Conclusions:** In this PN program, referrals were mostly needed for nutrition, sexology, and psychology. While attendance was high for some services, rates were suboptimal for the most common referrals, especially sexology counseling. Efforts to better convey referral rationale and importance may increase uptake and access to comprehensive quality-of-life focused care. Research Sponsor: None.

Patient needs and attendance to referrals.

	Baseline referrals N=421 (%)	Baseline - 3m attendance %	3m referrals N=357 (%)	3m - 6m attendance %	6m N=261 (%)
Nutrition	361 (86)	47	278 (78)	52	202 (77)
Sexology	-	-	291 (82)	0	206 (79)
Psychology	287 (68)	58	181 (51)	58	102 (39)
Support group	197 (47)	90	90 (25)	95	47 (18)
Wigs	175 (42)	87	22 (6)	64	8 (3)
Lymphedema	134 (32)	28	144 (40)	23	171 (66)
Geneticist	126 (30)	69	42 (12)	43	25 (10)
Fertility preservation	78 (19)	52	19 (5)	100	3 (1)
Geriatrics	7 (2)	67	5 (1)	80	5 (2)

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

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Background: In October 2017, an ASCO, Friends of Cancer Research (FoCR), and US FDA (ASCO/FoCR/FDA) task force recommended that common eligibility criteria be modified to make trials more inclusive. We examined whether patterns of HIV-related eligibility criteria changed over time in relation to these recommendations. **Methods:** Trial eligibility criteria were abstracted from ClinicalTrials.gov for any phase, US-based clinical treatment trials for patients with cancer from 2010-2024. Trials were classified as not excluding, conditionally excluding (ie, excluding under specific circumstances such as unstable or untreated cases), or completely excluding patients with HIV. Eligibility criteria were classified using OpenAI language models with prompt refinement and independent validation. Interrupted time series analyses were used to determine whether the recommendations in 2017 were associated with changes in HIV criteria. We also examined whether eligibility-criteria changes varied by phase and lead sponsor (federal vs. industry). **Results:** We evaluated 20,751 trials, mostly phase I-II (80.3%), with 7.8% federally and 40.6% industry funded, including breast (19.1%), lung (11.0%), prostate (16.2%), and colorectal (14.1%) cancers. The AI classification achieved 97% accuracy on the development sample and 94% on an independent validation sample. Overall, patients with HIV were wholly excluded in 28.9%, conditionally excluded in 26.1%, and not excluded in 45.0% of trials. The guidance was associated with an increase in conditional exclusion (13.1% to 29.1%; $p < .001$) and no exclusion (24.1% to 28.9%; $p = .002$), and a decrease in wholly exclusion (62.8% to 42.0%; $p < .001$). Similar shift patterns were observed across trials with different main funding sources (federal vs industry) and phases (I-II vs III) (Table). **Conclusions:** Following the ASCO/FoCR/FDA task force recommendations, HIV exclusion criteria shifted predominantly from complete exclusion to conditional exclusion, indicating progress toward more inclusive clinical trial designs. **Acknowledgement:** We thank Dr. Roy Burstein, PhD, at the Institute for Disease Modeling, Gates Foundation, for his invaluable advice. **Research Sponsor:** None.

HIV exclusion criteria before and after the guidance.

	Jan 2010-Oct 2017, No. (%)	Nov 2017- Dec 2025 Without guidance (%)	With guidance (%)	p
All				
C	4175 (48.1)	62.8	42.0	<.001
Cond	1905 (22.0)	13.1	29.1	<.001
N	2597 (30.0)	24.1	28.9	<.001
Federal led				
C	342 (41.5)	41.4	22.3	<.001
Cond	299 (36.2)	36.2	57.2	<.001
N	184 (22.3)	22.3	20.5	0.40
Industry led				
C	1589 (48.7)	61.1	40.2	<.001
Cond	532 (16.3)	12.6	25.5	<.001
N	1141 (34.9)	26.3	32.6	<.001
Phase 1-2				
C	3742 (53.8)	69.3	46.6	<.001
Cond	1622 (23.4)	13.4	30.1	<.001
N	1581 (22.8)	17.3	22.5	<.001
Phase 3				
C	958 (46.3)	52.0	29.1	<.001
Cond	442 (21.4)	10.2	26.2	<.001
N	666 (32.2)	37.8	44.7	0.10

C/Cond/N: completely/conditionally/not excluded.

Impact of a centralized APP-led peer-to-peer program on patient access, provider burden, and institutional revenue.

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Background: Prior authorization (PA) and peer-to-peer (P2P) requirements impose a significant administrative burden on oncology clinicians, contributing to burnout and care delays. At our Comprehensive Cancer Center, internal data showed frontline Advanced Practice Providers (APPs) and oncologists spent unsustainable hours on insurance denials. To mitigate clinical fatigue and optimize workflows, we launched a centralized initiative transitioning P2P responsibilities from frontline clinicians to a specialized APP team. **Methods:** Following a successful pilot project, a centralized P2P program was established for outpatient diagnostic imaging denials. Based on early success, the program expanded to include outpatient medication-related denials. A dedicated APP team utilized standardized workflows, documentation, and formal escalation pathways to manage all outpatient P2P referrals. Program performance was evaluated on these metrics: 1) Access to Care: Measured by completion rate, authorization turnaround time (TAT) and pre-authorized status at arrival. 2) Provider Burden: Assessed by administrative hours reclaimed from frontline staff and qualitatively via a provider satisfaction survey. 3) Institutional ROI: Evaluated via denial overturn rates and net reclaimed revenue from authorized billable services. **Results:** Centralization markedly improved operational efficiency. The program achieved a clear increase in P2P completion rate from 80% provider-led baseline to 99% by centralized team. This coupled with a reduction in TAT for both imaging and medication authorizations, increased the percentage of patients arriving with pre-authorized status by 12% in the first two years. Overturn rates and positive disposition for initial denials rose to 85% or greater compared to the provider-led baseline of 78%. Frontline clinicians reported a substantial decrease in daily administrative tasks, facilitating increased patient-facing hours and improved work-life integration. Financially, the program demonstrated a robust ROI by securing authorization for high-cost services previously denied and providing payer trend data to inform broader managed care strategies. **Conclusions:** Centralizing P2P responsibilities within a dedicated APP team is a multidimensional solution that extends beyond revenue recovery. This model effectively mitigates provider burnout, optimizes patient flow, and protects clinical capacity. As oncology practices face increasing complexity in 2026, this scalable model offers a vital roadmap for balancing financial health with workforce sustainability. Research Sponsor: None.

Operational and clinical drivers of subcutaneous PD-1/PD-L1 inhibitor adoption: A mixed-methods analysis of U.S. oncology practice patterns.

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Background: Subcutaneous (SC) formulations of PD-1/PD-L1 inhibitors have recently been approved across multiple solid tumors. While these agents offer operational and patient-centric advantages, their perceived clinical value relative to established intravenous (IV) formulations remains unclear. Understanding real-world oncologist perceptions may inform future adoption patterns and practice impact. **Methods:** A national mixed-methods study surveyed 102 U.S. hematologist-oncologists from academic (44%, n=45) and community (56%, n =57) practices across all U.S. regions (Nov- Dec 2025). A structured online questionnaire assessed brand utilization, regimen sequencing, physician satisfaction, switching behavior, and perceived comparative benefit between pembrolizumab- and nivolumab-based therapies using Likert-type scales and utilization metrics. All participants met predefined patient volume and clinical practice criteria. Eight qualitative interviews explored drivers of brand choice, sequencing, and switching decisions. **Results:** Across tumor types, oncologists reported modest current use of SC PD-1/PD-L1 inhibitors, with incremental uptake expected over the next six months. SC formulations were viewed as convenience-enhancing rather than clinically transformative, with reduced chair time (75% reporting significant benefit), improved infusion center efficiency (68%), and better patient experience (70%) cited as key benefits. Approximately half of PD-1/PD-L1-eligible patients across NSCLC, melanoma, and RCC were considered suitable for SC administration. Perceived benefit was largely limited to monotherapy and maintenance settings, with limited added value in curative-intent or combination regimens where infusion time is driven by other agents. In NSCLC, projected near-term uptake of SC PD-1/PD-L1 therapy was highest among PD-L1-high patients receiving monotherapy, while in melanoma and RCC, SC was more often positioned later in the treatment sequence, particularly after treatment stability. Insurance coverage (39% reporting a significant barrier) and cost (58%) were the primary barriers to broader adoption, outweighing concerns about safety (22%) or efficacy (27%). Overall uptake was expected to primarily substitute for IV monotherapy rather than expand total PD-1/PD-L1 use. **Conclusions:** U.S. oncologists view SC PD-1/PD-L1 inhibitors as operational alternatives to IV therapy, with adoption driven by efficiency and patient convenience and constrained by payer dynamics. SC administration is best positioned to enhance care delivery in monotherapy and maintenance settings, with limited incremental value in curative-intent or combination regimens. Addressing real-world access barriers will be key to broader integration across solid tumors. Research Sponsor: None.

Patient-reported barriers to treatment access and home delivery in rare cancers across five European countries.

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Background: Patients with rare diseases, including rare cancers, frequently experience barriers to timely treatment access. Sciensus, an end-to-end pan-European service partner, and Rare Patient Voice, a patient-led advocacy organisation, conducted a multicountry, European survey to characterise treatment logistics, delivery models and patient burden, with a focus on implications for oncology populations. **Methods:** A cross-sectional survey was conducted in December 2025 among adult patients with rare diseases, including cancer diagnosis, and caregivers across Italy, the United Kingdom, France, Spain, and Germany. Quantitative and qualitative data were collected on treatment access, medication collection or home delivery, financial and emotional burden, reliability of services, and participation in Early Access Programs (EAPs). Descriptive analyses were performed. **Results:** Among 860 respondents, approximately 120 (14% of total; 28% of validated rare disease responses) reported a cancer diagnosis spanning ~34 cancer types. While most respondents reported infrequent treatment delays, a notable minority experienced frequent disruptions. Over half reported no access to, or lack of awareness of, home delivery services. However, more than 40% indicated that home delivery would significantly or fundamentally improve quality of life. Ratings of homecare reliability varied widely, ranging from very poor to excellent, indicating substantial inconsistency across delivery models and regions. **Conclusions:** Patients with rare cancers in Europe experience fragmentation and heterogeneity across treatment access pathways. Limited awareness, variable availability, and inconsistent reliability of homebased delivery services likely contribute to ongoing burden. Additional longitudinal study of burden should be conducted to confirm the findings of the experiences in this study. Expanding, standardising and systematising patient-centred delivery models represents a key opportunity to improve continuity of care and quality of life for oncology patients with complex needs. Research Sponsor: Sciensus.

Advancing health equity in oncology: Virtual collaborative behavioral health engagement and outcomes among Medicaid-insured and BIPOC patients.

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Background: Depression and anxiety are common among patients with cancer, yet access to behavioral health care remains limited, particularly for Medicaid-insured and racially minoritized populations. We evaluated reach, baseline symptom burden, and longitudinal outcomes of a virtual collaborative behavioral health program embedded within community oncology.

Methods: We conducted a retrospective cohort study of patients referred to a virtual collaborative behavioral health program (Cerula Care) across community oncology practices from 2024–2026. Outcomes included representation of Medicaid-insured and BIPOC patients among those initiating care, baseline symptom burden assessed by PHQ-9, GAD-7, and FACT-G7 stratified by insurance (Medicaid vs commercial+Medicare) and race/ethnicity (BIPOC vs White), and longitudinal symptom change during program participation. Independent t-tests were used for between-group comparisons, and paired t-tests were used for within-patient comparisons. **Results:** Between program launch and data cutoff, 1,400 patients were referred by oncology providers; 850 consented and scheduled an intake, and 631 completed intake and initiated behavioral health care. Among 631 patients initiating behavioral health care, 43.5% identified as BIPOC (36.5% Black) and 18.7% were Medicaid-insured, indicating a strong reach into populations historically underserved by behavioral health services. Baseline symptom severity was significantly higher among Medicaid-insured compared with commercial+Medicare patients across all measures, indicating clinically meaningful greater symptom burden. Baseline severity did not differ by race/ethnicity. Improvements in depression, anxiety, and quality of life were observed over time. Between-group differences in symptom improvement by insurance or race were not statistically significant, though Medicaid-insured and BIPOC patients showed directionally greater PHQ-9 and FACT-G7 improvement, and Medicaid-insured greater GAD-7 improvement. Patient-reported experience indicated high acceptability (Net Promoter Score 88); 60% reported improved oncology visit adherence and 61% improved adherence to non chemotherapy medications. **Conclusions:** Embedding virtual collaborative behavioral health in community oncology was associated with high reach among Medicaid-insured and BIPOC patients. Medicaid-insured patients entered care with greater symptom burden yet experienced symptom improvements comparable to commercially insured and Medicare patients, with similar outcomes across racial/ethnic groups. These findings support collaborative care as a scalable strategy to expand access to behavioral health services and promote equitable supportive oncology care. Research Sponsor: None.

FALCON-Lung: Evolving global real-world treatment choices and outcomes for metastatic NSCLC in different patient populations.

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Background: Despite rapid global adoption of immune checkpoint inhibitors (ICI) for meta-static non-small cell lung cancer (mNSCLC), real-world treatment access, selection, time on treatment and transitions between regimens remain poorly characterized across health systems and patient populations. Whether observed outcomes are consistent across regions, data sources, and age groups is largely unknown. Addressing these gaps at scale requires a federated analytic approach with standardized analyses across sites, enabling reliable and comparable results while preserving patient privacy. **Methods:** We launched FALCON (Federated Alliance for Large-scale Cancer Observational Network), the largest federated, most diverse oncology network supporting observational cancer research, and its subnetwork FALCON-Lung. FALCON-Lung includes 23 sites (hospitals, registries, public-private) providing longitudinal cancer data from 2015 onwards standardized to OMOP common data model, from 11 countries in Europe, US and Australia. All sites completed data quality assessments and targeted improvements to improve completeness and overall cancer data quality. Analyses were executed locally using shared analytic code without sharing patient-level data. **Results:** Among 111,574 NSCLC pts included, 62% developed metastatic disease, of whom 59% initiated antineoplastic drugs within three months; 88% received a guideline-recommended 1st line regimen. ICI uptake rose sharply between 2017 - 2019; by 2022 59% received ICI ($\pm$ platinum) in 1st line. ICI monotherapy showed a tendency toward longer overall survival (OS) compared with platinum ($\pm$ ICI), although no single regimen demonstrated a consistent advantage across all databases. OS decreased with age across sites. Patients aged ≥ 81 years were less likely to receive systemic therapy and, when treated, more often received ICI monotherapy. No clear or consistent differences in OS were observed between different treatment regimens in this age group. **Conclusions:** In this global federated study, ICI uptake showed consistent patterns across sites and regions. OS varied across sites and no consistent survival advantage was observed for ICI regimens, either as monotherapy or in combination, although higher OS with ICI monotherapy was observed in some settings. Older patients (aged ≥ 81 years) were more frequently treated with ICI monotherapy without a corresponding survival advantage, possibly reflecting real-world treatment selection driven by tolerability rather than biomarkers. Research Sponsor: iCAN.

	Total	18-64y	65-81y	$\geq 81y$
NSCLC	111,574	36,239	62,328	13,007
Metastatic NSCLC	68,678	24,059	36,397	8,222
1st line systemic therapy	40,619	15,226	21,397	3,980
1st line guideline-approved systemic therapy	35,560	13,458	18,725	3,361
1st line in 2022 (%)				
ICI monotherapy	17	12	18	32
ICI + platinum doublet	42	43	45	26
Other guideline-approved regimen	41	45	37	43

Coverage of subcutaneous versus intravenous oncology therapies by US commercial health plans.

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Background: Several widely used intravenous (IV) oncology therapies have recently been reformulated for subcutaneous (SC) administration. Compared with IV infusions, SC formulations reduce administration time and chair use, improve patient convenience, and enable more flexible sites of care. At the same time, SC formulations may alter established reimbursement and contracting arrangements, including shifts away from buy-and-bill payment, changes in site-of-care management, and differences in how net costs are realized by payers. We examined how US commercial health plans prioritize SC formulations relative to IV formulations in their drug coverage policies. **Methods:** We used the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) Database to identify US commercial health plans with coverage policies for both SC and IV formulations of oncology therapies. SPEC includes detailed treatment access criteria from 17 large US commercial health plans. Coverage policies were current as of December 2025. The unit of analysis was a plan-drug combination, e.g., UnitedHealthcare’s policies for trastuzumab. Coverage was classified as *IV preferred*, *on par*, or *SC preferred*, depending on if one formulation is required before another. **Results:** We identified 86 coverage policies across 6 oncology therapies. One payer excluded the SC formulation from coverage in two instances, thereby denying enrollees access to the therapy. Among the remaining 84 policies, 8 (9.5%) were classified as *IV preferred* and 76 (90.5%) as *on par*; no policies classified the SC formulation as preferred (Table 1). Coverage varied across therapies, with the frequency of IV-preferred coverage among payers covering both formulations ranging from 0% to 21%. Among the 76 on-par policies, 55 (72.4%) allowed patients to initiate treatment with either the IV or SC formulation without prior treatment requirements. In contrast, 21 (27.6%) required patients to first try and fail an alternative therapy before coverage for either formulation was granted. These step-therapy requirements were more common for older therapies with available biosimilars, and the required prior therapy was most often a biosimilar of the reference product. **Conclusions:** Across six oncology therapies, most US commercial plans covered SC and IV formulations on par, with a minority preferring IV and none preferring SC. Preferences varied by product, and access restrictions mainly reflected step-therapy requirements for older therapies with available biosimilars. Research Sponsor: National Pharmaceutical Council.

Overview of coverage for intravenous (IV) and subcutaneous (SC) formulations.				
Drug	# Payers Covering IV & SC Formulations	SC Only Preferred	Coverage Parity (SC vs IV)	IV Only Preferred
Drug A	16	0	14 (87.5%)	2 (12.5%)
Drug B	15	0	14 (93%)	1 (7%)
Drug C	15	0	14 (93%)	1 (7%)
Drug D	15	0	15 (100%)	0 (0%)
Drug E	14	0	11 (79%)	3 (21%)
Drug F	9	0	8 (89%)	1 (11%)
Total	84	0	76 (90.5%)	8 (9.5%)

Inpatient financial toxicity among women hospitalized with breast cancer in the United States, 2013–2022.

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Background: Financial toxicity is an increasingly recognized consequence of cancer care. While the outpatient costs of breast cancer are well described, national trends and drivers of inpatient financial toxicity are not well understood. We evaluated temporal trends in hospitalization volume, inflation-adjusted inpatient charges, and factors associated with high financial toxicity among women hospitalized with breast cancer in the United States. **Methods:** We performed a retrospective analysis of the National Inpatient Sample (2013–2022), including women aged ≥ 18 years with a breast cancer diagnosis. Survey weights, strata, and clusters were applied. Charges were inflation-adjusted to 2022 USD. High financial toxicity was defined as inpatient charges ≥ 75 th percentile. Temporal trends were assessed using weighted regression, and multivariable survey-weighted logistic regression identified predictors of high financial toxicity. **Results:** An estimated 1.70 million weighted hospitalizations were identified. Annual hospitalizations declined significantly (P for trend < 0.001), from 178,660 in 2013 to 168,630 in 2022, with a nadir in 2020. In contrast, mean inflation-adjusted inpatient charges increased by 35.5%, from \$58,869 to \$79,797 (P for trend < 0.001), totaling more than \$119.3 billion in cumulative charges. Most hospitalizations occurred at urban teaching hospitals (71.2%). On multivariable analysis, urban teaching (OR 3.84, 95% CI 3.58–4.12) and urban non-teaching hospitals (OR 3.53, 95% CI 3.28–3.79) had nearly four-fold higher odds of high financial toxicity compared with rural hospitals. Compared with White patients, Hispanic (OR 1.53), Asian/Pacific Islander (OR 1.44), and Black patients (OR 1.10) had higher odds. Private insurance (OR 1.14) and residence in the highest income quartile (OR 1.35) were associated with increased odds, while older age was associated with lower odds. Odds of high financial toxicity increased steadily over time, peaking in 2020 (OR 1.58) (P for trend < 0.001). **Conclusions:** Despite declining hospitalization rates, inpatient financial toxicity among women with breast cancer has worsened substantially, driven primarily by hospital setting and structural factors. Racial and ethnic disparities were also evident, with minority groups experiencing higher odds of high inpatient charges. These findings underscore the need for value-based strategies and policy interventions to mitigate inpatient financial burden in oncology care. Research Sponsor: None.

Geographic distribution of cancer treatment trials and population-level cancer outcomes in the U.S.

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Background: Access to cancer clinical trials varies geographically in the U.S., yet the relationship between trial availability and population-level cancer outcomes is poorly characterized. Understanding this relationship is critical for policymakers and trial sponsors seeking to reduce disparities in cancer outcomes. **Methods:** We conducted an ecological analysis of U.S.-based cancer treatment trials (1990–2025). Trial availability was measured using population-adjusted cumulative trial density (trials/10,000 population) and classified as none, low, medium, or high. County-level cancer mortality-to-incidence ratios (MIRs) were used to indicate post-diagnosis outcomes (lower MIR is better). Associations with trial density were assessed using logistic regression, with and without adjustment for the structural factors, including area deprivation index (ADI), health system performance, and area type (metro, micro, non-metro/non-core). Analyses were stratified by area type and ADI to stabilize estimates and assess associations across strata. **Results:** Between 1990 and 2025, 32,332 U.S.-based trials were conducted. The majority of counties (1,680, 52%; 10% of the U.S. population) had no trials. In counties with trials, counts ranged from 1 to 6,840 and density from 0.05 to 1,992 per 10,000 population. Compared to counties without trials, low-, medium-, and high-density counties were more likely to have lower MIR (OR = 1.9, 3.6, and 3.3, respectively; all $p < .001$). After adjustment for structural factors, associations persisted in medium- and high-density counties (OR = 1.7, 1.9; $p < .001$), but not in low-density counties (OR = 1.2; $p = .30$). Associations were strongest in metro counties (Table), with ORs of 1.91, 2.61, and 2.61 in high-ADI areas (all $p < 0.0001$). In low-ADI areas, medium and high density were associated with lower MIR (OR=2.58 and 2.00; $p < .001$), but low density was not (OR=1.33; $p = 0.70$). **Conclusions:** Cancer clinical trial availability in the U.S. is highly concentrated and strongly associated with improved population-level cancer outcomes. The co-occurrence of low trial density, structural deprivation, and higher cancer MIRs highlights opportunities to improve cancer outcomes by expanding the geographic reach of trial infrastructure. Research Sponsor: None.

Associations between trial density and MIR.

Areas	Trial Density	OR*	p	Adjusted OR*	p
All counties	None	Ref			
	Low	1.90	<.001	1.16	.30
	Medium	3.64	<.001	1.72	<.001
	High	3.34	<.001	1.86	<.001
Metro	None	Ref			
	Low	2.10	.005	1.37	.30
	Medium	3.70	<.001	2.31	.005
	High	4.13	<.001	2.83	.001
Micro	None	Ref			
	Low	1.35	.05	1.10	.60
	Medium	2.00	.001	1.33	.20
	High	2.35	<.001	1.46	.04
Non-metro/non-core	None	Ref			
	Low	0.97	.90	0.88	.80
	Medium	3.72	.01	3.74	.02
	High	2.37	.01	1.86	.10
Low ADI	None	Ref			
	Low	1.33	.07	1.25	.20
	Medium	2.58	<.001	2.38	<.001
	High	2.00	<.001	1.91	<.001
Higher ADI	None	Ref			
	Low	1.91	<.001	1.36	.05
	Medium	2.61	<.001	1.59	.02
	High	2.61	<.001	1.99	<.001

*Odds of lower MIR.

Access to immunotherapy and molecular diagnostics for lung adenocarcinoma in Syria: A mixed-methods study from the country's main cancer center.

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Background: Immunotherapy is now a standard-of-care treatment for lung cancer across most stages. Access to immunotherapy and molecular diagnostic tests in conflict-affected countries such as Syria remains poorly described. As the principal cancer center in Syria, Al-Bairouni University Hospital (ABUH) provides care for nearly three-quarters of all cancer cases nationally. We conducted this study to evaluate access to immunotherapy and molecular diagnostic services at ABUH. **Methods:** A mixed-methods study was performed between 2022 and 2024 at ABUH. This study included a retrospective cohort of all patients diagnosed with lung adenocarcinoma. Quantitative data included disease stage at diagnosis, molecular testing rates, and immunotherapy utilization. In addition, a qualitative patient survey was thematically analyzed to explore barriers to treatment access in a separate cohort of patients with mixed tumor types. **Results:** Among 2,920 patients diagnosed with lung cancer, 1,393 (47.7%) had lung adenocarcinoma. The median age at diagnosis was 61 years; 79.7% of patients were male. Smoking history was as follows: Current 792 (56.9%), Former 268 (19.2%), never smoked 318 (22.8%) At presentation, 3 patients (0.2%) had stage I disease, 40 (2.9%) stage II, 174 (12.5%) stage III, and 778 (55.8%) stage IV disease, staging was unknown for the rest of the patients. EGFR mutation testing was performed by ABUH for 226/1393 patients (16.2%) only, with positive results identified in 124 cases (8.9%). PD-L1 testing was conducted by ABUH in only 32/1393 patients (2.3%) and was positive in 23 (1.65%). Of all patients with lung adenocarcinoma, only 5 patients (0.6%) with stage IV disease received immunotherapy. All were treated with nivolumab. Thematic analysis of qualitative data (35 patients) revealed that high treatment costs and limited drug availability are the primary barriers to accessing immunotherapy. **Conclusions:** This study represents the first evaluation of access to immunotherapy for patients with lung cancer in Syria. Even at ABUH, the country's main cancer center, access to immunotherapy and molecular testing remains markedly limited. International collaboration is necessary to expand diagnostic infrastructure, standardize data reporting, and enhance financial protection mechanisms. These are critical steps toward achieving better cancer care in Syria. Research Sponsor: None.

Assessment of CAR-T clinical trial availability and accessibility in the United States.

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Background: Chimeric antigen receptor T-cell (CAR-T) therapy has transformed outcomes in hematologic malignancies and is increasingly evaluated in solid tumors. CAR-T trials requires specialized infrastructure, potentially limiting access by geography and institutional concentration. We assessed the national distribution of CAR-T clinical trials, population distant from trial sites, and institutional clustering. **Methods:** All active U.S. interventional Phase I-III CAR-T trials (adult/pediatric) were identified via ClinicalTrials.gov (accessed January 2026). Trial locations were geocoded by ZIP code and linked to 2020 Census ZIP Code Tabulation Areas. Population access was defined as residence within 30 or 60 miles of a trial site using Haversine distance. Rurality (RUCA codes), income quartiles, and race/ethnicity (ACS 2023) were evaluated to assess disparities. Institutional concentration was assessed by the proportion of trial sites contributed by individual institutions. **Results:** Out of 264 identified trials, 189 were selected, conducted across 356 unique institutions. More than 85% of trials were early phase(Phase I–II), spanning lymphoma, myeloma, leukemia, and solid tumor indications. Access was limited. At a 30-mile radius, 43.3% of the U.S. population (~145 million individuals) lacked proximity to an active CAR-T trial site; 27.1% (~91 million) remained without access at 60 miles. Within 30 miles, lack of access affected 94.1% of rural residents, compared with substantially lower coverage in urban areas, and 63.2% of individuals in the lowest income quartile. By race and ethnicity, 37.4% of Hispanic and 32.0% of Black populations lacked access within 30 miles. These patterns were consistent when access was defined at 60 miles. Trial availability was highly centralized. The top 10 of institutions accounted for over 60% of all CAR-T trials, led by large academic centers such as City of Hope, Memorial Sloan Kettering, MD Anderson, Texas Children’s Hospital, and Stanford University. These centers are located in major metropolitan regions, resulting in dense trial availability for populations living nearby while leaving large geographic regions without access. In contrast, approximately 60% of participating institutions hosted only a single CAR-T trial, indicating limited diffusion of trial infrastructure beyond major academic hubs. **Conclusions:** CAR-T clinical trial access in the United States is restricted by both geographic exclusion and marked institutional concentration. As CAR-T indications expand, addressing these structural bottlenecks will be critical to improving equitable access and ensuring broader participation in cellular therapy development. Research Sponsor: None.

Access to CAR-T clinical trials.		
Population Group	30 mi	60 mi
Overall US Pop	43.3%	27.1%
Rural Pop	94.1%	65.6%
Lowest income quartile	63.2%	45.8%
Hispanic	37.4%	25.9%
Black	32.0%	20.1%

20-year trends in socioeconomic disparities in breast cancer care for patients aged < 65 years old.

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Background: Socioeconomic disparities (SES) in cancer care have been well described, especially for younger patients with limited financial reserve and insurance vulnerability. It remains unclear, however, whether innovations in breast oncology have mitigated or exacerbated these gaps over time. We evaluated nearly 20-year trends across key breast cancer treatment and diagnostic modalities and sought to determine whether advances in care promote, or further undermine, health equity. **Methods:** Using the National Cancer Database, we identified working-aged individuals (18–64 yo) diagnosed with breast cancer from 2004–2022. As surrogates for improvements in breast cancer care, we examined: (i) Oncotype DX testing for stage I–II ER/PR-positive, HER2-negative disease; (ii) immediate breast reconstruction (IBR) after mastectomy; (iii) receipt of neoadjuvant chemotherapy (NACT) for stage II HER2-positive (HER2+) and triple-negative breast cancer (TNBC); and, (iv) immunotherapy by subtype and stage (2018–2022). We used multivariable logistic regression to generate adjusted predicted probabilities by median income quartile (MIQ) and year (or year group). Median Income Disparities (MID) were measured as the difference between the highest and lowest MIQ. **Results:** The final sample included 1,349,691 patients with mean age 51.8 (SD 8.64). Patient population included 7.7% Hispanic, 72.3% Non-Hispanic White, 13.2% Black, 5.9% Asian, and 0.9% unknown race/ethnicity. 76.7% of patients were privately insured, 10.8% Medicaid-covered, 6.2% Medicare-covered, 1.5% other, 1.8% unknown, and 3.1% uninsured. During the study period, overall adoption of treatment increased substantially over time, with SES disparities differing across modality. Oncotype DX testing demonstrated persistent income-related disparities across the study period (MID: 4.2–5.5%, $p < 0.05$ for all). The largest and most durable inequities were seen in post-mastectomy IBR (17.60% in 2004–2008, narrowing to 11.70% in 2018–2022, $p < 0.05$ for all). Receipt of NACT was associated with modest income-based differences that were greatest during years of rapid uptake for stage II HER2+ (4.9% in 2014–2017, $p < 0.05$) and TNBC (4.8% in 2018–2022, $p < 0.05$) breast cancer. Adoption of immunotherapy rose sharply from 2018–2022 across all incomes, with modest but narrowing gaps for stage III–IV disease (MID: 4.9% in 2019, $p < 0.05$ to 1.1% in 2022, NS). Adjustment for insurance status did not significantly change socioeconomic gradients. **Conclusions:** Socioeconomic disparities in breast cancer care for women <65 years old vary markedly by treatment modality and adoption phase. Advancing equitable access to best-practice breast cancer care will require interventions at the health system, societal guidelines, and policy levels. Research Sponsor: None.

Clinical trial participation among adolescents and young adults diagnosed with cancer in the United States (2004-2021).

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Background: Adolescents and young adults (AYAs, 15–39 years) have low historical participation in cancer clinical trials (CTs) than pediatric patients, which limits access to novel therapies and slows progress in outcomes. Although cooperative-group networks and AYA-focused initiatives have improved accrual, enrollment remains uneven across care settings and patient subgroups, highlighting the need for contemporary population-level estimates of participation and its predictors. **Methods:** The National Cancer Database was utilized to identify AYAs diagnosed between 2004 and 2021 with one of the 20 cancer types associated with the highest mortality. Patients with confirmed malignant neoplasms, known vital status, and ≥ 6 months of follow-up were included. The final analytic cohort comprised 865,923 patients. The primary endpoint was documented CT participation (yes/no). Multivariable logistic regression was used to estimate adjusted odds ratio (aOR) of enrollment by diagnosis epoch, age group, sex, race/ethnicity, insurance status, area-level education and median income, residence, Charlson-Deyo comorbidity score, and receipt of surgery, radiation, and systemic therapy. **Results:** Overall, 2,621 patients (0.3%) were enrolled in a CT. Enrollment increased from 0.1% (2004–2009) to 0.2% (2010–2013), 0.3% (2014–2017), and 0.5% (2018–2021); compared with 2004–2009, enrollment was higher in 2018–2021 (aOR: 4.92, 95% CI: 4.34–5.60). Compared to those aged <24 years, the odds of enrollment were lower for ages 25–29 (aOR: 0.52, 95% CI 0.46–0.58), 30–34 (aOR: 0.45, 95% CI 0.41–0.51), and 35–39 (aOR: 0.46, 95% CI 0.41–0.50). Enrollment was lower among non-Hispanic Black (aOR: 0.84, 95% CI 0.74–0.96) and Hispanic patients (aOR: 0.79, 95% CI: 0.69–0.90) compared to non-Hispanic White patients. Compared with uninsured patients, enrollment was higher among those with private (aOR: 1.74, 95% CI 1.38–2.21) or government insurance (aOR: 1.60, 95% CI: 1.26–2.05), and was also higher in areas with greater education attainment (aOR: 1.14, 95% CI: 1.03–1.25) and individuals in the high median income group (aOR: 1.13, 95% CI: 1.02–1.25). Patients who had received radiation (aOR 1.56, 95% CI 1.44–1.70) or systemic therapy (aOR 3.59, 95% CI 3.23–4.01) were more likely to enroll. **Conclusions:** CT participation among AYAs was exceedingly low but has increased over time. Differences in enrollment by age, race/ethnicity, insurance, and area-level socioeconomic measures suggest persistent barriers to CT access and participation. These findings support expanding trial availability beyond high-resource settings, strengthening AYA-focused referral pathways and infrastructure, and implementing equity-centered strategies such as navigation, reduced trial burden, and financial/insurance support to improve representation and access to investigational therapies. Research Sponsor: None.

Financial vulnerability among U.S. cancer survivors: Differences by veteran status and VA health care utilization in the National Health Interview Survey, 2020–2024.

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Background: Current national comparisons of financial factors affecting cancer care among Veterans and non-Veteran adults with a self-reported history of cancer are limited. Moreover, little is known about how financial vulnerability influences Veterans receiving care primarily through the VA system versus in community settings. We hypothesize that Veteran status and primary care setting (VA vs. community) are associated with differences in financial vulnerability and related barriers to medical care among U.S. adult survivors of cancer. **Methods:** We pooled 2020–2024 National Health Interview Survey data (n=19,410) to examine associations between Veteran status, VA care use, and financial vulnerability among adult survivors from cancer (including non-melanoma skin cancer). Missing data were addressed using multiple imputation leading to an analytic sample size n=18,846. Survey-weighted logistic regression models accounted for complex sampling and adjusted for age, sex, cancer site, number of cancers, years since diagnosis, poverty ratio, and survey year. Analyses were limited to years when outcomes were collected. Two comparisons were conducted to understand the unique social factors Veterans face compared to non-Veteran patients and differences between primary setting of Veteran care: Model(A) Veterans vs. non-Veterans and (B) VA primary users vs. non-primary VA users. Binary outcomes included delayed care due to cost, delayed care due to transportation barriers, inability to afford care, unpaid medical bills, insurance gaps, medication cost-skipping, and inability to pay expenses. Sensitivity analyses compared weighted and unweighted models. **Results:** The analytic sample of adult survivors from cancer was n=18,846 from 2020–2024 (mean age 68 years; 43% male) and included 2,511 (13%) who self-reported as Veterans (mean age 74 years; 94% male). Adjusted models showed Veteran status was associated with higher odds in care delay due to transportation barriers (OR 1.57; 95% CI, 1.13–2.19) and lower odds of worry regarding unpaid medical bills (OR 0.79; 95% CI, 0.68–0.91) and difficulty obtaining medical care due to cost OR 0.78(0.63–0.98). All other compared variables were not significant. Among Veterans, those who primarily used the VA had lower odds of delaying care due to cost (OR 0.34; 95% CI, 0.17–0.69), not obtaining medical care due to cost (OR 0.50; 95% CI, 0.35–0.72), and skipping medication due to cost (OR 0.25; 95% CI 0.12–0.49). Sensitivity analyses supported these patterns. **Conclusions:** Veterans who are primarily VA users have cost-related vulnerability without a difference in delaying care to non-Veteran counterparts. Such systems that remove financial hardship may be an approach to improve care for survivors from cancer in the U.S. Research Sponsor: None.

Recovery with residual disparities: Real-world patterns of platinum chemotherapy use after the 2023 drug shortage.

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Background: The 2023 national shortages of cisplatin and carboplatin disrupted standard cancer treatment across multiple malignancies. Although the acute effects have been described, patient-level evidence of recovery in platinum chemotherapy access after supply stabilization is limited. We evaluated real-world recovery in platinum initiation across platinum-dependent cancers. **Methods:** We conducted a retrospective cohort study using the TriNetX U.S. Collaborative Network. Adults with platinum-sensitive malignancies, including lung, ovarian, bladder, uterine, testicular, and head and neck cancers, were identified using ICD-10-CM and ICD-O codes and assigned according to the national platinum chemotherapy shortage timeline: shortage (February 10, 2023–January 31, 2024) and post-shortage (July 1, 2024–June 30, 2025) eras. The primary endpoint was time from cancer diagnosis to first receipt of any platinum chemotherapy (cisplatin or carboplatin), analyzed using Kaplan–Meier methods and multivariable Cox proportional hazards models, adjusted for demographic characteristics, NCI Comorbidity Index, risk factors, BMI, and cancer type. Secondary analyses evaluated agent-specific initiation (cisplatin vs carboplatin) and heterogeneity of recovery across cancer sites. Prespecified subgroup analyses assessed differences in recovery by sex and race/ethnicity within matched cohorts. **Results:** The analysis included 33,856 patients diagnosed during the shortage and 30,256 diagnosed post-shortage. Platinum initiation improved post-shortage compared with the shortage period (adjusted hazard ratio [aHR], 1.11; 95% CI, 1.09–1.14; $p < .001$), with median time to initiation decreasing from 206 to 128 days. This improvement was driven primarily by increased carboplatin initiation, while cisplatin initiation continues to stall. Recovery patterns varied by cancer type, with greater improvement observed in ovarian and head/neck cancers and incomplete recovery in bladder cancer. Across eras, slower platinum initiation was observed among older patients (aHR per year increase, 0.99), male patients (aHR 0.92), and racial/ethnic minority groups, including Black (aHR 0.92) and Hispanic patients (aHR 0.90). Comorbidities associated with platinum toxicity, such as CKD (aHR, 0.79), neuropathy (aHR, 0.63), heart failure (aHR, 0.93), and liver disease (aHR, 0.84), were also associated with delayed initiation. **Conclusions:** After resolution of the 2023 platinum shortage, platinum chemotherapy initiation improved across multiple cancers, providing patient-level evidence of recovery in access. However, recovery was heterogeneous, driven largely by carboplatin, and modified by patient clinical and demographic factors, suggesting that restoration of drug supply does not uniformly translate into timely or equitable recovery of standard-of-care treatment. Research Sponsor: None.

Trends in incidence, survival, and cause of death in Kaposi sarcoma in the anti-retroviral therapy era.

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Background: Kaposi sarcoma (KS) is a malignancy driven by human herpesvirus-8 infection and is most commonly associated with HIV. Although often considered indolent, KS can cause significant morbidity and mortality, particularly if HIV is uncontrolled. This study aimed to characterize current incidence and survival trends in KS using the Surveillance, Epidemiology, and End Results (SEER) Database. **Methods:** Cases of KS were identified using ICD-O-3 codes 9140-9143 in the SEER Research Plus Data (17 Registries, 2000-2022). SEER registry incidence rates were calculated over time. Overall survival (OS) across diagnostic eras was estimated using Kaplan-Meier methods. Multivariable Cox models were used to assess associations between race/ethnicity, neighborhood income, rural-urban status, and mortality, adjusting for age, sex, and year of diagnosis. Cause-of-death analyses were performed using SEER cause-specific recodes. **Results:** 9,931 patients with KS were identified, 91% male and 9% female. Racial and ethnic distribution was 45% non-Hispanic White (NHW), 24% Hispanic, 24% Black, 3.7% Asian/Pacific Islander (A/PI), and 0.7% American Indian/Alaska Native (AI/AN). Registry incidence of KS declined from 0.33 per 100,000 in 2000-2004 to 0.22 in 2015-2019 and 0.20 in 2020-2022. One-year OS in 2000-2004 was 77.3% (95% CI 75.7-78.9), in 2015-2019 was 82.2% (95% CI 80.4-83.9), and in 2020-2022 was 80.9% (95% CI 78.3-83.5). In multivariable analyses, Black patients had higher mortality compared with NHW patients (HR 1.55, 95% CI 1.43-1.67), while mortality did not differ significantly among Hispanic, A/PI patients, or AI/AN patients. Residence in the highest neighborhood income quartile was associated with improved overall survival compared with the lowest quartile (HR 0.81, 95% CI 0.73-0.89). Across 2000-2022, HIV/infectious causes accounted for 55.6% of deaths (95% CI, 53.9-57.2), followed by cardiovascular disease (15.1%) and cancer-related causes (13.3%). In cause-specific analysis, later year of diagnosis was strongly associated with lower HIV/infectious mortality (HR 0.96 per year, 95% CI 0.96-0.97), whereas mortality from cancer did not improve over time. **Conclusions:** In the modern antiretroviral therapy era, KS incidence and HIV-related mortality have declined. Despite these advances, inequities persist, with higher mortality observed among Black patients and persons residing in poorer neighborhoods. These findings highlight the need for focused efforts to address disparities in KS outcomes. Research Sponsor: None.

Adjusted hazard ratios for overall survival in Kaposi sarcoma.			
Variable	Adjusted HR	95% CI	P value
Race/Ethnicity			
Non-Hispanic White	Reference	-	-
Black	1.55	1.43-1.67	<0.001
Hispanic	1.02	0.95-1.11	0.54
Asian/Pacific Islander	1.02	0.86-1.20	0.82
American Indian/Alaska Native	1.26	0.89-1.80	0.20
Neighborhood Income			
Highest vs Lowest Quartile	0.81	0.73-0.89	<0.001

Fertility concerns, counseling, and preservation in AYA females with early-stage breast cancer: Chemotherapy receipt and timing.

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Background: Adolescent and young adult (AYA) females with early-stage ER-negative and/or HER2-positive breast cancer commonly receive chemotherapy to reduce risk of recurrence. Fertility concerns, counseling, and preservation may influence chemotherapy decisions and time to chemotherapy (TTC) initiation. **Methods:** We surveyed AYA survivors of stage I–III premenopausal ER-negative and/or HER2-positive breast cancer treated at Kaiser Permanente Northern and Southern California (2013–2022). Fertility concerns were defined as not having completed desired family size or being unsure about having completed desired family size at diagnosis. We summarized receipt of fertility counseling, receipt of chemotherapy, and use of oocyte/embryo cryopreservation for fertility preservation (FP). Among fertility-concerned patients who received chemotherapy, TTC (days from diagnosis) was assessed separately for neoadjuvant chemotherapy (NAC) vs for adjuvant chemotherapy (AdjC). Time to NAC was natural log-transformed and modeled with multivariable log-linear regression to estimate relative differences in TTC, adjusting for stage, study site, ER, HER2, age, and diagnosis year. **Results:** Of 363 respondents, 197 (54%) had fertility concerns at diagnosis; 183/197 (93%) received chemotherapy, similar to 153/166 (92%) among those without concerns ($p=0.7$). Of the concerned chemotherapy recipients, 45 (25%) saw a fertility specialist but did not pursue FP while 55 (30%) underwent FP. For the 112 fertility-concerned NAC recipients, FP was associated with longer TTC than no fertility specialist counseling (mean=41 vs. 30 days; adjusted ratio=1.39; 95% CI 1.15–1.69), whereas fertility specialist counseling without FP was not (mean=31 vs. 30 days, adjusted ratio=1.04; 95% CI 0.86–1.25). For the 71 fertility-concerned AdjC recipients, TTC was similar for patients who did not see a fertility specialist (mean=63 days), those who froze oocytes/embryos (mean=65 days), and those who saw a fertility specialist but did not pursue FP (mean=69 days). **Conclusions:** In this AYA breast cancer cohort, there was no evidence that fertility concerns led patients to decline chemotherapy. FP was associated with a modest delay in NAC initiation (<2 weeks on average). Research Sponsor: National Cancer Institute; P01CA233432.

Time to chemotherapy (TTC) among 183 AYA patients with ER- and/or HER2+ breast cancer and fertility concerns.

Fertility-focused care	N (n=183)	Neoadjuvant chemotherapy (n=112)	Mean TTC, days	Relative difference in TTC, adjusted ratio (95%CI)	Adjuvant chemotherapy (n=71)	Mean TTC, days
No fertility counseling from a specialist	83 (45%)	55 (49%)	29.6	Reference	28 (39%)	62.6
Received fertility counseling from a specialist						
No fertility preservation	45 (25%)	28 (25%)	30.7	1.04 (0.86,1.25)	17 (24%)	68.6
Fertility preservation	55 (30%)	29 (26%)	41.2	1.39 (1.15,1.69)	26 (37%)	64.6

Impact of the Taylor Cancer Research Center (TCRC) and Tempus AI TIME Partnership on clinical trial start-up and accrual.

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Background: TCRC is a nonprofit oncology community practice serving patients in North-western Ohio. TCRC’s partnership with the Tempus AI TIME program leverages proprietary software and nursing teams to support patient matching across a portfolio of industry-sponsored clinical trials. Trials may be rapidly opened "prospectively" before an eligible patient is identified, or "just-in-time" (JIT) once a patient is identified and ready to consent, allowing studies to be activated in response to patient need. The goal of this partnership is to utilize AI-enabled technology and clinical workforce support to alleviate site burden associated with activating and enrolling patients to oncology clinical trials, thereby increasing patient access to novel therapies and optimizing resource utilization. **Methods:** Tempus’ AI-enabled platform analyzes trial eligibility criteria and compares this against patient-level information from a combination of structured EMR data, natural language processing, and large language models. All patients are evaluated against the full TIME trial portfolio nightly, with potential matches reviewed by Tempus nurses. Patients likely to be eligible for a trial are communicated to TCRC for final confirmation. Trials are rapidly activated through a standardized operational model including a pre-negotiated clinical trial agreement, rate card, and central IRB. Program metrics include number of patients pre-screened, trial activation timelines, and trial consents. **Results:** From June 2024 to August 2025, Tempus nurses spent approximately 219 hours pre-screening 1,195 patients from TCRC, yielding 278 potential matches across 92 TIME trials. TCRC activated 16 TIME trials, leading to a total of 66 consents. Within the same time, TCRC activated 9 non-TIME trials resulting in 30 consents. TIME trials averaged 4.1 consents per trial, compared to 3.3 consents for non-TIME trials. TIME activations averaged 10.5 business days for JIT and 15.9 days for prospective trials, versus 55.4 days for non-TIME trials. **Conclusions:** TCRC’s partnership with the Tempus AI TIME program, including enhanced patient pre-screening resources and rapid trial activation model, reduced trial start-up time with an increase in total consents and consents per trial compared with traditional trials. TCRC activated TIME trials 4x faster with a 2x increase in interventional consents and 120% increase in overall consents compared with non-TIME studies. This demonstrates how AI-enabled trial matching, combined with a streamlined operational model, can improve resource utilization and patient access to precision oncology trials in a community setting. Research Sponsor: None.

	Average activation time (days)	Interventional trials	Consents per trial (interventional)	Observational trials	Consents per trial (observational)	Total consents	Consents Per Trial
TIME	13.7	12	2.3	4	9.8	66	4.1
Non- TIME	55.4	6	1.1	3	7.6	30	3.3

User-centered design of a COPD care pathway embedded in oncology care for patients receiving immune checkpoint inhibitors.

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Background: Chronic obstructive pulmonary disease (COPD) is one of the most common comorbidities among patients treated with an immune checkpoint inhibitor (ICI) for cancer, and it is often underdiagnosed and undertreated. We aimed to assess COPD treatment burden among patients with cancer and design a scalable intervention. **Methods:** This mixed-methods study enrolled (1) patients with confirmed/suspected COPD and ICI-treated cancer, and (2) clinicians providing ambulatory cancer or COPD care. Semi-structured surveys assessed treatment burden, self-confidence in COPD care, and barriers. Interviews, guided tours, and focus groups informed the user-centered design of a novel COPD care pathway, and the primary endpoint was participant-perceived feasibility. Qualitative analysis used a matrix approach informed by interview-guide constructs and emergent concepts, with quotations synthesized iteratively. **Results:** Between Feb-Dec 2025, the study team screened 478 individuals to enroll the planned cohort of 100 participants, including 20 patients and 80 clinicians. Nearly all participants completed a survey ($n = 96$), and 36 completed either an interview, tour, or focus group. Most patients reported their diagnosis of COPD had been confirmed (90%), and all were ≥ 50 years old. Clinicians were nurses (47%), physicians (44%), or APPs (6%); 41% practiced at a community oncology clinic. Most patients would use COPD-related services if integrated into oncology visits (75%) and 65% felt they had effective treatment options for both cancer and COPD. Nearly all clinicians (97%) agreed that COPD increased the risk of complications during cancer treatments, and 59% agreed that COPD care should be addressed within oncology clinics. Although most reported feeling confident in managing COPD in patients with cancer (80%), many reported a lack of skills to do so (e.g., teaching inhaler technique, 34%). Commonly cited barriers were insufficient time (63%), limited availability of COPD providers (65%), and COPD medication costs (50%). Qualitative analysis identified key themes: limited awareness of COPD guidance in oncology; resource constraints in community clinics; reliance on specialist referrals; conditional willingness to implement a COPD pathway if it did not detract from cancer care; and needs for educational materials and interoperable electronic medical records. These integrated datasets informed the design of a COPD care pathway to be embedded within oncology infusion visits using flowchart-based decision support to stratify COPD control (green/yellow/red) and support self-management and targeted clinician education at the point of care. **Conclusions:** COPD imposes a substantial treatment burden on patients with cancer, but there are actionable opportunities for care delivery. A user-centered COPD care pathway was designed for feasibility in community oncology settings. Research Sponsor: National Center for Advancing Translational Sciences; 5K12TR004931-02; National Cancer Institute; P30CA012197.

Greening a chemotherapy day ward.

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Background: Cancer care is climate toxic and contributes to the triple planetary crisis which threatens human health and cancer care delivery. Despite this toxicity, sustainability guidelines in oncology are lacking. Our objectives are based on the sustainability touchpoints identified in previous research in our department. Study aims were to understand prescribing patterns, quantify plastic waste, and assess patients' and healthcare professionals' views on acceptability of proposed "green" strategies with the aim to develop a green prescribing checklist. **Methods:** A prospective review of systemic anti-cancer therapy (SACT) delivery at a tertiary oncology outpatient unit was performed. Variables collected included SACT regimen details, dosing interval extensions, supportive medication details and treatment value as rated by the ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS). Daily plastic waste output was measured. Anonymous surveys of patients and healthcare professionals were developed using previously validated questionnaires and circulated among adult patients attending cancer services locally and cancer care professionals nationally. Survey domains included sustainability knowledge, perceived barriers/facilitators, and willingness to adopt sustainability measures such as oral therapy. Findings were reported using descriptive statistics. Institutional and ethical approval was received prior to study commencement. **Results:** Selected findings show 23% (n=200/864) of supportive medications were given intravenously (IV). There was widespread adoption of subcutaneous formulations and extended dosing intervals. Most regimens with ESMO-MCBS scores showed substantial clinical benefit. Each patient attendance generated a mean of 46 grams of plastic waste. Seventy-two healthcare professionals responded to the survey; 97% (n=70/72) agreed that climate change adversely impacted human health and 82% (n=59/72) agreed that sustainable practices can decrease the effects of climate change yet only 15% (n=11/72) reported routinely considering environmental impacts when prescribing. Barriers to sustainable practices included time 65% (n=47/72), inadequate training 61% (n=44/72) and lack of institutional support 63% (n=45/72). A total of 211 patients submitted responses; 91% (n=190/208) agreed that reducing environmental impact should be a priority for hospitals, and 82% (n=159/194) were in favour of oral medications over IV where appropriate. **Conclusions:** This study, integrating provider and patient perspectives, demonstrates support for sustainable practices in oncology, but ad-hoc current implementation of same. The findings will guide development of a green checklist informed by patients and prescribers, followed by implementation and re-audit. Patient-centred strategies can align high value cancer care with planetary health and fill the current gap in sustainable oncology practice. Research Sponsor: Health Service Executive.

Accelerated diagnostic pathway for undifferentiated malignancy via interventional radiology triage: A comparative effectiveness study.

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Background: Efficiently triaging patients presenting with imaging findings suggestive of malignancy but lacking a definitive tissue diagnosis poses a considerable challenge for large cancer centers. Without a tissue diagnosis in the setting of metastatic disease it is unclear which specialized medical oncologist would be the optimal physician to see the patient. Traditional referral patterns may lead to significant diagnostic delays until the patient reaches the appropriate oncologist. We evaluated the efficacy of a dedicated "Rapid Biopsy" (RB) pathway, which directs such patients immediately to the Interventional Radiology (IR) Outpatient Clinic for streamlined, image guided diagnosis and compared this new pathway to the traditional, standard institutional referral approach. **Methods:** This retrospective cohort study included 1157 patients at Memorial Sloan Kettering Cancer Center (MSKCC) who underwent a first diagnostic biopsy between 2020 and 2023. The cohort comprised 532 patients from the prospectively enrolled RB program and 625 patients in a rigorously matched comparison cohort (CC), derived from standard referrals who presented with an "unknown primary" malignancy, excluding any patient with a history of prior tissue sampling or recurrence. The primary endpoints were the mean time from initial consultation to biopsy and the mean time from initial consultation to treatment initiation. Independent t-tests were used for cohort comparison. Patients exhibiting outlier time-to-treatment intervals exceeding 90 days were excluded from the treatment analysis. **Results:** The RB and CC cohorts were well-matched demographically (mean age RB: 65.75 years; CC:66.05 years). Malignancy was confirmed in 90.4% and 92.3% of the respective cohorts. The RB pathway demonstrated a 71% reduction in time from initial consult to biopsy than the CC (4.59 vs 15.66 days, $p<0.001$), representing an 11.07 reduction. Furthermore, this operational efficiency translated into a 63% reduction in time from initial consult to treatment compared to the CC (14.57 vs 39.88 days, $p<0.001$), achieving an 11.88 day reduction in time to start. **Conclusions:** The dedicated Interventional Radiology first Rapid Biopsy pathway provided a clinically significant meaningful acceleration in the cancer diagnostic and treatment process, saving 11 days from consult to biopsy and nearly 12 days to definitive treatment initiation. This model effectively streamlines care by eliminating multi-specialty diagnostic detours prevalent in traditional triage, establishing a crucial operational standard for comprehensive cancer centers managing new suspected malignancies. Research Sponsor: None.

Patient-reported performance status as a predictive tool for mortality and supportive care needs in patients with advanced cancer.

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Background: Performance status is a key prognostic factor among patients with advanced cancer and can inform the need for supportive care services. However, assessment and documentation of performance status is inconsistently integrated into standard oncology care. Patient-reported performance status (PRPS) is a surrogate for clinician-assessed performance status and has the potential to address this challenge. We piloted a decision support tool in our electronic health record (EHR) that uses PRPS to prompt clinician assessment of performance status and suggest referrals to supportive care services. **Methods:** We identified patients with advanced cancer using a pre-built and validated registry driven by ICD codes in our EHR (EPIC). For patients with advanced cancer seen at one of our clinics, a multiple-choice question with options derived from the Eastern Cooperative Oncology Group (ECOG) scale in patient-friendly language was added to the pre-visit questionnaire sent electronically prior to oncology visits. For patients with a poor PRPS (2 or greater), a clinical decision support tool alerted providers of the patient's self-reported performance status, encouraged input of the clinician's ECOG assessment, and suggested referral orders to supportive care services such as palliative care, nutrition, and social work. We assessed the relationship between PRPS and ECOG with mortality using logistic regression and by calculating median time to death stratified by patients' highest (poorest) score. **Results:** Between 3/11/24 and 3/11/25, 3,376 PRPS surveys were completed by 1,343 oncology patients. Seventeen percent of patients reported poor PRPS (≥ 2). Worsening PRPS was strongly associated with mortality (3% for PRPS 0 vs. 44% for PRPS 4) and with shorter median time-to-death (163 days for PRPS 0 vs. 19 days for PRPS 4). PRPS correlated with clinician-assessed ECOG ($\rho=0.3$, $p<0.001$) and predicted mortality ($\rho=0.8$) comparably with ECOG ($\rho=0.7$). By contrast, ECOG documentation by clinicians was incomplete in 39% of patients. **Conclusions:** Results suggest feasibility of a PRPS-driven decision support tool to flag patients with advanced cancer and declining function at greatest risk of mortality. PRPS can help allocate limited supportive care resources and prompt advance care planning discussions for patients with greatest need. Research Sponsor: None.

Impact of a patient-facing app to address surgical oncology patients' social determinants of health: Preliminary results of a phase II clinical trial.

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Background: Unmet Social Determinants of Health (SDH) needs, including housing, transportation, food insecurity, utilities, and social support, are associated with adverse outcomes in cancer care, including delays in treatment, missed appointments, and hospital readmissions. Few interventions have been rigorously evaluated to address these SDH needs in surgical oncology populations. We conducted a Phase II randomized controlled trial to evaluate whether a patient-facing mobile application (Carealth), integrated with a follow-up resource referral platform (findhelp.org), could improve clinical and process outcomes compared to a “sham” app that included an attention-control (static CDC site). **Methods:** We enrolled adult patients with cancer (or suspected cancer) scheduled for surgery at three large U.S. centers. Participants were randomized to Carealth (intervention) or sham (control). We assessed 30-day readmission after surgery, distribution of where resources were sought among interventions clients (among those with baseline needs), time from consultation to surgery, and missed/rescheduled visits within 90 days. Analyses used descriptive statistics, Fisher’s exact tests and crude odds ratios for readmission, Kaplan–Meier/log-rank methods for time to surgery, and proportional odds models for missed visits, under an intention-to-treat framework. **Results:** Of 585 patients screened, 161 were randomized (81 intervention, 80 control). Baseline characteristics were well balanced, with 17% reporting at least one SDH need at baseline. App uptake was 80% overall. Thirty-day readmissions were rare and similar between groups, occurring in 5 of 80 patients (OR 1.64, $p = 0.72$). Median time to surgery was 45 days in the intervention group vs 49 days in controls (log-rank $p = 0.42$). Missed/rescheduled visits within 90 days did not differ (proportional OR 1.28, $p = 0.79$). Among participants with SDH needs, multiple resource pathways were used, including counselor or patient navigator services, community or online resources, and the Carealth app; a subset reported partial or complete resolution of needs through the app. **Conclusions:** In this Phase II trial, an SDH-focused patient-facing app achieved outcomes comparable to standard-of-care navigation with respect to readmissions, time to surgery, and appointment adherence. While underpowered for rare clinical events, the intervention demonstrated high uptake and sustained patient engagement, supporting its potential role as a scalable, low-resource adjunct to existing support and navigation services. Larger trials enriched for patients with unmet SDH needs are warranted to assess clinical and health-system impact. Clinical trial information: NCT06688513. Research Sponsor: The National Institutes of Health (NIH); 75N91023C00056.

National implementation of electronic patient-reported outcomes (ePROs) for remote symptom monitoring in oncology: The OncoPRO initiative.

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Background: Remote symptom monitoring with electronic patient-reported outcomes (PROs) during cancer care improves quality of life, reduces acute care events, lengthens time on treatment, and can improve survival. US oncology practices are increasingly implementing PROs, but barriers to implementation remain. To facilitate uptake of PROs, the OncoPRO Initiative was established as a national PRO learning collaborative with funding from PCORI, in partnership with ASCO, the American Cancer Society, the PROTEUS Consortium, federal agencies, practice networks, and the major EHR and PRO software vendors. Oncology practices/health systems may join OncoPRO at no cost if they are committed to implementing PROs and can submit implementation metrics for monitoring progress. Practices are sorted into “affinity groups” by EHR and PRO software systems. Affinity groups meet monthly, led by coaches from the ASCO, PRO experts, and representatives of respective technology companies. Affinity groups follow a curriculum of key topics in PRO implementation, exchange training materials and information about facilitators and experiences, and provide feedback to software vendors. Little is known on how such learning collaboratives can support PRO growth. **Methods:** Implementation measures and characteristics were identified to quantify progress including the total number of practices joining, the phase of these practices (early implementation, scale-up, maintenance), topic areas for support requested by practices, number of personnel trained for PRO at practices, number of patients enrolled in PRO at practices, and proportion of enrolled patients completing PRO surveys. Data were collected via direct EHR data transfers and surveys. **Results:** Since 3/1/2024, 23 community and academic oncology practices/health systems have joined OncoPRO, across 23 different states, among which 13 practices were in early implementation, 7 in scale-up, and 5 in maintenance. These practices were sorted into four monthly affinity groups, in which the most commonly requested topics were: personnel roles/responsibilities; workflow; patient/clinician engagement; key performance metrics; technology customization; integration with quality programs; symptom management pathways; and billing/coding. Practice participation in monthly meetings has been 100%. Data are available from 12 initial practices, which collectively enrolled 47,052 patients over their initial 15 months of the program, with 24,566 patients (52%) completing at least one PRO survey. **Conclusions:** The OncoPRO learning collaborative is successfully supporting practices across the US to implement PROs, with strong practice engagement and high patient participation. Research Sponsor: Patient-Centered Outcomes Research Institute; DI-2023CI-31283.

Achieving epidemiologically representative enrollment and social determinants of health in the phase III evERA Breast Cancer study (NCT05306340).

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Background: Clinical trials have historically under-enrolled patients (pts) from racial and ethnic minority groups, resulting in study populations that do not reflect the epidemiology of cancer in the United States (US), limiting generalizability of the findings. In parallel, social determinants of health (SDOH) are increasingly recognized as key drivers of cancer outcomes, yet are infrequently collected in oncology trials due to operational, ethical, and privacy concerns. The Phase III evERA breast cancer (BC) study (Mayer et al ESMO 2025) was intentionally designed to address both challenges through proactive enrollment strategies and prospective SDOH data collection. **Methods:** evERA BC is a global study in pts with ER+, HER2- advanced BC. In the US, a multi-pronged operational strategy was implemented to achieve epidemiologically representative enrollment, including expanded and pragmatic eligibility criteria, prioritization of community-based sites, real-time enrollment monitoring, patient navigation and financial support, and advocacy partnerships. A tailored survey assessing 5 key social determinants of health (education, income, employment status, marital status, insurance type) was offered to US pts to support a protocol-specified exploratory SDOH efficacy objective. **Results:** The multifaceted operational enrollment strategy used in the evERA BC study resulted in a US cohort (n=144 of total accrual 373) whose racial and ethnic composition exceeded SEER epidemiologic distributions for ER+, HER2- advanced BC for African American (AA) (12.5% vs 11.1%), Asian (9% vs 5.7%), and Hispanic (H) pts of any race (16% vs 8.9%). Enrollment for the aggregate White race (71.5%) and non-Hispanic (NH) ethnicity (83.3%) categories were slightly lower than SEER estimates for White race (82.9%) and NH ethnicity (91.1%). These enrollment patterns contrast with historic Phase III BC trials, in which AA pts typically comprise <5% and H pts <9% of enrolled populations. Of the 144 U.S. evERA BC pts, 128 (89%) completed the optional SDOH survey, demonstrating feasibility of SDOH data collection in a clinical trial setting and informing evaluation of potential trends and associations with outcomes. **Conclusions:** The evERA study demonstrates that key operational strategies can achieve epidemiologically representative enrollment while enabling robust and compliant SDOH data collection in oncology clinical trials. These findings provide a practical roadmap for industry sponsors seeking to improve recruitment of underrepresented populations and to generate more clinically meaningful and generalizable evidence by integrating social context into trial design and data interpretation. Clinical trial information: NCT05306340. Research Sponsor: F. Hoffmann-La Roche Ltd.

Implementation of an expedited cancer workup clinic for uninsured patients at a metropolitan safety net hospital.

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Background: Timely evaluation of patients with suspected cancer is essential; yet delays in diagnosis and treatment remain common in safety-net health systems, particularly for uninsured or underinsured patients. Such delays are associated with advanced stages of disease at the time of diagnosis and increased mortality. While inpatient evaluation can facilitate multidisciplinary coordination, it is associated with higher costs. Outpatient delivery models designed to expedite cancer workups have been demonstrated to reduce time to diagnosis and number of hospitalizations. We describe outcomes from an Expedited Workup Clinic (EWC) in a large Los Angeles County safety-net hospital. **Methods:** The EWC was designed to coordinate outpatient imaging, biopsy, and oncology specialty referrals for vulnerable patients with suspected malignancy. All patients were uninsured and lacked a primary care provider. Referrals originated from the Emergency Department (ED), Urgent Care, or inpatient admissions. We retrospectively analyzed outcomes from 2022 to 2025 using real-world data extracted from the Electronic Health Record. **Results:** 255 patients were referred to the EWC encompassing 153 men (60%) and 102 women (40%). 155 patients (60%) were Hispanic/Latino, with other represented ethnicities including 28 (10.9%) Asian/Pacific Islander, 22 (8.6%) Black/African American, and 14 (5.5%) White/Caucasian. Spanish was the preferred language of 150 patients (58.8%). The majority of patients (87.9%) were referred from the ED with a median time to first EWC appointment of 11 days (IQR 7–14). From the first EWC appointment, the median time to imaging was 6 days (IQR 1–14), to biopsy was 21 days (IQR 12–54), and to initiation of oncologic treatment was 51 days (IQR 34–83). 92 patients (36.1%) ultimately had a negative malignancy workup, and 38 patients (14.9%) were lost to follow-up. Among patients with confirmed malignancy, the most commonly identified primary sites were colorectal (19.2%), lung (10.6%), hematologic (9.6%), pancreatobiliary (9.6%), prostate (6.7%), head and neck (6.7%), hepatic (6.7%), renal (4.8%), gynecological (3.8%), melanoma (3.8%) and breast (3.8%). **Conclusions:** The EWC demonstrates the feasibility of providing timely malignancy evaluation for high-risk, uninsured patients within a resource-limited setting. These findings support the use of an outpatient rapid evaluation clinic, while surfacing opportunities for improvement including reducing the number of patients lost to follow-up. Further evaluation of cost-effectiveness and access barriers may continue to strengthen the design of rapid workup clinics meant to serve our most vulnerable patients. Research Sponsor: None.

PRiMAL (precision randomized clinical trial comparing MTB assisted care to usual care): Quality of life analysis in patients with newly diagnosed non-small cell lung cancer (NSCLC).

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Background: Precision medicine—tailoring cancer treatment to a tumor’s genomic profile—is more effective and less toxic than traditional chemotherapy. However, its use in community oncology remains limited. Molecular Tumor Boards (MTBs), interdisciplinary teams that interpret genomic data and guide treatment, have improved precision medicine adoption and clinical outcomes, especially in academic centers. However, MTBs are less accessible in community practices, where most cancer care is delivered. **Methods:** The PRiMAL trial is a prospective, parallel-group, cluster randomized trial, comparing MTB assisted care (MTB-AC) to usual care in 10 community medical oncology practices aligned with the Markey Cancer Network. MTB-AC included nurse navigator assistance with next generation sequencing (NGS) ordering, MTB referral, and communication with treating oncologists. Usual care allowed access to the MTB at the discretion of treating oncologist. Eligible patients had untreated stage IIb-IV NSCLC. The co-primary endpoints were 1-year overall survival and health related quality of life (QOL) as measured by the Functional Assessment of Cancer Therapy (FACT) Trial Outcome Index-Lung Cancer (FACT-L TOI), FACT-G, and FACT-L Cancer (FACT-L) administered at baseline, 8 weeks and 12 weeks after treatment initiation. A multilevel linear mixed-effects model was used to estimate the intervention effects for the QOL outcomes while controlling for demographic, clinical, and socioeconomic covariates. **Results:** At the data cut-off of 1/12/26, 405 pts were included for assessment of QOL at baseline (MTB, n=250; usual, n=155). Baseline demographics and disease characteristics were similar for sex, age, race, ethnicity, histology, stage and performance status. QOL assessments were completed by 292 patients at 8 weeks and 245 patients at 12 weeks; MTB-AC patients experienced numerically greater declines at 8 weeks compared to usual care (FACT-L TOI: -2.7 vs -0.5; FACT-G: -1.9 vs 0.50; FACT-L: -1.4 vs 1.1), but these differences were not significant. Between weeks 8 and 12, QOL was estimated to have declined in usual care patients while MTB-assisted care patients improved, FACT-L TOI (3.28, 95% CI: 0.10 to 6.46); FACT-G (between-group difference: 3.97, 95% CI: 0.56 to 7.38); and FACT-L (4.70, 95% CI: 0.58 to 8.81). Survival is immature. **Conclusions:** The preliminary analysis showed that MTB-AC demonstrated significant, and in some cases clinically meaningful, improvement in QOL between weeks 8 and 12 after treatment across all three FACT measures compared to usual care, suggesting a delayed but meaningful benefit of MTB-AC. Clinical trial information: NCT05254795. Research Sponsor: Eli Lilly.

Addressing health-related social needs for cancer patients: An implementation assessment.

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Background: Health-related social needs (HRSNs) are associated with delayed diagnosis and treatment, worsened quality of life, and higher recurrence and mortality rates for cancer patients. Health systems are beginning to recognize the tremendous impact of HRSNs by recommending standardized HRSNs screening and referral in cancer care. Further research is needed to effectively design and implement HRSNs interventions for cancer patients. We evaluated the implementation of a novel community health worker (CHW) referral and navigation intervention to address unmet HRSNs in a National Cancer Institute (NCI)-designated comprehensive cancer center serving a highly disadvantaged community of patients in Bronx County, NY. **Methods:** We conducted a retrospective study of cancer patients utilizing data from HRSNs screenings, clinician CHW referral orders, and CHW navigation services between October 2023 and March 2025. Patients were identified as eligible for CHW assistance if they were screened for and self-reported at least one unmet HRSN. We organized process and outcome measures using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) implementation framework and evaluated measures through descriptive statistics. **Results:** There were 30 cancer center clinical practices who adopted the HRSNs screening tool. A total of 8,591 patients were screened for unmet HRSNs, with 20.5% self-reporting at least one unmet HRSN. Of those with at least one unmet HRSN (n=1,758), 43.4% were referred to CHWs by clinicians. Referral rates to CHWs ranged from 26-55% by clinical practice. Of patients referred to CHWs, 794 (64.5%) were assisted with HRSNs navigation by CHWs, with the most common HRSNs identified as financial (50.3%), housing (48.7%), and food insecurities (45.5%). CHWs were successful in outreaching referred patients (95.5%) in a timely manner (Median: 3 days from referral order, IQR: 1-6 days), connecting patients to at least one social service (98.9%), and resolving or improving at least one social need (97.6%). The median annual cost to implement and maintain the CHW referral and navigation intervention to address unmet HRSNs was \$345.58 per patient. **Conclusions:** Implementation of CHW referral and navigation services within an NCI-designated comprehensive cancer center was feasible and effective in addressing unmet HRSNs within a safety-net cancer population. CHWs were successful in reaching patients and connecting them with essential social services that helped to resolve their HRSNs. Further research is needed to improve clinician screening and referral and understand the impact of CHW navigation on oncologic care delivery and clinical outcomes. Research Sponsor: None.

Identifying patients at risk for non-receipt of guideline-concordant treatment in pancreatic cancer using electronic health record data and machine learning.

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Background: Non-receipt of guideline-concordant treatment (GCT) for pancreatic cancer is associated with worse outcomes and occurs disproportionately in safety-net settings. Timely identification of patients at risk using traditional approaches remains challenging. We developed machine learning (ML) risk prediction models using electronic health record (EHR) data available at presentation to predict non-receipt of GCT and support targeted navigation. **Methods:** We conducted a retrospective analysis of patients with pancreatic cancer treated at two safety-net hospitals in Alabama from 2018–2022. GCT was defined based on NCCN guidelines. Candidate predictors included demographic, clinical, laboratory, access-to-care and healthcare utilization variables available at presentation. Primary outcome was non-receipt of GCT. Data were split into stratified 80/20 training and test sets given class imbalance (2/3rd received GCT). Feature engineering was applied to reduce overfitting from high-cardinality variables. Classification and Regression Tree (CART) analysis was used to explore feature interactions and rank predictors. Multiple ML models were trained using PyCaret with default hyperparameters. Model performance was evaluated on the test set, with recall prioritized to reflect a screening use case in which false positives were acceptable. **Results:** Of 902 patients, 67.5% (n=609) received GCT. CART identified 30 candidate features. Highly ranked features included Area Deprivation Index, age, albumin, time from symptom onset to start of workup, employment status, presence of primary care physician, BMI and ECOG performance status. Performance metrics of the top 5 models are summarized in Table 1. Across models, test-set accuracy ranged from 72.9% to 86.2%, and recall for non-GCT ranged from 35.6% to 61.0%. Light Gradient Boosting model demonstrated the strongest overall screening performance, achieving the highest recall (61.0%), precision (94.7%), F1 score (0.74), and AUC (0.94). **Conclusions:** ML models using EHR data readily available at presentation can identify patients at high risk for non-receipt of GCT, driven in part by modifiable access-to-care and social vulnerability factors. Integration of these models into EHR workflows could enable automated risk flagging at diagnosis and trigger early referral to navigation and supportive services, with the potential to improve treatment delivery and outcomes. Research Sponsor: U.S. Department of Defense.

Test-set performance of machine learning models.					
Model	Accuracy	AUC	Recall	Precision	F1 score
Decision Tree Classifier	0.79	0.77	0.51	0.77	0.61
Logistic Regression	0.73	0.79	0.36	0.66	0.46
Light Gradient Boosting Machine (LGBM) Classifier	0.86	0.94	0.61	0.95	0.74
Extreme Gradient Boosting (XGB) Classifier	0.81	0.87	0.54	0.80	0.65
Ada Boost Classifier	0.77	0.85	0.46	0.73	0.56

Real-world implementation of an integrated exercise medicine model within routine oncology care.

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Background: Exercise is an evidence-based intervention for people with cancer, with demonstrated benefits for physical function, symptom burden, and treatment tolerance. Despite international guideline recommendations, exercise remains inconsistently implemented as a prescribed medical treatment in routine oncology care. This study describes the real-world implementation of an integrated Exercise Medicine model embedded within a supportive oncology service. **Methods:** This descriptive implementation study reports on the Lift Model of Care, a clinician-led supportive cancer care service established in Australia in 2018. Exercise Medicine is delivered as a core, medically prescribed intervention and integrated with Physiotherapy, Psychology, Dietetics, and subspecialty services across the cancer continuum. Exercise prescriptions are individually tailored and dosed by qualified clinicians in accordance with Clinical Oncology Society of Australia exercise guidelines and delivered in a medically supervised environment. Routinely collected service data were analysed descriptively. The primary outcome was annual service reach and treatment volume from 2018 to 2025. Secondary outcomes included patient-reported experience measures related to Exercise Medicine. **Results:** Annual service reach increased from 607 individuals in 2018 to 1,353 individuals in 2025. Delivery of Exercise Medicine increased from 2,077 to 12,255 treatments annually, reflecting sustained growth in access and longitudinal engagement. Concurrent increases in Physiotherapy, Psychology, Dietetics, and Lymphoedema services were observed, supporting coordinated multidisciplinary care delivery. Patient-reported experience data demonstrated high acceptability, with over 90% of respondents reporting high satisfaction and perceived improvements in fatigue, strength, functional capacity, and ability to tolerate cancer treatment. **Conclusions:** This real-world implementation study demonstrates the feasibility of embedding Exercise Medicine as a prescribed treatment within routine oncology care at scale. The model provides a pragmatic framework for integrating guideline-recommended exercise into standard cancer pathways and may inform broader adoption across health systems. Research Sponsor: None.

Therapeutic strategies and reduced drug spending as a signal of early impact of the Enhancing Oncology Model.

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Background: Building on lessons learned from the predecessor Oncology Care Model, the Centers for Medicare & Medicaid Services designed the Enhancing Oncology Model (EOM), a voluntary, two-sided risk, episode-based payment model, to incentivize participating practices to provide high-quality, patient-centered oncology care while targeting Medicare spending reductions. At the start of the model, 44 oncology practices voluntarily joined EOM. Practices are held financially accountable for 6-month episodes of care for Medicare Fee-for-Service beneficiaries with 7 high-risk cancers. The objective of this study is to evaluate how practices implemented EOM and whether they were able to reduce Medicare spending during its first six months of implementation. **Methods:** To identify strategies practices used to meet model goals, we interviewed 93 key informants during site visits at 6 EOM practices from November 2024 through February 2025. We analyzed claims-based impacts on spending using a difference-in-differences approach using a sample of episodes of care from EOM practices and propensity score matched comparison practices during a baseline period (July 1, 2018 – June 30, 2022) and the first performance period of the model (July 1–December 31, 2023). **Results:** EOM practices reported focusing on reducing drug expenditure. Strategies included (1) substitution to value-based treatment alternatives, such as biosimilars, while mitigating the impact of drug shortages; (2) dose rounding and weight-based dosing to minimize waste and improve efficiency; and (3) avoiding drugs with limited clinical benefit, such as white blood cell growth factors for metastatic tumors. While not statistically significant, we found the model reduced total Medicare spending by \$646 per episode (1.1%; 90% confidence interval [CI]: −\$1,724, \$433), likely driven by reductions in Part B systemic cancer therapy payments of \$645 per episode (90% CI: −\$1,622, \$332). This is consistent with practice reports of implementing value-based prescribing strategies. **Conclusions:** Early EOM implementation results show emerging evidence of systemic cancer therapy payment reductions. These findings may reflect expanded biosimilar availability and practices' strategic focus on value-based drug substitution and dosing. Research Sponsor: Centers for Medicare and Medicaid Services.

Association of routine electronic symptom monitoring with reduced opioid use in patients with head and neck cancers.

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Background: Patient reported outcomes (PROs) have become increasingly important in modern healthcare. Head/neck cancer (HNC) is associated with numerous side effects that significantly impact patients quality of life short and long term. We developed FACT-HN-RAD, a brief cancer and treatment specific PRO aiming to efficiently capture side effect burden for patients with HNC undergoing radiotherapy (RT). Here we report the clinical implementation of this measure through the electronic medical record (EMR) at two institutions. **Methods:** The PRO was prospectively integrated into routine clinical care for patients with HNC through deployment in the EMR weekly during RT (up to 7 weeks) and at 1-, 3-, 6-, 9-, and 12-month post RT. We compared a historic cohort of patients (treated July 2021-July 2023) to those treated after PRO deployment (Aug 2023-Aug 2025), assessing PRO adherence, opioid use, emergency room (ER) encounters and inpatient admissions. Baseline demographic characteristics were summarized using descriptive statistics. Clinical outcomes were compared using parametric and nonparametric statistical tests. **Results:** OF the 2,288 patients, 1,304 were in the PRO cohort and 984 were in the historic cohort. Patients had a median age of 65 (IQR 56-73) and were mostly White (81.9%), non-Hispanic (91.3%), and current/former smokers (57.5%) with a median of 20 smoking pack years (IQR 3.8-46.5). In the PRO cohort, 51.9% (n=677) submitted at least one response to the assigned PRO. Within each individual patient for the total assigned series, within patient adherence was 50.9% (ie each patient filled out approximately half of the assigned PROs over a one year timeframe). Patients in the PRO cohort required less opioids with 49.1% (n= 640) receiving any opioid prescription in the PRO cohort as compared to 60.9% (n=577) historically (p<0.001). The average daily strength of opioids decreased 28% in the PRO cohort (mean MME 150.1mg, SD 458.7) versus historically (mean MME 207.9mg, SD 574.8) (p<0.001), and the total opioids prescribed to patients decreased 44% in the PRO cohort (mean MME 3,565mg, SD 12,105) versus historically (mean MME 6,363mg, SD 18,387) (p<0.001). Patients in the PRO cohort overall had fewer ER visits during and within the first year after finishing RT, with 13.3% (n=173) visiting the ER as compared to 29.4% (n=289) historically (p<0.001). Patients in the PRO cohort had fewer inpatient admissions within the first year after finishing RT, 28.8% (n=375) as compared to 48.8% (n=480) historically (p<0.001). **Conclusions:** We demonstrate that the integration of routine electronic PROs into the care of patients undergoing HNC RT is associated with clinical benefits when compared to a historic cohort including reduced opioid use, reduced ER visits, and reduced inpatient admissions. This promising approach in the definitive RT setting warrants further study in a randomized clinical trial. Research Sponsor: PROTEUS Consortium.

Rethinking cancer attribution in oncology VBC models: E&M vs treatment-based approach.

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Background: Patients with multiple cancers are uncommon. In value-based care models such as EOM (Enhancing Oncology Model), episode attribution and financial accountability rely on assigning a cancer type based on the plurality of predefined E&M visits. However, this administrative approach may not accurately represent the cancer for which a patient is receiving active treatment, especially in the presence of concurrent malignancies. Despite this, little is known about how often the E&M based cancer type differs from the treatment-based cancer type. **Methods:** We analyzed EOM performance period data (July 2023–June 2025) from practices in The US Oncology Network. Injected based initiating episodes were identified using EOM Part B claims that occurred at practices' sites, then matched to the Electronic Health Record by patient, drug, and initiating date. For oral agents, additional to patient, drug and prescribing provider, order dates within 60 days of the fill date in Part D Claims was used as a proxy in matching process. Cancer type associated with the initiating treatment was extracted from the EHR and then compared with EOM-attributed cancer types. **Results:** Episodes were predominantly triggered by injection-based chemotherapy with 13,803 initiated in physician office setting, and 5,441 were initiated by oral chemotherapy. Matching rates to an initiating event in EHR differed substantially by route: ~ 90% for injection-initiated episodes vs. about 40% for oral-initiated episodes. Among injection-based episodes, 5% of episodes did not have a treatment-based cancer diagnosis in EHR and 4.5% had discordant cancer diagnoses, while oral-based episodes showed markedly higher rates of missing cancer diagnosis at 32%, with 24% mismatched diagnoses. Chronic leukemia and prostate had a higher proportion of oral initiations and correspondingly lower matching rates. Oral-initiated episodes demonstrated particularly low EHR matching in breast, lung, prostate, and small intestine/colorectal cancers. **Conclusions:** Cancer attribution in VBC models remains challenging, particularly for episodes initiated with oral therapies. As the use of oral agents continues to expand and patients increasingly present with concurrent cancers, attribution difficulties are likely to grow, resulting in greater discordance over time. Incorporating treatment-based cancer type into attribution could improve accuracy and better align assigned cancer types with actual care in value-based oncology models. Research Sponsor: None.

EHR matching by route of chemotherapy initiation.

Cancer Type	Injection Episodes (n)	Injection Concordance (%)	Oral Episodes (n)	Oral Concordance (%)
Breast Cancer	3836	91.8%	727	23.9%
Chronic Leukemia	171	83.6%	1370	50.1%
Lung Cancer	3539	93.1%	323	31.3%
Lymphoma	1724	84.6%	512	47.9%
Multiple Myeloma	1976	93.2%	1211	73.6%
Prostate Cancer	558	83.2%	1210	21.4%
Small Intestine/Colorectal Cancer	1999	89.1%	88	21.6%

Modernizing injectable cancer care delivery: A telemedicine-supported home injection model for breast cancer care.

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Background: Among the growing population of premenopausal patients with breast cancer, years-long endocrine therapy often requires repeated clinic-administered injections, creating substantial time burden and adherence challenges. This pilot evaluated the feasibility of a telemedicine-supported home injections program designed to improve access, convenience, and patient experience. **Methods:** Patients were recruited from 4 outpatient medical oncology practices at a comprehensive cancer center between October 2024 and January 2025. Eligibility criteria included a breast cancer diagnosis, an active treatment plan including leuprolide and/or denosumab, and use of the patient portal. Patients proceeded to pilot participation after insurance approval for outpatient administration of medications and (if applicable) acceptability of copay cost. Patients and/or caregivers received in-clinic training by nursing staff on injection preparation and administration, were provided both written and video-based educational material and were followed for up to 2 home injections over a 6-month period, with telemedicine support. The primary outcome was feasibility, assessed by home injection completion rates. Patient and clinician satisfaction were assessed using the Net Promoter Score (NPS) and rates of continued at home injection administration post pilot completion. Patients were also invited to participate in 60-minute semi-structured exit interviews. **Results:** Of 105 eligible patients, 54 agreed to participate in the pilot and 24 obtained insurance approval for the medication with an acceptable copay. All 24 patients were trained in injection administration of intramuscular leuprolide, of whom 50% had no prior injection experience. Overall, 96% successfully completed one home injection, 79% of patients completed two home injections, and 75% continued home administration after follow-up. Notably, only 1 patient discontinued home injection administration due to telemedicine scheduling related issues. Patients reported high satisfaction, citing time savings and convenience as key benefits. Both patients and providers strongly endorsed the model with highly compelling net promoter scores of 69 and 61, respectively. **Conclusions:** This pilot demonstrated the feasibility of a telemedicine supported home injection care delivery model for breast cancer patients in the oncology setting, evidenced by high completion rates and patient preference to continue home administration. Educational materials and optional telemedicine visits for initial injections were leveraged to support adherence without increased healthcare utilization. Further evaluation across broader geographic, demographic, and payor mix is warranted to inform scale up. An ongoing pragmatic trial (NCT06954337) is testing this approach as part of an innovative model of care: Enhanced Telehealth. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health; P50 CA271357; National Cancer Institute/U.S. National Institutes of Health; P30 CA008748.

Feasibility and implementation of remote geriatric assessment-guided supportive care (GAIN-S) in public oncology settings.

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Background: The ASCO Global Guideline recommends routine geriatric assessment (GA) for adults aged ≥ 65 years with cancer to identify vulnerabilities beyond standard oncology evaluation and guide tailored management. However, real-world implementation of GA-guided interventions in low-resource settings remains limited. Building on prior feasibility work in private (PRI) oncology settings, we evaluated the feasibility and implementation of a remote, multidisciplinary GA-guided intervention in public (PUB) oncology settings in Brazil. **Methods:** We conducted a prospective feasibility and implementation study in PUB settings, with contextual reference to prior PRI experience. Patients aged ≥ 65 years initiating chemotherapy underwent baseline GA assessing functional status, depressive symptoms (GDS), cognitive screening (Mini-Cog), chemotherapy toxicity risk (CARG), nutritional status, and quality of life (FACT-G), with repeat assessment at 12 weeks. Identified impairments prompted referral to telehealth interventions (geriatrics, nutrition, psychology/psychiatry, exercise). Feasibility outcomes included recruitment, GA completion, referral recommendations, and follow-up retention. Implementation barriers in PUB settings were prospectively documented. **Results:** A total of 109 patients were included (PRI n=61; PUB n=48). The PUB cohort was younger (mean age 72 vs 76), included a higher proportion of Black participants (58% vs 44%), had lower education (no/limited 19% and elementary school 50% vs college degree 47%), and more advanced disease (92% stage III-IV vs 54% stage IV). Baseline geriatric vulnerability was similar (median CARG 6 vs 7, GDS 2); weight loss was more frequent in PUB (54% vs 36%). Quality of life was lower in PUB (FACT-G -5 points). GA identified actionable vulnerabilities, with 21% referred to ≥ 1 specialist (vs 33% in PRI) and 44% to ≥ 2 specialists (vs 28% in PRI). Key challenges included delayed recruitment, limited digital literacy (63%), restricted videoconferencing (73%), delays in nutritional supplements (38%), and exercise adaptation (50%), prompting ongoing, context-specific adaptations. **Conclusions:** Remote GA delivery and identification of actionable vulnerabilities were feasible in PUB settings in Brazil. Similar geriatric vulnerability profiles and characterization of implementation barriers support the scalability of GA-guided care in low-resource settings. Clinical trial information: NCT07084454. Research Sponsor: Rising Tide Foundation for Clinical Cancer Research; CCR-24-200; Conquer Cancer The ASCO Foundation; Conquer Cancer The ASCO Foundation; Conquer Cancer The ASCO Foundation.

From plenary to practice: A large language model (LLM)–based thematic analysis of landmark clinical trial discussions and factors influencing their real-world adoption.

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Background: Landmark trials define standard-of-care (SOC), yet the translation of trial evidence into routine practice remains poorly characterized. LLMs enable the systematic extraction of nuanced clinical discourse from unstructured EHR data previously infeasible at scale. We performed an LLM-based thematic analysis of past ASCO Plenary Session (PS) trial discussions to better understand the nature of shared decision-making in routine care and characterize themes influencing SOC adoption. **Methods:** We designed a retrospective study of clinician-documented discussions with patients about PS trials presented at ASCO Annual Meetings 2021–2025. 2 trials (negative study; non-therapeutic trial) were excluded. Patient records from the Flatiron Health Database with mention of a relevant trial/NCT number within 2 years of presentation were selected. We prompted an LLM (Claude 4.5 Sonnet) to summarize documentation of clinician-patient trial discussions and extract: 1) context of discussion, 2) clinician sentiment toward trial (positive, neutral, negative) and 3) documented receipt of trial therapy (yes/no; if no, reason why not). To characterize the gap in SOC adoption, a thematic analysis was performed using a multi-model consensus approach (Gemini 2.5pro, GPT-4o, Claude 4.5 Sonnet) to identify EHR-documented discussion themes associated with trial treatment omission. LLMs provided supporting evidence for all answers; a human-in-the-loop approach was used to verify concordance between LLM-extracted themes and expert clinical interpretation. LLMs were hosted on Flatiron Health private servers and HIPAA compliant. **Results:** The study included 8650 patients and 21 trials discussed across 15 cancer types. Common discussion topics were: efficacy (78%), eligibility (78%), patient education (63%), and toxicity (28%). Clinician sentiment across studies was favorable (47%–93% positive), yet real-world trial therapy initiation occurred in only 64% of cases. Main themes associated with trial treatment omission were: clinical factors (biomarker ineligibility, comorbidities), systemic barriers (insurance, transportation, incarceration), and patient preferences (prioritizing quality of life, preserving life roles). **Conclusions:** This is the largest thematic analysis of clinician-patient trial discussions to date. We uncovered rich qualitative insights into how clinicians engage in shared decision-making with their patients, balancing positive evidence and sentiment with practical and patient-centered factors that define individualized care. Novel LLM methods can transform clinician-patient narratives into actionable evidence to mitigate disparities and optimize real-world SOC adoption. Future work will examine thematic differences by cancer type and prevalence and correlate findings with outcomes. Research Sponsor: Flatiron Health, Inc.

Unmet rehabilitation needs in cancer survivors: A population-level analysis.

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Background: Decades of evidence demonstrate that patients across the cancer continuum may benefit from validated rehabilitation services, yet delivery remains inconsistent. Prior reports of underuse have largely relied on small, single-site cohorts and have lacked population-level estimates of service need, referral, and visit completion, contributing to the assumption that provider reluctance to refer is a primary driver. Using post hoc exploratory analyses of population-level trial data, we evaluated patient- and system-level factors associated with non-use of rehabilitation services. **Methods:** This secondary analysis used data from the Enhanced Electronic Health Record-Facilitated Cancer Symptom Control (E2C2) pragmatic trial, an unblinded, stepped-wedge, cluster-randomized cohort study comparing an EHR-embedded symptom surveillance and management system with usual care. All patients receiving care in Mayo Clinic Midwest medical oncology practices were enrolled regardless of cancer stage or phase. Symptoms and physical function were assessed using 11-point numerical rating scales linked to oncology encounters. Sociodemographic and clinical characteristics and all outpatient rehabilitation encounters across the Mayo Clinic Enterprise were extracted from the EHR. Rates and types of completed, canceled, and no-show rehabilitation encounters were examined. **Results:** Between March 28, 2019, and January 31, 2023, 50,207 patients were enrolled; 34% reported moderate or severe physical function impairment during follow-up. Despite this, only 8,818 patients (17.6%) completed at least one rehabilitation encounter. Of 91,220 encounters scheduled, 57,669 (63.3%) were completed (mean 6.5; median 3 per participant), leaving a substantial proportion canceled or no-showed (n=33,523, 36.7%). Completed encounters were predominantly physical therapy (68.3%), with fewer occupational therapy (16.4%), physician (9.4%), and speech therapy (4.2%) visits. Encounters were concentrated among patients with breast, hematologic, gastrointestinal, and genitourinary cancers. Completion was more likely among patients who were older, female, partnered, retired, and federally insured, whereas cancellations and no-shows were more common among younger, racial or ethnic minority, urban, unpartnered, employed, college-educated, and commercially insured patients (all $P < 0.001$). Virtual visits and encounters in community (vs academic) settings were more likely to be completed (all $P < 0.001$). **Conclusions:** A substantial gap persists between cancer survivors' rehabilitation needs and service receipt, varying by cancer type and sociodemographic factors. High cancellation and no-show rates suggest that underuse extends beyond referral and underscore the need for redesigned, more accessible rehabilitation delivery models. Research Sponsor: None.

Implementing a clinical research coordinator–led care delivery model (CRC model) in an early-phase oncology program: A pilot to streamline workflow, improve collaboration, and enhance patient-centered trial conduct.

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Background: Early-phase oncology trials involve medically complex patients with narrow enrollment windows. Traditionally, CRC roles focused on data management and scheduling, with limited integration into visit-based workflows, creating gaps in protocol execution and prescreening. This pilot embedded CRCs into patient-facing workflows to improve visit preparedness, protocol reliability, and enrollment readiness in biomarker-driven Phase I trials. **Methods:** CRCs were embedded alongside investigators and research nurses during patient visits to support coordination of protocol requirements. This included standardized patient schedule education; CRC-led week-ahead planning; proactive symptom monitoring with escalation pathways; multidisciplinary supportive care coordination; and prescreening/enrollment support for biomarker-driven trials, including tissue tracking and coordination of enrollment-sensitive testing timelines. A pre- and post-evaluation was conducted. Active patients during matched 8-month pre- and post-implementation periods were identified through a CRC-maintained prescreening tracker and electronic health record review. Protocol deviations were categorized by primary attribution. Visit preparedness, timeliness of symptom escalation, supportive care coordination, and prescreening workflow adoption were assessed. Statistical significance was evaluated using the Wilcoxon signed-rank test. **Results:** Scheduling protocol deviations decreased from 42 pre- to 20 post-implementation (52% reduction), driven by fewer missed or delayed assessments and communication gaps. CRC-led week-ahead reviews improved visit preparedness, with assessment-related deviations decreasing from 37 to 4 over matched 8-month periods (~89% reduction). CRC presence centralized protocol and logistical oversight, supporting timely trial readiness in Phase I. CRC-led prescreening improved visibility into tissue availability, biomarker testing status, and cohort eligibility. Mean time to tissue submission decreased from 9 business days pre-implementation (range, 2–25; n = 20) to 2.2 business days post-implementation (range, 1–4; n = 20; $p = 3.54 \times 10^{-5}$). Across three tissue-dependent interventional trials, identification of patients meeting protocol-specified eligibility criteria increased from 39 to 59 over matched 8-month periods (51.3% increase). **Conclusions:** Adopting a CRC model improved operational reliability and prescreening efficiency, enabling faster tissue submission, quicker identification of biomarker-eligible patients, and top of scope team function. Programs facing trial complexity or staffing constraints may benefit from CRCs in visit support and prescreening roles to improve efficiency and trial access. Research Sponsor: None.

Spatial heterogeneity of structural inequities in diagnostic delay and survival in early-onset colorectal cancer in a large urban catchment area.

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Background: Disparities in early-onset colorectal cancer (EO-CRC) stage at diagnosis and survival persist despite expanding specialty care, suggesting that structural and neighborhood-level factors, beyond traditional access measures, influence timeliness of cancer detection and treatment. We applied geospatial modeling integrating clinical data with census-based Social Vulnerability Index (SVI) and historical redlining to characterize geographic variation in diagnostic delay and median overall survival (mOS). **Methods:** We retrospectively analyzed 214 patients diagnosed with EO-CRC (<50 years) treated at an urban tertiary center (2018–2025), identified via ICD-10 codes. Geocoded addresses were linked to census-tract level SVI and Home Owners' Loan Corporation redlining grades (A/B vs C/D). Access was quantified using network drive-time and Euclidean distance to colorectal surgery and gastroenterology. Spatial analyses in ArcGISPro included hotspot mapping, tract-level aggregation, and Geographically Weighted Regression (GWR) to model spatially varying associations between race, stage, access, and OS. GWR residuals $>\pm 2$ standard deviations (SD) identified clusters of excess risk. **Results:** Among 214 patients: 32% were non-White; 62% were stage III/IV; 49% lived in redlined neighborhoods. Time from symptom onset to diagnosis was non-linear with access: patients living <5 miles (89 days) and >20 miles (101 days) from specialty care experienced longer delays than those 5–10 miles (67 days) or 10–20 miles (72 days) away ($p<0.01$), consistent across drive-time and Euclidean measures. GWR demonstrated that the effects of race and stage on diagnostic delay (median local $R^2=0.52$, range 0.28–0.67) and OS (median local $R^2=0.46$, range 0.23–0.60) varied by location. High-residual clusters (>2 SD above predicted delay) localized to the Southeast and East neighborhoods of the catchment area, where non-White patients experienced 48–82 excess days of diagnostic delay after adjustment for stage, access, and SVI. High-residual areas had higher emergency or inpatient index presentation than in low-residual areas (42% vs 21%, $p=0.01$). The mOS was significantly lower in high-SVI vs low-SVI tracts (22 vs 38 mo; HR 1.9, $p<0.01$), in redlined versus non-redlined neighborhoods (24 vs 50 mo; HR 2.1, $p<0.002$). Within low-SVI areas, non-White patients had inferior mOS compared to White patients (28 vs 37 mo, HR 1.5, $p=0.001$). **Conclusions:** Spatial modeling suggests that EO-CRC disparities reflect place-based structural factors beyond clinical stage or proximity to care. Clustering of excess diagnostic delay and inferior survival in historically redlined and high-SVI neighborhoods identifies priority geographies for future studies integrating clinical and population data to design targeted, place-based navigation and early-detection interventions. Research Sponsor: None.

Effect of an EHR-facilitated symptom surveillance intervention on rehabilitation utilization in cancer patients.

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Background: Rehabilitation services (physical medicine and rehabilitation [PM&R], physical therapy [PT], occupational therapy [OT], and speech-language pathology [SLP]) improve physical function, symptom burden, and quality of life for cancer survivors, yet utilization remains low due to persistent barriers. The collaborative care model-based Enhanced Electronic Health Record-Facilitated Cancer Symptom Control (E2C2) pragmatic trial improved symptom burden and palliative care utilization. Using post hoc exploratory analyses of population-level trial data, we evaluated whether this EHR-facilitated approach also increased rehabilitation service use. **Methods:** E2C2 was conducted across Mayo Clinic Midwest medical oncology practices using an unblinded, stepped-wedge, cluster-randomized cohort design. The EHR-embedded intervention targeted SPPADE symptoms (sleep interference, pain, impaired physical function, anxiety, depression, and fatigue). Symptoms and physical function were assessed using 11-point numerical rating scales linked to oncology encounters. Patients received self-management materials for moderate symptoms (4–6/10) and care manager support for severe symptoms (7–10/10). All outpatient rehabilitation encounters across the Mayo Clinic Enterprise were abstracted. Mixed-effects Poisson models estimated intervention effects on rehabilitation visits during the first 365 days of exposure. **Results:** Between March 28, 2019, and January 31, 2023, 50,207 patients were enrolled. Intervention and control conditions included 31,719 and 28,938 patients, respectively, with 10,450 contributing data to both periods. Cross-sectionally, 25% of participants reported moderate and 9% severe physical function impairment. Of 91,220 rehabilitation encounters scheduled, 57,669 (63.3%) were completed. Completed encounters were predominantly PT (68.3%), followed by OT (16.4%), physician visits (9.4%), and SLP (4.2%). The intervention was associated with a more than fourfold increase in completed rehabilitation encounters during the six weeks following index symptom assessment (adjusted mean 2.22 [95% CI, 0.14–4.29] vs 0.54 [0.40–0.68]; incidence rate ratio 4.11 [1.43–11.82]; $P=0.009$). Scheduled encounters also favored the intervention but did not reach statistical significance. **Conclusions:** An EHR-embedded symptom surveillance intervention increased short-term rehabilitation service completion, but overall utilization remained low relative to the prevalence of physical function impairment, highlighting the need for system-level strategies to translate symptom identification into sustained rehabilitation engagement. Research Sponsor: None.

Impact of the Navya Earthshot-enabled clinical decision support system on treatment turnaround time in oncology care: A real-world study from a tertiary cancer center in India.

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Background: Delays in Oncology care often result from systemic inefficiencies and patient-related barriers, leading to delayed treatment decision. Navya Earthshot is a validated Artificial Intelligence (AI) enabled clinical decision support system that matches patient records to standard-of-care oncology guidelines to generate evidence-based treatment recommendations. This study evaluated the real-world impact of Navya Earthshot implementation at a Tertiary Cancer Centre in India on turnaround time (TAT) for cancer directed treatment decision. **Methods:** This was a prospective, pre-post observational study conducted in two phases at a tertiary cancer centre in India. Baseline data collected prior to Navya Earthshot integration (December 2023–February 2024; $n = 148$) were compared with data from the post-implementation phase (February 2025–May 2025; $n = 488$). Navya Earthshot was embedded into routine clinical workflows, matching patient-specific clinical information to National Cancer Grid (NCG) guidelines to generate treatment options. These recommendations were reviewed by treating oncologists and discussed in daily multidisciplinary tumour boards. Patients were tracked from registration through diagnostic completion to treatment decision. The primary outcome was the turnaround time (TAT) for treatment decision, defined as the number of days from patient registration to treatment decision. Statistical comparisons were performed using the Mann–Whitney U test, with significance set at $p < 0.05$. **Results:** A total of 636 patients were included in the analysis, with 148 (pre-implementation phase) and 488 (post-implementation phase). Median TAT decreased from 21.4 Interquartile Range (IQR) days pre-implementation to 16.73 days (IQR) post-implementation, representing a 21.8% reduction ($p < 0.05$). The use of the Navya Earthshot decision support system was associated with a statistically significant reduction in overall TAT. This reduction reflects faster progression from patient registration through diagnostic completion to treatment decision in the post-implementation cohort. **Conclusions:** Integration of Navya Earthshot-enabled decision support system significantly improved treatment decision timelines in a high-volume public oncology setting. These findings demonstrate that scalable, guideline-aligned, patient-centric AI solutions can enhance workflow efficiency and strengthen end-to-end cancer care delivery in resource-constrained environments. Research Sponsor: None.

Impact of Navya Earthshot implementation on turnaround time for treatment decision.				
Metric	Pre-Implementation Phase	Post- Implementation Phase	% Change	p-value
Turnaround Time (TAT)	21.4 days	16.73 days	↓ 21.8%	<0.05

Trial characteristics and results reporting among oncology clinical trials involving African countries.

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Background: Sub-Saharan Africa (SSA) faced ~801,000 new cancer cases and ~520,000 cancer deaths in 2020, with deaths projected to reach 1 million annually by 2030. African trial activity remains scarce (<1% of global trials), with sparse reporting. We measured results reporting for oncology trials involving African sites and identified trial characteristics associated with results disclosure. **Methods:** Using ClinicalTrials.gov, we identified 1,140 completed oncology trials (1992–2023) involving ≥1 African site. We classified trials by country, institution, region, and funder, reporting proportions, ORs (95% CI), and multivariable logistic regression. **Results:** Among 1,140 trials across 38 countries, most were single-country (93.7%), single-institution (76.7%), and North Africa only (58.2%). Most were non-industry-sponsored (68.8%), interventional (79.5%) and randomized (61.1%). Enrollment was ≤100 participants in 666 trials (58.4%). Overall, 25.2% posted results. Multi-country trials reported more than single-country (59.7% vs 22.8%); multi-institution exceeded single-institution (60.5% vs 14.4%). SSA-only (48.0%) and both-region trials (72.1%) exceeded North-Africa-only (7.2%). Industry-funded reported more than non-industry (70.5% vs 4.6%). Phase III exceeded other phases (64.0% vs 10.6%). In multivariable analysis, industry sponsorship, multi-institution and multi-country configuration, SSA region, and phase 3 status were independently associated with results posting (Table 1). **Conclusions:** Nearly three-quarters of completed oncology trials conducted in Africa have not publicly reported results, highlighting substantial research waste and a critical ethical failure to translate participant contributions into accessible evidence. This analysis identifies independent, actionable determinants of reporting transparency. Strengthening African clinical trial infrastructure and coupling reporting requirements with systematic monitoring and accountability are essential to improve evidence generation and promote equity as the continent's cancer burden continues to rise. Research Sponsor: None.

Multivariable predictors of results reporting.

Predictor	Adjusted OR (95% CI)	p-value
Industry funding (ref: non-industry)	28.40 (19.1-42.2)	0.001
Multi-institution (ref: single)	5.81 (4.08-8.26)	0.001
Multi-country (ref: single)	2.12 (1.18-3.81)	0.012
Sub-Saharan only (ref: North Africa)	6.82 (4.68-9.94)	0.001
Both regions (ref: North Africa)	8.46 (3.45-20.7)	0.001
Phase 3 (ref: other/NA)	3.24 (2.26-4.64)	0.001
Interventional (ref: observational)	4.12 (1.48-11.5)	0.007
Enrollment >100 (ref: ≤100)	1.89 (1.32-2.71)	0.001

Cancer stigma in low- and middle-income countries: A scoping review of frameworks, measurement approaches, and interventions.

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Background: The incidence and mortality rates of cancer are rising fastest in low- and middle-income countries (LMICs). While cancer early detection and treatment are increasingly available in LMICs, several care barriers contribute to persistent disparities in survival outcomes. One identified barrier is stigma regarding cancer and its treatment approaches. However, there is limited literature on validated measurement tools for cancer stigma and interventions to address this stigma in LMICs. **Methods:** A systematic search of six electronic databases (OVID Medline, Embase, Web of Science, EBSCO: Africa-Wide Information, EBSCO: Global Health, and WHO Global Index Medicus/ African Index) was performed on August 17, 2023, and updated on November 20, 2025. Two reviewers independently screened 3174 titles/abstracts and 425 full-text articles. Three researchers extracted data from 129 eligible articles following sufficient agreement on pilot testing. The findings were synthesized using descriptive statistics and content analysis based on the Health Stigma and Discrimination framework. **Results:** Of the 129 articles, the study types included: cross-sectional surveys (109, 84%), randomized controlled trials (9, 7%), prospective cohorts with an intervention (9, 7%), one prospective cohort with no intervention, and one retrospective study. The studies were from 30 LMICs, with the plurality from China (59, 46%), followed by Turkey (12, 9%) and Kenya (10, 8%). Many studies focused on general cancer stigma (rather than a particular type of cancer) (34, 26%) and involved patients with cancer (90, 70%) or the general community (22, 17%). The studies commonly assessed stigma at the individual (113, 88%) and interpersonal (97, 75%) socio-ecological levels. 126 (98%) studies included a quantitative cancer stigma measurement tool, with the most common established tools being the Social Impact Scale (SIS, 33, 26%) and the Cancer Stigma Scale (CASS, 13, 10%). However, many used other adapted cancer stigma or HIV stigma scales. 41 (33%) studies were validation studies of a tool in the local context, 58 (46%) used previously validated tools, and 27 (21%) did not mention local validation. There were 18 studies with interventions, most of which focused on educational approaches, and 15 (83%) were published since 2021. **Conclusions:** This review demonstrates a wide variation in tools and validation practices in studies measuring cancer stigma in LMICs. Effective comprehensive interventions remain lacking and should be the focus of future studies. Research Sponsor: Harvard Catalyst CMerit/KL2; TR002542-05; Breast Cancer Research Foundation-AACR Career Development Awards to Promote Diversity and Inclusion; AGR-25-0533; Center of Global Cancer Medicine, Dana-Farber Cancer Center.

Validation of pathology-based triage for the 21-gene recurrence score: A meta-analysis and qualitative synthesis of the Magee equations.

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Background: The 21-gene OncotypeDX (ODX) recurrence score (RS) is the standard for chemotherapy decision-making in HR+/HER2- early breast cancer (EBC), but cost limits accessibility in resource-constrained settings. The Magee equations (MEs) use routine pathology features (Nottingham grade and IHC; ER/PR/HER2/Ki-67) to estimate RS. We performed a meta-analysis to validate MEs performance as a triage tool for ODX testing and a qualitative synthesis to identify sources of discordance, highlighting the transition toward objective digital pathology AI models. **Methods:** A systematic review identified validation studies comparing MEs with RS in HR+ EBC. Studies with sufficient data to construct a 2X2 contingency table were included; neoadjuvant trials were excluded. Primary outcomes were Negative Predictive Value (NPV) for identifying low-risk cases (RS <26 for the current TAILORx cutoff and RS<31 for the historical cutoff) and ODX test sparing rate (TSR). Data were pooled using random-effects models. Qualitative themes regarding interpretation variability were extracted from study results and discussion sections. **Results:** Thirteen studies met the inclusion criteria, representing 5396 patients in global cohorts from the USA, Mexico, Colombia, Jordan, France, Belgium, and Canada. For RS >26, Magee <18 achieved pooled NPV of 0.96 (95% CI: 0.94-0.97) and TSR 61% (95% CI: 51%-69%). For RS >31, NPV increased to 0.99 (95% CI: 0.97-1.00) and TSR 52% (95% CI: 44%-59%). Pooled diagnostic performance for Magee <18 predicting RS <26 demonstrated 83% sensitivity and 71% specificity (AUC 0.81, LR+:2.53, LR-:0.28). Qualitative analysis of discordance identified: (1) Inter-observer variability: Nottingham mitotic counts and Ki-67 scoring were the primary drivers of score fluctuations. (2) IHC quantification: Variations in H-score calculation and Allred-to-H-score conversion introduced heterogeneity (3) Pre-analytical and biological factors: Inflammation and stromal proliferation occasionally inflated genomic RS; selection of non-representative blocks and intratumor heterogeneity further contributed to discordance (4) Technological solutions: Digital pathology and AI models emerge as solutions to standardize these variables. **Conclusions:** Magee-based triage provides a safe and cost-effective strategy for HR+ EBC risk stratification, with NPV up to 99% for excluding high-risk disease and sparing up to 61% of ODX testing. These results confirm a robust histopathological signal. Transitioning to objective digital pathomics provides a pathway to reduce manual subjectivity and democratize precision oncology globally. Research Sponsor: None.

Pooled diagnostic accuracy of Magee equations by cutoff.				
Magee score and RS cutoff	Number of studies	Total patients	Pooled NPV (95% CI)	ODX test sparing rate (95% CI)
Magee <18/ RS>26	8	4153	0.96 (0.94-0.97)	61% (51%-69%)
Magee <18/ RS>31	5	1243	0.99 (0.97-1.00)	52% (44%-59%)

Representing people's experience of cancer and its treatment (ResPECT) pilot study: A global collaborative study to improve cancer care and outcomes as part of the Lancet Commission on Cancer and Health Systems.

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Background: Measurement of cancer burden increasingly informs survivorship research, health system design, and policy. Existing approaches rely on structured patient-reported outcome measures, which are costly to administer, culturally constrained, and difficult to scale globally. Advances in artificial intelligence (AI), particularly large language models (LLMs), offer the opportunity to systematically analyze unstructured patient narratives at scale. The ResPECT pilot study evaluates whether an LLM-driven framework can assess multidimensional cancer burden from patient-reported free text. **Methods:** Adult cancer patients and survivors provided structured burden ratings (Likert scale, 1–10) and open-text narratives describing physical, psychological, social, financial, and other impacts of cancer and its treatment. Unstructured text was analyzed using a retrieval augmented generation (RAG) architecture combining dense semantic embeddings (Nomic Embed), an open-weight LLM (Mistral 7B), and an ensemble retriever integrating vector similarity search and BM25 retrieval. Performance was evaluated across three predefined domains: (1) analytical concordance with quantitative analyses across 23 hypotheses as well as (2) contextual correctness and (3) hallucination rate over 50 questions, assessed by two independent reviewers. **Results:** A total of 1,642 participants from 23 countries were analyzed; 66.9% identified as female and 22.0% identified themselves to be part of an underrepresented group. Overall, impact on psychological well-being was ranked significantly higher compared to physical, social, or financial well-being (all $p \leq 0.001$). Younger participants and individuals identifying with underrepresented groups reported significantly higher overall and domain-specific burden, while U.S. participants reported greater financial burden than UK participants ($p \leq 0.001$). The LLM-based analyses reproduced quantitative findings in 21 of 23 hypotheses (91.3% concordance). Contextual correctness was 90% (90 of 100), and hallucinations occurred in 3% (3 of 100) of generated responses, predominantly involving minor paraphrasing of patient quotations. The LLM consistently identified key themes, particularly related to psychological well-being, including emotional stress, depression, relationship strain, isolation, guilt, and hope. **Conclusions:** The ResPECT initiative demonstrates that an LLM-driven framework can reliably provide and effectively scale qualitative insights into cancer burden from a patient perspective. While we acknowledge that the current pilot is not representative of cancer patients worldwide, the ResPECT approach may be scalable to derive comparable and actionable insights to inform investment in cancer services around the world. Research Sponsor: None.

Understanding barriers to the clinical breast exam in Telangana, India: A survey study of participants and non-participants in underserved rural and urban areas.

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Background: In low-resource settings where mammography is not feasible, Clinical Breast Examination (CBE) performed by trained healthcare workers is an effective alternative for breast cancer early detection. Despite prior success of large-scale CBE programs in India, national uptake remains extremely low. This study evaluated knowledge, attitudes, beliefs, and structural barriers associated with participation in CBE screening among women in rural and urban Telangana, India and assessed factors influencing participation. **Methods:** We conducted a prospective, nested case-control study in October 2025, in which CBE participants and non-participants were drawn from the same source population. Women aged >35 years who were non-pregnant and able to consent were approached during home visits or at primary health centers (PHCs) to complete standardized surveys; participation in CBE was voluntary. Surveys captured sociodemographic factors, breast cancer knowledge, attitudes toward CBE, stigma, and treatment beliefs. Multivariable logistic regression was used to estimate odds ratios (ORs) and 95% confidence intervals (CIs) for factors associated with CBE participation, adjusting for relevant sociodemographic and belief-based covariates. **Results:** A total of 669 women were included (urban n=426; rural n=243), of whom 421 participated in CBE (participants) and 248 declined (non-participants). Among 403 CBE participants, 81.1% (n=327) reported never having had a prior breast examination. Belief that CBE is necessary even in the absence of symptoms was strongly associated with participation (81.1% vs 51.6%, $p<0.001$) as was belief that breast cancer is curable (80.6% vs 56.9%, $p<0.001$). There was no difference in fear of stigma between participants and non-participants (62.2% vs 65.3%, $p=0.61$). Fear of losing the breast was highly prevalent among non-participants (72%) and independently associated with lower participation (OR 0.49, 95% CI 0.28–0.87). After adjustment, urban residence was associated with lower odds of participation compared with rural residence (adjusted OR 0.28, 95% CI 0.14–0.56) as was higher household income (>₹100,000 vs ≤₹15,000; adjusted OR 0.24, 95% CI 0.12–0.46). Among non-participants, the most cited facilitators for future participation were examination by a doctor (33.5%), clinic-based exams (28.2%), and convenient timing (28.2%). **Conclusions:** Participation in CBE is influenced by modifiable belief-based and structural barriers that vary by setting. Addressing fears related to diagnosis and treatment of breast cancer and tailoring CBE delivery strategies may improve uptake and enhance early detection of breast cancer in low-resource settings. Research Sponsor: Charles M. Balch, M.D. Endowed International Fellowship in Surgical Oncology.

Interpretable machine learning to identify health system levers for survival outcomes of patients with breast cancer.

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Background: Breast cancer is the most commonly diagnosed cancer and a leading cause of cancer death among women worldwide. Despite advances in screening and treatment, global disparities in breast cancer outcomes remain stark. The mortality-to-incidence ratio (MIR) is an ecological measure of cancer control performance. We applied interpretable machine learning to quantify country-level determinants of the breast cancer MIR within the health system, facilitating examination of interrelated factors for each individual country. **Methods:** We developed a CatBoost gradient-boosting model with SHAP (SHapley Additive exPlanations) analysis to predict female breast cancer MIR across 185 countries using GLOBOCAN 2022 data. Health system indicators were compiled from WHO, World Bank, and DIRAC databases, including GDP per capita, UHC index, radiotherapy centers per 1000 population, health spending metrics, workforce densities (physicians, nurses, surgical workforce per 1000), pathology services, gender inequality index, and breast screening program status. The model was trained with repeated leave-one-country-out cross-validation (10 repeats; 1850 total predictions) and nested hyperparameter optimization. SHAP values quantified country-specific feature attributions. **Results:** The model demonstrated robust predictive performance, with $R^2 = 0.793$ (95% CI: 0.726–0.844), RMSE = 0.068 (95% CI: 0.060–0.076), and correlation $r = 0.891$ ($p < 0.001$). Global SHAP analysis identified GDP per capita as the most influential predictor (mean |SHAP| = 0.0245), followed by the UHC index (0.0217), physicians per 1000 population (0.0196), the gender inequality index (0.0151), radiotherapy centers per 1M population (0.0150), and nurses/midwives per 1000 (0.0143). The binary breast screening program indicator showed low importance (0.0066), reflecting collinearity with other health system measures. Country-specific SHAP decompositions revealed substantial heterogeneity in dominant drivers, with workforce density and deficits in radiotherapy infrastructure emerging as major barriers in lower-resource settings. **Conclusions:** Strategic investments in healthcare workforce development, radiotherapy infrastructure, and UHC expansion are associated with improved national breast cancer survival, alongside complex health system strengthening factors. These findings enable evidence-based, context-specific prioritization of health system strengthening interventions for global breast cancer control, though prospective validation is needed. Research Sponsor: Prostate Cancer Foundation; National Cancer Institute.

Interpretable machine learning to identify health system levers for survival outcomes of patients with prostate cancer.

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Background: Global disparities in prostate cancer outcomes are among the most pronounced across all cancer types. While incidence continues to rise globally, mortality reductions are more pronounced in countries with advanced healthcare systems. Understanding how health system factors relate to prostate cancer outcomes is critical for targeted policy interventions, particularly as the cancer burden is projected to rise substantially. We used explainable machine learning models to examine how these factors are associated with prostate cancer outcomes across countries. **Methods:** We compiled national mortality-to-incidence ratios (MIRs) for prostate cancer from GLOBOCAN 2022 and integrated them with system-level indicators from the WHO, the World Bank, UN agencies, and the Directory of Radiotherapy Centres (DIRAC). Variables included GDP per capita, the Universal Health Coverage (UHC) index, radiotherapy center density, physician and nursing workforce capacity, pathology services, and health expenditure composition. We implemented a CatBoost ensemble with repeated cross-validation and integrated SHAP (SHapley Additive exPlanations) for feature attribution to quantify country-level determinants of prostate cancer MIR while accounting for nonlinear, context-dependent relationships. **Results:** The model demonstrated strong predictive performance ($R^2 = 0.796$, RMSE = 0.078, correlation = 0.892). SHAP analysis identified radiotherapy center density, UHC index, and GDP per capita as the leading system drivers of MIR. Countries with robust radiotherapy capacity and comprehensive UHC consistently achieved lower MIR, whereas higher generic health spending alone showed a weaker correlation with outcomes. Yemen exhibited the highest MIR (0.720), driven by deficits in GDP, gender inequality, radiotherapy infrastructure, and UHC. The United States achieved the lowest MIR (0.107), driven by extensive radiotherapy density, high health expenditure, and robust coverage systems. Country-specific SHAP decompositions revealed heterogeneity: in higher-income settings, radiotherapy and health workforce predominantly lowered MIR, whereas in lower-SDI countries, lack of insurance and infrastructure remained major barriers. **Conclusions:** SHAP-empowered machine learning accurately predicts country-level prostate cancer MIR and provides actionable policy guidance. Investments in radiotherapy infrastructure and universal health coverage are likely to yield greater reductions in mortality than undifferentiated budget increases. This reproducible framework enables data-driven resource allocation and supports a precision-aligned approach to global cancer control, emphasizing equity, access, and the optimization of system-specific interventions. Research Sponsor: Prostate Cancer Foundation; National Cancer Institute; P30 CA008748.

Machine learning approach to identify country-specific drivers of global cancer outcomes.

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Background: Global disparities in access to cancer diagnostics and care drive substantial variation in cancer outcomes worldwide. Identifying actionable health system factors at the country level is critical to improving survival and closing global equity gaps. We applied explainable machine learning methods to explore the interrelations among these interrelated factors. **Methods:** We developed and validated a machine learning model using data from 185 countries, obtained from GLOBOCAN 2022, WHO, and the World Bank. Mortality-to-incidence ratios (MIRs) were predicted using repeated leave-one-country-out cross-validation. SHapley Additive exPlanations (SHAP) analysis decomposed each prediction into country-specific health system-feature attributions, revealing the principal drivers of cancer outcomes. **Results:** The model achieved robust performance ($R^2=0.852$; $RMSE=0.057$; $Pearson\ r=0.923$, $p<0.001$). Globally, GDP per capita, radiotherapy center density, and the universal health coverage (UHC) index were the top contributors to MIRs. SHAP analysis revealed significant heterogeneity, identifying distinct priority drivers for each country. For example, radiotherapy infrastructure was most impactful in Turkey, UHC in Brazil and Ghana, and GDP per capita in Malaysia and China. Higher health spending as a percent of GDP was often paradoxically associated with higher MIR, underscoring the need not only for sufficient funding but also for strategic allocation. We developed a web tool that provides policymakers with country-specific SHAP estimates. **Conclusions:** Explainable machine learning translates global associations into actionable, country-specific insights. Access to radiotherapy, workforce development, and UHC expansion are consistently associated with improved cancer survival. These findings support resource prioritization in national cancer control planning and inform hypothesis generation for future causal studies. National-level analyses guide targeted investment in infrastructure and health coverage, potentially accelerating progress toward reducing global disparities in cancer mortality. Research Sponsor: Prostate Cancer Foundation; National Cancer Institute; P30 CA008748.

Leukemia mortality in Latin America and the United States: A population-based analysis.

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Background: Leukemia outcomes depend on timely diagnosis, specialized care, and access to effective therapies. Despite improvements in high-income settings, population-level leukemia mortality in Latin America remains incompletely characterized. Comparisons across regions are further complicated by differences in diagnostic capacity and mortality reporting. We compared leukemia mortality across Latin American countries and the United States (US), using U.S. Hispanic individuals as the reference population, to characterize regional disparities, age-specific patterns, and temporal trends. **Methods:** We conducted a population-based analysis of leukemia mortality using the WHO Mortality Database for 15 countries and U.S. National Vital Statistics/SEER data. The burden of leukemia mortality was assessed from 2008 to 2019. Mortality rate ratios (MRRs) were estimated using Poisson regression. Trends were assessed using Joinpoint regression, and associations with the Human Development Index (HDI) were evaluated using linear regression. **Results:** Among children (0-19 years), most Latin American countries had significantly higher leukemia mortality than U.S. Hispanic children (MRRs 1.23-3.18), with the highest rates observed in Mexico (2.58/100,000; MRR = 3.18) and Ecuador (2.49/100,000; MRR = 3.06). In contrast, U.S. non-Hispanic White, African American, Asian/Pacific Islander, and American Indian/Alaska Native children had lower mortality than U.S. Hispanic children. Among adults (≥ 20 years), leukemia mortality patterns were heterogeneous. U.S. non-Hispanic White adults had higher mortality than U.S. Hispanic adults (9.6/100,000; MRR = 1.74), as did higher-HDI Latin American countries, including Uruguay and Costa Rica, whereas most countries demonstrated comparable or lower mortality. Childhood leukemia deaths were dominated by ALL, while adult mortality showed greater subtype heterogeneity, with a predominance of AML, chronic leukemias and a high proportion of deaths coded as leukemia not otherwise specified (NOS). Higher HDI was associated with lower mortality among young adults, but higher reported mortality among elderly adults. **Conclusions:** Leukemia mortality across Latin America and the US remains highly heterogeneous, with substantial excess mortality among children and older adults in several countries. Age associations with HDI and the high burden of leukemia NOS coding suggest disparities and limitations in diagnostic capacity and registry. Research Sponsor: None.

Leukemia mortality* and subtype distribution.

Population	Children Mortality Rate	Children MRR	Adult Mortality Rate	Adults MRR
U.S. non-Hispanic White	0.5	0.65	9.6	1.74
Mexico	2.58	3.18	5.76	0.92
Ecuador	2.49	3.06	5.47	0.88
Colombia	2.22	2.5	6.05	0.85
Uruguay	1.31	1.1	7.15	1.35
Costa Rica	1.28	1.05	7.09	1.13
Leukemia subtype	Children (%)		Adults (%)	
ALL	50-70		10-20	
AML	15-25		25-40	
Chronic leukemias	<5		20-35	
Leukemia NOS	8-40		17-50	

*Reference group: U.S. Hispanics.

Machine learning–based decision support for ICU admission in febrile oncology patients: Optimizing care delivery and resource allocation.

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Background: In febrile oncology patients, distinguishing self-limiting illness from life-threatening sepsis is a critical challenge for care delivery, particularly in resource-constrained settings. Over-triage strains limited critical care capacity, while under-triage compromises patient safety. We aimed to develop and validate a machine learning–based decision support tool to assist clinical judgment in identifying patients requiring intensive care.

Methods: In a retrospective cohort of 149 febrile oncology patients, we extracted routinely available clinical features (including MASCC score, qSOFA, hypotension status, tumor characteristics, and comorbidities). We developed an XGBoost classifier to predict ICU admission and compared its performance against logistic regression and standard clinical risk scores (MASCC, qSOFA). Model performance was rigorously evaluated using 10×5-fold cross-validation with bootstrap confidence intervals, with specific attention to its utility as a supportive screening tool. **Results:** Of 149 patients, 81 (54.4%) required ICU admission. The XGBoost model demonstrated superior discrimination with an AUROC of 0.934 (95% CI: 0.863–1.000), significantly outperforming logistic regression (0.917), MASCC (0.656), and qSOFA (0.838). The model showed excellent calibration (Brier score: 0.092). Crucially, in a sensitivity analysis excluding hypotension—a clinically obvious trigger for ICU transfer—the model retained high discriminative ability (AUROC 0.887), indicating its value in identifying high-risk patients before hemodynamic collapse. **Conclusions:** This machine learning model effectively identifies febrile oncology patients requiring ICU admission, significantly outperforming traditional scores. By functioning as a high-fidelity decision support tool, it holds the potential to improve care delivery outcomes: ensuring timely escalation for high-risk patients while preventing unnecessary resource utilization for stable patients. Ultimately, this tool is designed to augment, rather than supersede, expert clinical judgment in complex acute care settings. Research Sponsor: None.

Oncology drug shortages and disruptions to cancer treatment delivery in Mexico: A national oncologist survey.

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Background: Oncology drug shortages increasingly disrupt cancer care delivery worldwide, yet quantitative data describing their impact on treatment decisions in middle-income countries are limited. This study evaluates how drug and supply shortages affected cancer treatment delivery in Mexico during 2024–2025. **Methods:** Between September and December 2025, we conducted a national, cross-sectional, anonymous online survey of practicing oncologists in Mexico. The survey, promoted by the Mexican Society of Oncology (SMEO), consisted of structured multiple-choice questions assessing whether oncology drug or supply shortages required treatment modifications during routine clinical practice within the preceding 12 months. Respondents could select multiple types of treatment adaptations. Descriptive statistics were used to summarize responses. **Results:** A total of 196 oncologists and hematologists completed the survey. Overall, 191 respondents (97.4%) reported performing at least one therapeutic modification due to drug or supply shortages. The most frequently reported modifications were changes in treatment regimen (79.6%), omission of one or more planned treatment cycles (71.9%), and delayed or non-timely administration (62.8%). Additional adaptations included substitution with alternative drugs within the same pharmacologic class (57.7%), non-clinically indicated dose reductions (37.8%), and use of non-guideline-approved regimens (25.5%). Referral of patients to other institutions because of treatment unavailability was reported by 12.8% of respondents. Only 2.6% reported no treatment modifications. **Conclusions:** In this national survey of oncologists and hematologists, drug and supply shortages in Mexico were highly prevalent and associated with frequent, clinically meaningful disruptions to cancer treatment delivery, including regimen changes, treatment omissions, and delays. These findings highlight a substantial challenge for cancer care delivery in a middle-income setting and underscore the need for health-system strategies aimed at preserving treatment continuity. Research Sponsor: None.

Shortage-related therapeutic modifications reported by oncologists (n = 196).	
Therapeutic modification due to shortage	n (%)
Any modification performed	191 (97.4)
Change of treatment regimen	156 (79.6)
Omission of ≥1 planned treatment cycle	141 (71.9)
Delayed / non-timely administration	123 (62.8)
Drug substitution within same class	113 (57.7)
Non-indicated dose reduction	74 (37.8)
Non-guideline-approved regimen	50 (25.5)
Referral to another institution	25 (12.8)
No modifications performed	5 (2.6)

Expanding access to tyrosine kinase inhibitors for treatment of Philadelphia chromosome–positive acute lymphoblastic leukemia in low- and middle-income countries.

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Background: Acute lymphoblastic leukemia (ALL) is a hematological malignancy affecting 300,000 people worldwide, with an estimated incidence of 100,000 new cases annually. An important cytogenetic abnormality, the Philadelphia chromosome, causes an aggressive form of disease that affects 3–4% of pediatric and 20–30% of adult patients. Since the early 2000s, tyrosine kinase inhibitors (TKIs) have dramatically transformed the treatment of Philadelphia chromosome positive ALL (Ph+ALL). In high-income countries, different TKI regimens in combination with chemotherapy achieve remission rates >90%, but survival rates in low- and middle-income countries (LMICs) are persistently worse, largely due to access barriers, including high costs of innovative therapies. **Methods:** The Max Foundation provides TKIs at no cost to eligible patients with Ph+ALL and other diseases in resource-limited settings worldwide. We conducted a retrospective review of all patients with a diagnosis of PH+ALL initiating treatment with TKIs between January 1, 2007 and July 31, 2025 through the Glivec International Patient Assistance Program (2007–2017) or Max Access Solutions (since 2017). Data on age at diagnosis, treatments, sex, country of origin, program status, and reason for closure were analyzed using descriptive statistics, with correlations between available variables and length of treatment explored. **Results:** Of 1,671 patients enrolled, 342 (20.5%) remained active at the time of analysis. Males accounted for 967 patients (57.9%). Patients enrolled from 47 LMICs in the Americas (542, 32.4%), Asia excluding India (414, 24.8%), Eastern Europe (365, 21.8%), Africa (219, 13.1%), and India (131, 7.8%). Median age at diagnosis was 29, with 485 (29.0%) 18 years old or younger. Most patients (1594, 95.4%) initiated treatment with imatinib as first-line treatment; of these, 110 (6.9%) moved to a second-line treatment and 18 (1.1%) to a third-line. Among 1,329 closed cases, reasons for closure included death (526, 39.8%), lost to follow-up (291, 21.9%), and clinical reasons (260, 19.6%). Median treatment length was 17 months (range 0–197 months). Patients who died were older at diagnosis (median 34 vs 28 years old) and had a shorter median treatment duration (13 vs 19 months) compared with other patients. Treatment duration tended to decrease with age; with a significant negative correlation between age at diagnosis and total months of treatment ($r=-0.171$, $p<0.001$). Since 2024, 25 patients received additional supportive services through The Max Foundation, including transportation assistance. **Conclusions:** This program demonstrates the feasibility of providing TKIs for the treatment of PH+ALL in diverse resource-limited geographies. Increasing access to TKIs is a critical step in eliminating global disparities in the burden of Ph+ALL. Research Sponsor: None.

"Who even talks to her anymore?" Misalignment between cervical cancer care landscape and community awareness in Rwanda.

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Background: Cervical cancer remains the most common female cancer in Rwanda. Despite the significant advancement in early detection and treatment of cervical cancer in the country, many patients do not seek care or experience significant delays in seeking and getting care. Historically, elements of stigma have contributed to care non-engagement and patient delays. With ongoing growth and expansion of care services over the past decade, we sought to explore the current state of Rwandan patients' perspectives on and experience with cervical cancer stigma. **Methods:** We conducted an exploratory qualitative study using semi-structured interviews of a purposeful sample of 25 patients with cervical cancer, including 12 living with HIV, who were treated at a tertiary cancer facility in Northern Rwanda. Interviews were conducted in Kinyarwanda, audio-recorded, transcribed verbatim, and translated into English. Guided by the Health Stigma and Discrimination Framework, the team conducted thematic analysis supported by NVivo (LUMIVERO). **Results:** Our analysis revealed that cancer stigma remains prevalent in participants' communities, and this stigma has multifaceted impacts on their cancer care journey. Despite the national expansion in the availability of screening, early detection, and curative cervical cancer care services, patients continue to report limited community awareness of cervical cancer, with prevailing beliefs of fatalism and care scarcity. Knowledge gaps in cervical cancer diagnosis, treatment, and side effects contribute to stigmatizing behaviors by family members and neighbors, including rumors and social isolation. Participants also described perceptions of cancer incurability as contributing factors to social isolation. However, illness acceptance and religious engagement were identified as helpful coping mechanisms to mitigate stigma and promote care-seeking. Finally, participants' lived experiences with cervical cancer and survivorship motivated them to encourage others in their community to participate in screening and seek medical care. **Conclusions:** Our findings highlight the influence of community beliefs about cervical cancer on medical care-seeking behavior and community reception of patients. Some beliefs were misaligned with patients' current lived experiences with recent advances in the national cancer care environment. For Rwanda to achieve its cervical cancer elimination goals, these findings reinforce the need for continued community awareness of cervical cancer symptoms and treatment as well as sensitization to the available community assets for early detection and treatment. Research Sponsor: 2025 Breast Cancer Research Foundation; AGR-25-0533; Harvard Catalyst; TR002542-05; Center of Global Cancer Medicine, Dana-Farber Cancer Center.

National analysis of cancer care for refugees in Moldova during the war in Ukraine (2022–2025).

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Background: Following Russia's invasion of Ukraine in February 2022, Moldova, a non-EU country of 2.3 million, had one of Europe's highest refugee-to-population ratios (6.4%). To meet refugee cancer care needs, the Institute of Oncology and Moldova's Ministry of Health (MOH) established a multi-sectoral financing model with the International Organization for Migration (IOM) and the Blue Heron Foundation (BHF), an American NGO. Refugee patients received a free MOH-funded consultation and access to screening and early detection. Diagnostic tests were then funded by IOM and treatment costs covered by BHF for the initial 15 months of the war, after which all services were reimbursed by IOM-led projects. **Methods:** We conducted a retrospective review of Ukrainian refugee cancer patients at Moldova's main oncology centers from May 1 2022 to July 30, 2025, with near complete national data. We analyzed demographics, diagnoses, diagnostic tests and treatments, and per-patient costs adjusted for PPP. **Results:** Of 1,398 Ukrainian refugees evaluated with suspicion of cancer, 681 (48.7%) were diagnosed with malignancy. 412 unique patients (60.5%) remained to receive medical services in Moldova. Among these, 391 were seen at the Institute of Oncology, 25 at Medpark International Hospital (including 7 seen at both institutions), and 3 at Republican Clinical Hospital. The cohort included 221 women (53.6%) and 191 men (46.4%) with an average age at presentation of 58.8 (range 5 – 88 years-old). The most common malignancies were breast (n=71, 17.2%), urological (n=62, 15%), colorectal (n=51, 12.4%), head and neck (n=40, 9.7%), and gynecological cancers (n=38, 9.2%). 292 patients (70.9%) had locoregional disease, 82 (19.9%) were metastatic, and 38 (9.2%) were unstaged. Diagnostic tests over 39 months included 400 CT scans, 70 bone scans, 69 MRIs, 5 PET-CTs, 83 mammograms, 129 endoscopies, and 20,265 lab tests. 326 (79.1%) received treatment, including 203 surgeries, 695 chemotherapy administrations, and 46 radiotherapy courses. Total costs for diagnostics and treatments covered by IOM and BHF at the Institute of Oncology were available for 305 patients, amounting to 9,943,111 MDL, equivalent to \$552,782 USD at an average exchange rate of 18.02 MDL/USD. This corresponds to a mean cost of \$1,812 per patient, or \$4,502 per patient in purchasing-power-adjusted (PPP) international dollars, using a Moldova PPP conversion factor of 7.24. **Conclusions:** This analysis shows that comprehensive cancer care for refugees in resource-limited settings is possible via rapid partnerships among different sectors. Moldova's model offers replicable lessons for other nations facing similar humanitarian challenges. However, to this day, refugees continue to depend on humanitarian donors such as IOM for cancer services, highlighting the need to develop sustainable financing mechanisms that move beyond emergency response. Research Sponsor: None.

Closing the gap in germline testing in patients with cancer through a clinic-based awareness initiative: From booth to patient's agenda.

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Background: Germline genetic testing (GT) is a standard of care for a broad range of patients (pts) diagnosed with cancer due to expanded guidelines and targeted treatments options. The consequent identification of hereditary cancer susceptibility syndromes (HCS) enables optimal surveillance measures, prophylactic interventions and the identification of at-risk family members. Unfortunately, GT rates in oncology are still low worldwide. Barriers are complex but commonly related to deferred appointments and overwhelmed pts. In Argentina, GT and genetic counseling (GC) have not been endorsed as a public health need, insurance coverage relies on a case-by-case basis and mainstreaming has not been fully implemented, therefore, integrating GT into oncology workflows remains a challenge. **Methods:** Our aim was to describe the impact on GT intake of an information campaign coupled with an appointment help desk in a cancer center. We conducted a high-risk, one-month awareness social media campaign, following a one-week, in-person, information booth (during 06/26/2024 -07/03/2024), strategically placed near the waiting room of a cancer center in Argentina. Both offered informative material and the possibility to attend a free, hybrid- mode, interactive, "meet the expert" session on 07/11/2024. For those who visited the booth, in-person orientation by health providers and scheduling for a personalized GC session (in person or by telemedicine) in the following 3 months was offered. After informed consent, information from social media, landing page interaction and medical records was extracted for analysis. Descriptive statistics with Stata program was performed. **Results:** On social media: ≥ 600 likes, ≥ 20 comments, ≥ 350 landing page visits, ≥ 278 interactions and 976 new e-mail contacts were registered in the landing page. A peak of 119 visits was recorded on 07/09/2024. Media engagement rate: 5,14 %. 814 individuals registered to the hybrid session with an attendance rate of 30% (245/814), with no differences related to format option (in-person 21/73: 29% and virtual 224/741: 30%, p-value 0.794954). At the booth: 165 pts requested in-person information, 160 were scheduled for a visit: first assessments (1As): 114/160 (71%). Compliance with appointment was 64% between 1As (73/114), GT was suggested to 92% of 1As (67/73) with GT intake of 49/73 (67%) by multi-gene germline panel. Overall, 10/160 HCS were identified (diagnostic yield in intention-to-treat): 6,5%: 3 gATM, 2 gBRCA1-2, 2 gHOXB13, 1 gCHEK2, 1 heterozygous MUTYH, 1 heterozygous FANCA. Risk-reducing surgeries were performed in 4/10 carriers. **Conclusions:** Social media engagement combined with lowering appointments barriers can achieve a high compliance to 1As genetic consultations, GT and consequently identification of HCS among high-risk pts with cancer in resource-limited scenarios. Research Sponsor: None.

Validation of a generative AI-based clinical decision support system for surgical extent in thyroid cancer in Brazil: Potential aid to de-escalating treatment to preserve function.

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Background: The decision between thyroid lobectomy (TL) and total thyroidectomy (TT) for differentiated thyroid carcinoma involves balancing oncological control with morbidity. While NCCN guidelines support TL for low-risk cases, clinical practice often favors TT due to risk aversion, exposing patients to lifelong levothyroxine dependence. We validated "Korina," a clinical decision support system based on the Gemini Large Language Model developed at Instituto do Câncer do Ceará (ICC), Brazil, to assess its ability to optimize surgical decision-making and identify candidates suitable for organ-preserving surgery. **Methods:** We validated the AI model using a retrospective thyroid cohort (N = 100). The median age was 47 years (IQR 38–55), 87% were female, and histology was predominantly papillary thyroid carcinoma (99%) with 1% follicular. The median reported nodule size was approximately 1.7 cm (IQR 1.2–2.4). We (three independent medical evaluators, one head neck specialist, blinded) compared the surgical recommendations of the AI and a senior head and neck surgeon against NCCN guidelines (ground truth). The primary outcome was the accuracy of the indicated surgical extent (TL vs. TT). Performance metrics included AUC, Accuracy, Precision, and Recall (Sensitivity) for identifying TL candidates. **Results:** In the validation analysis, the AI model demonstrated superior concordance with guidelines compared to standard clinical assessment. The AI achieved an Accuracy of 0.894 and an AUC of 0.895, significantly outperforming the clinician (Accuracy 0.532; AUC 0.542). Critical analysis revealed that the clinician had a high rate of unnecessary TT recommendations, with a Recall of only 0.083 (8.3%) for the TL class. In contrast, the AI model achieved a Recall of 0.833 (83.3%) for TL. **Conclusions:** The Gemini-based system (the first in Brazil to the best of our knowledge) outperformed standard clinical judgment in adhering to NCCN guidelines. The clinician demonstrated a bias toward aggressive surgery, missing over 90% of eligible lobectomy cases. Implementing this AI tool potentially could safely increase the rate of partial thyroidectomies, directly benefiting patients by preserving thyroid function and eliminating the lifelong burden of hormone replacement therapy for a significant proportion of cases. Research Sponsor: None.

Performance metrics of AI vs. clinician (reference: NCCN).					
Model	Precision	Recall (Sensitivity)	F1-Score	Accuracy	AUC
AI (Gemini)	0.952	0.833	0.889	0.894	0.895
Clinician	1.000	0.083	0.154	0.532	0.542

Validation of an AI-based clinical decision support system for guideline-concordant prostate cancer treatment at a Brazilian cancer center.

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Background: Clinical decision support systems (CDSS) based on large language models may improve adherence to evidence-based guidelines in prostate cancer. We developed a Gemini-based CDSS for localized and locally advanced prostate cancer treatment at Instituto do Câncer do Ceará (ICC), Fortaleza, Brazil, and conducted a validation study comparing its recommendations with National Comprehensive Cancer Network (NCCN) guidelines and real-world physician decisions. **Methods:** We retrospectively included 198 consecutive patients prostate cancer treated at ICC. For each case, the CDSS generated a recommended primary treatment. Independent clinician reviewers assigned reference NCCN-concordant treatment categories. We calculated per-treatment precision, recall, F1-score, and one-vs-rest AUC comparing CDSS and physicians, with particular focus on active surveillance (AS) and radical prostatectomy (RP). **Results:** Overall NCCN concordance was 87.9% for the CDSS and 82.3% for physicians. Treatment-level analysis showed that the CDSS more often and more accurately identified candidates for active surveillance. For AS, the CDSS achieved precision 1.00, recall 1.00, F1-score 1.00, and AUC 1.00, while physicians had precision 1.00 but substantially lower recall (0.24), F1-score 0.39, and AUC 0.62. In contrast, physicians more frequently recommended RP beyond NCCN indications: for prostatectomy, the CDSS showed precision 1.00, recall 1.00, F1-score 1.00, and AUC 1.00, whereas physicians had lower precision (0.40) with recall 1.00, F1-score 0.58, and AUC 0.90. **Conclusions:** In this single-center validation study, a Gemini-based CDSS for prostate cancer treatment achieved higher overall NCCN concordance than treating physicians and improved alignment with guidelines for the appropriate use of AS. These findings suggest that integration of large language model-based CDSS into clinical workflows at cancer centers in low- and middle-income settings may reduce overtreatment and support more value-based prostate cancer care. Although we did not include data on social impossibility of AS, the finding leads to reflections on the possibility of greater use of AS, even in a region with limited resources. Research Sponsor: None.

Performance of a Gemini-based clinical decision support system vs physicians for active surveillance and radical prostatectomy (NCCN-concordant treatment metrics).			
Treatment modality	Metric	CDSS (Gemini-based)	Physicians
Active surveillance (VA)	Precision	1.00	1.00
Active surveillance (VA)	Recall	1.00	0.24
Active surveillance (VA)	F1-score	1.00	0.39
Active surveillance (VA)	AUC	1.00	0.62
Radical prostatectomy (P)	Precision	1.00	0.40
Radical prostatectomy (P)	Recall	1.00	1.00
Radical prostatectomy (P)	F1-score	1.00	0.58
Radical prostatectomy (P)	AUC	1.00	0.90

A clinical prediction score to identify symptomatic patients at high risk for colorectal cancer in South Africa.

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Background: Colorectal cancer (CRC) is the third most diagnosed cancer globally with a rising incidence across sub-Saharan Africa. In South Africa (SA), advanced stage at diagnosis drives poor outcomes and limited endoscopic capacity makes early CRC diagnosis guidelines difficult to implement. We developed a clinical prediction score to identify patients with lower gastrointestinal (GI) symptoms at high risk for CRC in SA. **Methods:** Adults (≥ 18 years old) with ≥ 1 “red flag” lower GI symptom (weight loss, change in bowel habits, rectal bleeding, anemia, abdominal mass) referred for colonoscopy at two public hospitals in Durban were eligible for this prospective study (Sept 23, 2022 – Dec 9, 2025). Demographic and clinical data, results from a pre- or intra-colonoscopy POC-FIT, and colonoscopy results were recorded. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of POC-FIT for CRC were calculated. A clinical prediction score was derived using this cohort. The optimal number of prognostic factors for a predictive multivariate logistic regression model were determined using LASSO and model validation was done using bootstrapping technique. Overall performance was assessed using the scaled Brier score, Hosmer-Lemeshow test, and AUC. Analysis was performed using R (v 4.4.1). **Results:** Of 393 enrolled patients (median age 52 years, 54.5% female), 306 (77.9%) had a valid FIT result, with 194 (63.4%) positives. In this symptomatic cohort, the adenoma detection rate was 19.6%, with 15 low-risk (3.8%), 14 high-risk (3.6%) adenomas, and 31 (7.9%) CRCs. POC-FIT had 75% sensitivity, 38% specificity, 9% PPV and 95% NPV for CRC. If patients with a negative POC-FIT had not immediately proceeded to colonoscopy, 102 (33.3%) urgent colonoscopies could have been avoided, but diagnosis would have been delayed for 4 patients with high-risk adenomas and 6 with CRC. The LASSO model, utilizing $\lambda=0.017$, selected 3 variables associated with CRC: age greater/less than 50, weight loss (yes/no), symptom duration >3 months (yes/no) (risk score 0–3), with AUC 78.6% for predicting CRC (Table 1). Adding negative FIT result to the clinical prediction score (risk score 0–4) improved performance (AUC 79.2%). Setting a symptom score of ≥ 2 as positive, the specificity for diagnosing CRC was 47.9%, and sensitivity 95.8%. **Conclusions:** Among South African patients referred for diagnostic colonoscopy, FIT has a strong NPV but weak PPV for CRC. A clinical prediction score for CRC among symptomatic South African patients was derived with good performance for ruling out CRC. Future studies will validate this model in the primary care setting. Research Sponsor: ASCO/Conquer Cancer; 2023CDA-8960359887.

Clinical prediction score derived from cohort of symptomatic patients undergoing colonoscopy in Durban, South Africa.					
Clinical Score	No CRC	%	CRC	%	Total
0	30	100	0	0	30
1	105	99	1	1	106
2	112	91	11	9	123
3	32	74	11	26	43
4	3	75	1	25	4
Total	282	92	24	8	306

Delivering oncology care in Syria: Implementation lessons from conflict-affected and resource-limited settings.

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Background: Oncology services are often excluded from humanitarian health response packages despite the rising cancer burden in conflict-affected populations. In northwest Syria, protracted conflict disrupted referral pathways, depleted the specialist workforce, and constrained diagnostic infrastructure. The Syrian American Medical Society (SAMS) implemented a conflict-adapted oncology model that evolved from remote specialty support (2017) to decentralized service delivery with phased diagnostic strengthening and workforce development. We report multi-year program outputs as indicators of implementation feasibility and scale. **Methods:** We conducted a retrospective program evaluation using routinely collected, aggregate operational indicators from SAMS-supported oncology services in northwest Syria (fixed sites with referral/outreach pathways). Annual indicators (2022–2025) included: total patients served, new patients, new malignant diagnoses, total oncology diagnoses (benign + malignant), and chemotherapy administrations. Longitudinal patient-level outcomes were not consistently captured due to displacement, insecurity, and lack of a unified electronic medical record during early scale-up. **Results:** Total patients served increased from 20,779 (2022) to 28,392 (2025) (+36.6%). New patients increased from 4,648 to 12,467 (+168.2%). New malignant diagnoses increased from 1,373 to 2,000 (+45.7%), and total oncology diagnoses increased from 15,102 to 21,918 (+45.1%). Chemotherapy administrations increased from 7,177 to 15,008 (+109.1%). Key implementation milestones included the establishment of the Idlib Cancer Center (2018), phased immunohistochemistry enabled through cross-border workflows and remote expert interpretation, and the institutionalization of local diagnostic capacity through a pathology residency launched around mid-2023, supported by hybrid local/remote mentorship and digital pathology infrastructure (slide scanning for remote review). A persistent system gap was the lack of local radiotherapy, requiring cross-border referral pathways that were vulnerable to administrative and access disruptions. **Conclusions:** A phased “minimum oncology service package” integrating decentralized delivery, tele-enabled expertise, and staged diagnostic/workforce strengthening can be implemented and scaled in protracted conflict settings. In the SAMS model, structured fellowship teaching, e-consultations, and a virtual breast tumor board supported timely decision making, while missions and workshops reinforced local capacity. This transferable framework supports integrating oncology into humanitarian responses, alongside investment in radiotherapy access and continuity-of-care data systems. Research Sponsor: None.

Optimization of immunotherapy duration for advanced melanoma: The prospective OTIMAS trial.

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Background: Anti-PD1 monotherapy is a common option for first-line treatment for advanced melanoma in resource-constrained settings. A shorter duration of therapy and associated biomarkers of response can reduce financial burden for healthcare systems. **Methods:** In this phase 2 single-arm trial, pts with unresectable stage III-IV melanoma received pembrolizumab (Pem) 200mg intravenously every 3 weeks for a maximum of 12m. Primary endpoint was 24m progression-free survival (PFS); secondary endpoints included overall response rate per RECIST 1.1 and overall survival (OS) and safety. An additional course of therapy was allowed if progression was observed after 6m of treatment interruption. Exploratory analysis included miRNA cargo of small extracellular vesicles (sEVs) and cost-effectiveness analysis of 12m vs. 24m in the context of the universal Brazilian health system. **Results:** 29 pts were enrolled from Jan 2022 to Jan 2025. As of Sep 2025, all had completed treatment, with a median follow-up of 19.1m (0.6-45.3). Median age was 59 years (28-85), 55.2% were male, 72.4% had metastatic disease and 20.7% had ECOG-PS >1. 41.4% presented with high baseline LDH. 2 pts had acral melanoma. 20.6% had received previous chemotherapy. Median PFS was 5.7m (IC95% 3.1-8.4) and 24m-PFS, 23.8%. 2-y OS was 42.8% (IC 95% 24.2-61.4). ORR was 34.5% (10/29), with 51.7% DCR. Among 24.1% who completed 12m of Pem, only one pt experienced PD less than 6m after completion of Pem. One death due to immune related pneumonitis was observed. The percentage of variable expressed regions in sEVs differed according to immunotherapy (IO) response profile. Cost analysis showed that the medication cost was reduced by 53.75% when compared to the 2-year strategy. **Conclusions:** This trial demonstrated that one year treatment with IO is feasible and provides comparable outcomes to a standard 24m treatment (mPFS 5.6 range 3.4-8.2; 2-year OS 55% IC 95% 49-61%), regardless of response. This strategy can be cost effective and provide broader access to immunotherapy and improve resource allocation in public health systems. Specific miRNAs were identified for a potential response signature to select patients with long-term benefit. Clinical trial information: NCT07376317. Research Sponsor: Medical Oncology Department - Instituto do Cancer do Estado de São Paulo.

Optimization of geospatial oncologist placement: A maximum coverage problem approach.

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Background: Rural communities in the United States (US) experience persistent shortfalls accessing oncology care due to an uneven workforce distribution. Non-specific county-level metrics fail to pinpoint precisely where new oncologists can maximize impact. By adapting a maximal coverage algorithm to the ZIP code level, our study aims to provide a data-driven solution to physician placement by identifying high demand areas with significant unserved populations. **Methods:** We developed a model to simulate capacity-constrained maximal coverage expansion of oncology care with up to 500 oncologist placements per state, 40 kilometer catchment radii, and an assumption that one oncologist could cover up to 6,667 individuals over 55 years old (based on baseline US prevalence of 15 oncologists per 100,000 individuals over 55). We used physician data from the Doctors and Clinicians national downloadable file, geographical data from the US Census, and Rural-Urban Continuum Codes (RUCCs) to measure rurality. Outcomes measured included baseline state-level coverage, number of placements needed to achieve 90% state-level population coverage, and urban-rural placement differences. For continuous variables, the two-sample t-test was used for statistical significance. **Results:** Nationally, approximately 26 million additional individuals would gain coverage with 5,578 additional placements. 2,912 (52.2%) of the optimal ZIP codes were in rural counties. Placements provided a mean coverage of 4,684 people per physician. Median baseline state coverage was 67.8% (IQR 59.9%-77.1%), with 3 states having >90% coverage at baseline (Rhode Island, Connecticut, and New Jersey). To achieve 90% coverage, states required a median of 40 placements (IQR 18.25-63.25). Coverage gains per state were front-loaded with the first 25 oncologists in a state capturing on average 46.7% of all achievable gains. The states that required the greatest number of additional oncologists to achieve 90% coverage were: California (N=209), Florida (N=174), and Texas (N=163). The top five rural placements per state covered an average of 6,505 individuals while the top five urban placements per state covered an average of 6,220 individuals (p-value = 0.009). **Conclusions:** Our approach precisely identified underserved ZIP codes where oncologist placement would maximize access to care. Strategic placement of oncologists can lead to increased access to care, particularly for rural residents. These policies should initially be directed toward states and ZIP codes with the largest baseline gaps to maximize coverage and advance equitable healthcare access. Research Sponsor: None.

Scaling prior authorization for philanthropic funding with artificial intelligence (AI): Five-year outcomes from Indian Cancer Society Cancer Cure Fund (ICS-CCF) NavyaAI implementation.

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Background: Indian Cancer Society – Cancer Cure Fund (ICS-CCF) is one of the largest charitable program for directly reimbursable treatment expenses to needy cancer patients. The prior authorization process at ICS-CCF requires the Due Diligence Team (DDT) and the Governing Advisory Council (GAC) to review every application for compliance with standardized treatment guidelines, expected cure rates, and approved costs. To augment and enhance this process, ICS-CCF evaluated and implemented the use of Artificial Intelligence (AI) to support application review and recommendations over a five-year study period. This study is a five year report on operational outcomes to reduce dependence on expert oncologists in the prior authorization setting using AI for care delivery. **Methods:** The NavyaAI platform is a clinically validated AI model that matches clinical data from beneficiary applications (input) with available clinical evidence and National Cancer Grid (NCG) guidelines, adapted to ICS-CCF approval criteria (output). Applications in which the AI output matched the input were classified as “recommended” and forwarded directly to the GAC for approval. All remaining cases were referred to the DDT, comprising a minimum of two expert oncologists, who reviewed the applications and forwarded recommendations to the GAC as appropriate. Concordance between NavyaAI and GAC decisions was assessed. The time spent by the DDT reviewing referred applications was recorded. DDT reviews were conducted weekly, and GAC reviews were conducted bi-monthly. **Results:** From April 2020 to November 2025, a total of 12001 (malignant solid tumors 63.77% (7653/12001) and hemato-lymphoid malignancies 36.23% (4348/12001) applications were reviewed by NavyaAI. Of these, 82.58% (9,910/12001) were recommended, 1.71% (205/12001) were rejected, and 15.72% (1,886/12001) were referred to the DDT. Concordance between NavyaAI and GAC decisions was 99.57% (9,867/9,910) for authorizations and 92.68% (190/205) for rejections. The DDT spent an average of 3 minutes reviewing each application referred by NavyaAI. On average, NavyaAI forwarded 35 applications directly to the GAC per week, saving a minimum of 210 minutes of oncologist review time weekly. **Conclusions:** NavyaAI can independently review and assess the majority (~84%) of beneficiary applications for recommendation or rejection with high concordance to expert decision-making. Further implementation of AI-assisted authorization models is warranted to scale their long-term impact on quality, efficiency, and scalability of philanthropic funding decisions within governmental and non-governmental healthcare schemes. Research Sponsor: None.

Predicting immune-related adverse events (irAEs) with large language model (LLM) embeddings.

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Background: irAEs are a common side effect of immune checkpoint inhibitor (ICI) therapy. Predicting irAEs from clinical records relies on traditional machine learning methods, which require time-consuming and extensive feature engineering such as removing features with many missing values or imputing values. Using LLM vector embeddings to train classifier models may require less feature engineering and leverage LLM understanding of semantic information. We assessed whether this LLM method could predict development of irAEs 12 weeks after initiating an ICI. **Methods:** We used patient (pt) data from the Immuno-Oncology Registry, a database of cancer pts from 10 DC-Baltimore-based MedStar Health network hospitals and Hackensack Meridian Health system in New Jersey. The data were divided into training (80%) and testing (20%) datasets. The training dataset was oversampled to balance the irAE class distribution. Tabular data was serialized into natural language, then passed into a LLM with original text, 0-shot, 1-shot, or few-shot prompting. Due to LLM context length limits, pt information was separated into 9 components, and each component embedding was max-pooled before concatenation. The embeddings were used to train 4 classifier models with hyperparameter tuning: XGBoost, support vector machine (SVM), logistic regression (LR), and multilayer perceptron (MLP). Five different sentence transformer or text embedding LLMs were tested. Model classification performance was evaluated by Area Under the Receiver Operating Characteristic curve (AUROC). **Results:** Of the 1459 pts, 585 (40%) experienced irAE(s). The most common cancers were lung cancer (34.5%) and melanoma (27.7%). ICIs included anti-CTLA-4 (11.0%), anti-PD-1 (58.9%), anti-PD-L1 (4.6%), anti-PD-1 + anti-CTLA-4 (14.0%), anti-PD-1 + chemotherapy (3.1%), anti-PD-1 + tyrosine kinase inhibitor (0.07%), and others (8.4%). The most common irAEs were skin rash (14.5%) and colitis (8.9%). Median AUROC was highest for XGBoost (0.654), followed by LR (0.641), MLP (0.627), and finally SVM (0.596). Median AUROC was highest for 0-shot (0.641), followed by original (0.636), 1-shot (0.619), and few-shot (0.516). Of the LLMs tested, intfloat/e5-base combined with XGBoost and the original prompt demonstrated the strongest performance (AUROC = 0.712, see Table), although for 0-shot and 1-shot LR was a stronger classifier. **Conclusions:** Using LLM embeddings to train classifier models is feasible for making predictions with tabular medical data, works best with XGBoost, and does not need prompt engineering. This method requires less feature engineering and data processing compared to standard approaches and leverages the extensive pre-training and semantic understanding of LLMs to achieve predictive power. Research Sponsor: Georgetown Lombardi Comprehensive Cancer Center; CCSG P30CA051008; National Institutes of Health (NIH) Memorial Sloan Kettering Cancer Center (MSKCC); P30 CA008748; Georgetown Lombardi Comprehensive Cancer Center.

e5-base	original	0-shot	1-shot	few-shot
XGBoost	0.71	0.62	0.67	0.62
SVM	0.56	0.61	0.67	0.65
LR	0.64	0.66	0.69	0.64
MLP	0.63	0.65	0.65	0.59

The use of generative AI tools by cancer patients and caregivers: A cross-sectional survey of awareness, attitudes, and experiences.

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Background: Generative artificial intelligence (AI) tools offer novel avenues for patient support, yet data on their adoption in oncology remain limited. This study evaluated the awareness, attitudes, and usage patterns of these tools among cancer patients and caregivers to inform clinical integration. **Methods:** A descriptive, cross-sectional survey was conducted at a tertiary oncology center. Adult cancer patients and caregivers completed an anonymous, structured questionnaire assessing sociodemographics, digital literacy, AI usage patterns, and perceptions. Multivariate logistic regression identified independent predictors of AI use. **Results:** A total of 400 participants (68% patients, 32% caregivers; mean age 59 years) were included. While 75% were aware of AI chatbots, only 24% used them for cancer-related information. Multivariate analysis revealed that university-level education (adjusted odds ratio [aOR] = 4.47, $p < 0.001$), younger age (≤ 55 years; aOR = 2.64, $p < 0.001$), and recent diagnosis (< 1 year; aOR = 2.16, $p = 0.003$) were independent predictors of AI use (Table 1). Notably, 69.1% of users did not disclose their AI use to their physician. Despite this, no user reported decreased trust in their physician; in fact, 26.8% reported an increase. A substantial 73.3% of all participants expressed a willingness to use a physician-verified AI tool. Subgroup analysis revealed divergent usage patterns: caregivers used AI more regularly (weekly/daily: 54.3% vs. 30.6%; $p = 0.022$) and focused on researching medical terminology (62.9% vs. 38.7%; $p = 0.022$) and alternative medicine (34.3% vs. 16.1%; $p = 0.040$), whereas patients were significantly more likely to seek emotional support (22.6% vs. 5.7%; $p = 0.032$). **Conclusions:** Generative AI use among cancer patients and caregivers remains moderate and reflects a marked digital divide driven by age and education. The prevalence of “silent” AI use raises significant patient safety concerns related to the risks of unverified information. Nevertheless, the strong demand for physician-endorsed tools highlights a clear opportunity for clinical integration. Oncologists should proactively address AI usage to mitigate misinformation risks and ensure safe integration into clinical practice. Research Sponsor: None.

Independent predictors of generative AI use for cancer information (n=400).			
Parameter	aOR	95% CI	p value
Age (≤ 55 years vs. > 55 years)	2.64	1.594 - 4.381	< 0.001
Education level (University or higher vs. lower)	4.47	2.195 - 9.109	< 0.001
Time since diagnosis (< 1 year vs. ≥ 1 year)	2.16	1.289 - 3.625	0.003

Abbreviations: aOR, adjusted odds ratio; CI, confidence interval.

Identifying cancer cachexia using clinical reasoning artificial intelligence (AI).

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Background: Cancer cachexia, a severe wasting syndrome, affects up to 87% of cancer patients¹ and contributes to $\geq 20\%$ of cancer deaths². Despite this burden, $\sim 85\%$ of healthcare providers are unfamiliar with diagnostic criteria³, leaving patients often undiagnosed. This study evaluated whether a Clinical Reasoning AI model configured on four cachexia guidelines (Fearon⁴, Evans⁵, GLIM⁶ and mGPS⁷ criteria) and designed to emulate clinician chart review, could accurately identify cancer cachexia. **Methods:** Using structured (vitals, labs) and unstructured (clinical notes) electronic health record data the Clinical Reasoning AI employed retrieval-augmented generation⁸ and agentic techniques with large language models (LLMs) to: (1) retrieve clinically relevant information based on the clinical guidelines via natural language processing (NLP) and embedding, and (2) apply guideline-based reasoning to classify patients into Group 1 (no cachexia features), Group 2 (meets ≥ 1 guideline regardless of documented diagnosis), or Group 3 (documented cancer cachexia). Accuracy was assessed against a gold standard of 50 patients classified by two independent clinicians, with conflicts resolved by a third. Performance was compared against baseline methods: ICD coding (ICD-9 799.4; ICD-10 C80.9), NLP using keywords like cancer or cachexia, and LLMs (Vanilla OpenAI GPT-o4-mini) prompted without explicit instruction to use guidelines. **Results:** The Clinical Reasoning AI demonstrated high precision, sensitivity, and specificity, outperforming baselines, particularly for Group 2 patients. ICD and NLP methods could not detect Group 2, due to code- and keyword-based constraints. Performance of LLMs without guidelines worsened with structured and unstructured data, indicating sensitivity to data overload and inability to prioritise clinically relevant information. **Conclusions:** These results show that embedding clinical guidelines within a structured retrieval-and-reasoning architecture enabled accurate identification of cancer cachexia, addressing a critical gap where standard coding and keyword methods fail. The guideline-driven approach maintained accurate clinical reasoning while processing complex EHR data. The Clinical Reasoning AI model is currently being deployed at the point of care to assess real-world implementation and impact on patient outcomes. Research Sponsor: Pangaea Data.

AI Model	Group 2				Group 3			
	Precision	Sensitivity	F1	Specificity	Precision	Sensitivity	F1	Specificity
ICD	N/A	N/A	N/A	N/A	0.759	0.815	0.786	0.696
Simple NLP	N/A	N/A	N/A	N/A	0.727	0.593	0.653	0.739
Vanilla OpenAI GPT-o4-mini (unstructured data only)	0.500	0.500	0.500	0.765	0.594	0.704	0.644	0.438
Vanilla OpenAI GPT-o4-mini (structured and unstructured data)	0.500	0.062	0.111	0.971	0.385	0.185	0.250	0.652
Clinical Reasoning AI with GPT-o4-mini	0.762	1.00	0.865	0.853	0.964	1.00	0.982	0.957

Prospective evaluation of AI-assisted documentation and summarization in virtual multidisciplinary cancer conferences.

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Background: Multidisciplinary cancer conferences (MCCs) are central to high-quality oncologic decision-making but are frequently constrained by time-intensive and variable documentation processes. Artificial intelligence (AI) can enhance multidisciplinary collaboration by improving the accuracy, timeliness, and consistency of documentation. However, prospective evaluations of AI tools embedded within MCC workflows remain limited. **Methods:** We conducted a prospective pilot study at the Cancer Centre of Southeastern Ontario, a regional academic cancer center in Ontario, Canada. In October 2025, a hospital-approved AI system, Microsoft Copilot, was integrated into all virtual lung and gastrointestinal (GI) MCCs conducted via Microsoft Teams. All conferences were recorded and transcribed. Structured prompts for AI-generated summaries were co-developed with MCC stakeholders and refined through iterative Plan-Do-Study-Act (PDSA) cycles. AI-generated summaries were validated against clinician-prepared electronic health record (EHR) documentation. Two independent reviewers assessed case identification accuracy and concordance of key clinical content. Following validation, AI summaries were distributed to MCC participants after case discussions to support EHR documentation, with mandatory clinician verification prior to finalization. **Results:** A total of 125 patient cases from lung and GI MCCs were analyzed, of which 108 had corresponding clinician-prepared EHR documentation available for comparison. Inter-rater agreement between reviewers assessing concordance of AI-generated and clinician-prepared summaries demonstrated high agreement (Cohen's $\kappa = 0.87$). Case identification accuracy was high, with agreement rates of 97% for case number, 93% for medical record number, 96% for patient initials, 98% for presenter, 99% for diagnosis, and 99% for cancer stage; most identification discrepancies were minor and improved over time. Clinical content concordance was high, including discussion summaries at 99%, radiology at 99%, pathology at 98%, and treatment plans and next steps at 96%. Major discrepancies involving key clinical decisions were identified in 0.9% of cases. All AI-generated summaries were distributed within 24 hours following MCC completion, with a median clerical preparation time of 14 minutes per case. **Conclusions:** In this prospective, real-world evaluation, AI-assisted summaries integrated into virtual MCC workflows demonstrated high accuracy, strong safety performance, and meaningful efficiency gains. With mandatory clinician oversight, AI-supported summarization was feasible and timely, supporting its role as a scalable model for MCC documentation across oncology programs. Further multicenter studies are warranted to evaluate generalizability, clinician workload impact, and downstream effects on care delivery. Research Sponsor: None.

Assessing the true burden of immune-related colitis in lung cancer through large language model-enabled clinical phenotyping.

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Background: Immune checkpoint inhibitors (ICIs) have revolutionized lung cancer treatment but cause adverse events, including immune-related colitis (ir-colitis). Accurate identification of ir-colitis is critical for improving patient outcomes and clinical research. However, current methods relying on ICD codes have substantial limitations: non-specific categories that fail to capture the cases or distinguish cases from infectious or ischemic etiologies, as well as incomplete coding that leads to missed cases. Large language models (LLMs), with advanced natural language understanding capabilities, offer a scalable approach for automated phenotyping using unstructured clinical notes. We aimed to develop and evaluate an LLM-based approach for identifying ir-colitis in patients with lung cancer receiving ICIs and compare it with ICD code based method. **Methods:** We identified 5,278 lung cancer patients with ICI administration at Mayo Clinic (2012-2025). To investigate ir-colitis occurrence within two years after ICI initiation, patients were stratified into three ICD-based cohorts: (1) IR-Colitis, with clinician-assigned ir-colitis-specific diagnosis codes; (2) Non-IR Colitis, with colitis diagnosis codes excluding ir-colitis; and (3) No-Colitis, absent of any colitis-related codes. We used three open-source LLMs to process clinical notes : Llama4, MedGemma, and Qwen. Prompts were designed to extract both gold standard evidence (explicit ir-colitis terminology, such as "immune-mediated colitis" and "checkpoint inhibitor colitis") and supportive evidence (such as pathology and lab results). **Results:** Llama4 demonstrated superior accuracy among three LLMs in manual evaluation and was thus selected for all cohort analyses. Among ICD-based IR-Colitis patients (n = 339), 82.0% had confirmatory evidence while 18% lacked evidence, suggesting potential false-positive coding. In the Non-IR Colitis cohort (n = 297), LLM-based extraction identified 43.8% patients in fact had ir-colitis, demonstrating substantial misclassification. In the No-colitis cohort (n = 4,642, random sample of 996 for analysis), the LLM identified 10.7% with documented ir-colitis, revealing substantial missing by administrative coding. **Conclusions:** LLM-based phenotyping demonstrates superior sensitivity for identifying ir-colitis compared to ICD codes alone, successfully uncovering cases missed by administrative coding. This scalable approach enables more comprehensive case identification for immunotherapy safety research and clinical surveillance. Research Sponsor: None.

ICD-Based Cohorts	LLM-Identified ir-Colitis		
	Gold Standard Evidence	Supportive Evidence	Any Evidence
ir-Colitis (n = 339)	277/339 (81.7%)	275/339 (81.1%)	278/339 (82.0%)
Non-ir-Colitis (n = 297)	129/297 (43.4%)	126/297 (42.4%)	130/297 (43.8%)
No Colitis (n = 996)	106/996 (10.6%)	104/996 (10.4%)	107/996 (10.7%)

Correlation of tumor-naïve methylation-based preoperative ctDNA testing with pathologic upstaging and occult metastasis in early-stage solid tumors.

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Background: The TNM staging system serves as the cornerstone for most solid tumor treatment strategies. However, preoperative evaluation of early-stage cancers is not always reliable, with a particular propensity to overlook occult lymph node metastasis (OLNM) or even distant metastases. In turn, incorrect staging may lead to suboptimal perioperative decisions, including inappropriate surgical strategies, unjustified neoadjuvant therapy, and inadequate lymph node dissection. This study evaluated whether preoperative circulating tumor DNA (ctDNA) detected by methylation-based assay is associated with pathologic upstaging and the presence of OLN or distant metastasis across multiple types of solid tumor. **Methods:** This study analyzed preoperative blood samples from a validation cohort within a multi-cancer early detection (MCED) study, encompassing 16 high-burden cancer types in China. Lymphomas, liver cancer, and nasopharyngeal carcinoma were excluded, due to limited use of TNM staging and/or non-routine radical surgery. Patients who had received neoadjuvant therapy were also excluded. ctDNA was detected using a targeted methylation-based MCED assay. Associations between ctDNA positivity and discrepancies between clinical (cTNM) and pathologic (pTNM) staging—including upstaging due to OLN or distant metastasis—were examined statistically. **Results:** A total of 681 cases of clinical stage I–II cancers were analyzed, including lung cancer (n=124), breast cancer (n=113), colorectal cancer (n=88), gastric cancer (n=79), pancreatic cancer (n=55), cervical cancer (n=54), ovarian cancer (n=36), prostate cancer (n=34), esophageal cancer (n=32), endometrial cancer (n=31), bladder cancer (n=17), renal cancer (n=17), and gallbladder cancer (n=1). Preoperative ctDNA was detectable in 46.8% (184/393) of stage I and 71.5% (206/288) of stage II patients. ctDNA-positive patients were more likely to undergo pathologic upstaging than ctDNA-negative patients (16.9% vs. 6.9%; $p=0.0002$). For patients with clinical No (cNo), OLN (defined as preoperative cNo with postoperative confirmation of pN1–3) was more common in ctDNA-positive patients (12.6% vs. 4.7%; $p=0.0012$). Among clinically Mo patients, three were confirmed as pathologic M1, all ctDNA-positive. **Conclusions:** Methylation-based preoperative ctDNA testing correlates with pathologic upstaging and OLN, and may also be associated with occult distant metastasis. This finding supports the potential of ctDNA testing to refine preoperative staging and inform perioperative decision-making. Further validation with an expanded sample size will be conducted in an additional blinded cohort to confirm these findings. Research Sponsor: Shanghai Xiaohu Medical Laboratory Co. Ltd.

Sources matter: Learning to evaluate large language models for oncology treatment plans and changes observed by anchoring models to an oncology-specific database.

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Background: Large language models (LLMs) are increasingly evaluated for oncology decision support, yet guideline concordance and hallucinations remain variable across cancer types and tasks. Retrieval-augmented generation (RAG) may improve safety by constraining the evidence base used during generation. Prior oncology LLM studies report discordance with guideline-based care, but few describe a reproducible health-system “vetting mechanism” that couples guideline-only retrieval with clinician-scored safety rubrics across multiple oncology domains.

Methods: We assembled 316 de-identified oncology cases in a tumor-board template: medical oncology (breast, GI, GU, leukemia; n=216), gynecologic oncology (n=50), and neuro-oncology/CNS metastatic cancer (n=50). Each case was run on three systems: baseline GPT-4 (O1), NCCN-guideline anchored RAG (O2; guideline-constrained retrieval), and a literature-anchored system (OpenEvidence; O3). Oncologists independently scored outputs using a modified Generative Performance Score (mGPS; -1 to +1) combining guideline concordance with hallucination penalties; readability/rationality was scored on a 1–5 Likert scale. Inter-rater reliability was assessed ($\kappa = .63$). This workflow was designed as a pre-deployment model credentialing step for health-system governance (source policy → case bank → clinician-scored acceptance criteria). **Results:** Across all 316 cases (case-averaged), O2 achieved the highest mean total mGPS (0.75) compared with O1 (0.43) and O3 (0.59). In the medical oncology cohort (n=216), O2 outperformed O1 and O3 (mean mGPS 0.72 vs 0.35 and 0.54), with higher guideline concordance (0.85 vs 0.68 and 0.75) and lower hallucination penalties (-0.09 vs -0.25 and -0.19); readability was also highest for O2 (4.17 vs 3.22 and 3.86). In gynecologic oncology (n=50), O2 again performed best (mGPS 0.827) relative to O3 (0.697) and O1 (0.647). In the CNS cohort (n=50), mean composite mGPS favored O2 (0.82) over O3 (0.68) and O1 (0.55), while readability remained stable across models (3.55–3.73). Severe hallucination/unsafe recommendation rate: O1 [26%], O2 [5%], O3 [17%] (pre-specified definition; e.g., major fabricated citation or guideline-discordant harmful recommendation). **Conclusions:** In a 316-case, multi-domain clinician-scored evaluation, limiting retrieval to oncology guideline sources improved safety-aligned performance relative to unconstrained generation or literature-only anchoring. A guideline-constrained RAG configuration paired with clinician-scored rubrics and tail-risk reporting can serve as a practical health-system vetting mechanism for governance, re-validation, and change control of LLM decision support, including in resource-limited settings where reliable guideline-consistent recommendations are essential. Research Sponsor: None.

Impact of AI-augmented histopathology review on next-generation sequencing (NGS) success.

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Background: Insufficient nucleic acid quantity (QNS) can compromise NGS success (QNS rates can be >20%), necessitating re-biopsies and delaying therapy. While interventions like extended de-crosslinking (EXT) can rescue samples with low total nucleic acid (TNA) yield tissues, they prolong processing times, demanding a precise method to identify samples requiring such processing. We developed an AI system, Paige Predict (PP), that analyzes digitized H&E slides to predict NGS QNS and recommend tissue input quantity. This study evaluates PP in two contexts: (1) optimizing internal lab workflows by selectively routing high-risk samples to EXT, and (2) exploring its utility in an external setting, Cedars-Sinai (CS), to triage samples for comprehensive Tempus genomic profiling (CGP), requiring >50ng input, vs targeted low-input assays (>5ng) performed at CS. **Methods:** We conducted a validation study in the Tempus lab comparing a baseline period prior to introduction of EXT (July 2024 - Sept 2024 n=17,026) against an intervention period (Oct 2025 - Nov 2025, n=12,975) where PP automatically routed at-risk samples to EXT. To evaluate external utility, we also performed a retrospective analysis on a cohort of CS pts. We assessed PP’s ability to predict CGP QNS, and compared it against pathologist assessment for inter-institutional sample referral. **Results:** In the validation study, PP-guided EXT routing reduced joint DNA+RNA QNS rates by 19.6%, with a number needed to test (NNT; 1/Absolute Rate Reduction) indicating that for every 40.2 pts, one received a result that would otherwise not have. RNA QNS rates reduced by 15.9% (NNT 63.7) relative to the baseline period. This reduction was achieved while decreasing net tissue input by 16.7% and increasing TNA yields in the optimal range (100–1500ng) by 19.0% (NNT 10.1). Similar benefits were observed in the NSCLC subset. In the external CS cohort, PP could have triaged 74% of samples that failed Tempus CGP to low input sequencing at CS. Conversely, PP indicated that over 70% of samples sequenced at CS could have succeeded with Tempus CGP. **Conclusions:** PP significantly reduces NGS failure rates and improves tissue stewardship by deploying rescue workflows only when necessary. These analyses lay the groundwork for a future multi-institution prospective trial and establish PP as a scalable AI tool to amplify access to precision oncology. Research Sponsor: None.

(Tempus) EXT routing validation metrics (N=12,975 all / 3,530 NSCLC)	PP % change vs. baseline (p-value) / NSCLC subset	NNT vs. baseline / NSCLC subset	(Cedars-Sinai) retrospective analysis metrics (N=1,082)	PP % flagged for QNS (50ng)
DNA+RNA QNS rate	-19.6% (2.0e-9) / -30.4% (8.6e-9)	40.2 / 24.4	DNA QNS	74%
DNA pass & RNA QNS rate	-15.9% (1.1e-4) / -3.1% (7.0 e-1)	63.7 / 384.6	DNA Pass	16.4%
Optimal TNA range	+19.0% (2.0e-12) / +21.0% (5.3e-11)	10.1 / 9.0	Not referred	28.6%
Median N input slides	-16.7% (3.0e-11) / -14.3% (6.4e-7)	N/A		

Validation of electronic phenotyping algorithms for prostate cancer in All of Us and their impact on genetic association studies.

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Background: The *All of Us* Research Program enables large scale population-based genetic association studies of cancer. *All of Us* does not contain cancer registry data, risking misclassification of cancer diagnosis. Thus, validated electronic phenotyping algorithms for cancer diagnoses are needed. We sought to develop and validate prostate cancer (PCa) phenotyping algorithms in *All of Us*, and assess the impact of different algorithms on gene-cancer associations. **Methods:** We conducted a cross-sectional analysis of *All of Us* male participants aged ≥ 50 years with structured electronic health record (EHR), personal health history survey, and whole genome sequencing (WGS) data (Duke IRB Pro00119057). Using self-report of PCa history as the gold standard, we developed and evaluated two electronic phenotyping algorithms: (1) two PCa diagnosis codes; or (2) two PCa diagnosis codes plus evidence of PCa treatment with radical prostatectomy, radiotherapy, or androgen deprivation. For each algorithm, we computed positive predictive value (PPV), and negative predictive value (NPV) with 95% confidence intervals (CI). Using each algorithm, we conducted genetic association studies between PCa and rare pathogenic variants (RPVs) in PCa predisposition genes (*ATM*, *BRCA1*, *BRCA2*, *HOXB13* G84E) among male participants with structured EHR and WGS data. Included RPVs had pathogenic/likely pathogenic designation in ClinVar with at least two stars. Gene-based odds ratios (OR) and 95% confidence intervals (CI) were calculated using logistic regression, adjusting for age and top 5 principal components. **Results:** We included 21,883 males in the validation study of PCa phenotyping algorithms, 3,961 (18.1%) of whom reported a personal history of prostate cancer. Algorithm 1 demonstrated a PPV of 0.897 (95% CI 0.885 – 0.907) and NPV of 0.927 (95% CI 0.923 – 0.931). Algorithm 2 demonstrated a PPV of 0.927 (95% CI 0.910 – 0.942) and NPV of 0.864 (95% CI 0.860 – 0.869). In the study of gene-PCa associations, 94,446 male participants were included, except for *HOXB13* G84E ($n = 59,915$), which was limited to those of European ancestry. Associations between RPVs in PCa predisposition genes and PCa diagnoses using the two algorithms are shown in the Table. **Conclusions:** The inclusion of PCa treatment improves the PPV of PCa electronic phenotyping algorithms. PCa phenotyping definitions influence the results of downstream genetic association studies, and highlight the need for accurate and validated electronic phenotyping algorithms when using *All of Us*. Research Sponsor: None.

Gene	OR ^a (Algorithm 1 ^b)	95% CI ^c (Algorithm 1)	OR (Algorithm 2 ^d)	95% CI (Algorithm 2)
<i>ATM</i>	2.10	1.47 - 2.92	2.68	1.67 - 4.08
<i>BRCA1</i>	1.11	0.73 - 1.61	1.16	0.61 - 1.98
<i>BRCA2</i>	2.14	1.53 - 2.92	3.11	2.04 - 4.56
<i>HOXB13</i> G84E	3.88	2.75 - 5.39	3.31	1.98 - 5.22

^aOR = odds ratio.

^bTwo prostate cancer diagnosis codes.

^cCI = confidence interval.

^dTwo prostate cancer diagnosis codes plus treatment.

A context-constrained oncology agent for automated, guideline-concordant treatment decision support in precision oncology.

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Background: Precision oncology requires biologically plausible, clinically executable decisions aligned with regulatory approvals. General-purpose Large Language Models (LLMs) often produce recommendations rejected by molecular tumor boards due to semantic drift, inappropriate agent extrapolation, and ignored clinical constraints, raising significant safety concerns for point-of-care adoption. **Methods:** GenOnco is a constrained oncology agent integrating NCCN, ASCO, and ESMO clinical practice guidelines; FDA/EMA regulatory approvals; NEJM seminal articles and high-impact publications; curated clinicogenomic resources (e.g., Molecular Oncology Almanac); comprehensive clinical trials knowledge (ClinicalTrials.gov, landmark phase III results); and practice-changing trial evidence. The system utilizes a dual-layer architecture: a reasoning LLM paired with a deterministic, non-LLM clinical decision layer that enforces line-of-therapy requirements and actionability filters independent of generative output. We evaluated GenOnco on 102 multi-institutional oncologist-derived real-world solid tumor queries, independently scored by two blinded oncologists ($\kappa = 0.87$). Performance was benchmarked against published datasets: MEREDITH (200 cases) and Google DeepMind AMIE (100 cases). Primary endpoints were guideline concordance and clinical executability, analyzed via McNemar's test ($N = 162$). **Results:** GenOnco achieved 95.1% accuracy (95% CI: 91.2%–98.4%) on synthetic benchmarks and 93.1% (95% CI: 89.1%–96.5%) on real-world queries, eliminating 100% of expert-rejected outputs from comparators. GenOnco significantly outperformed GPT-4o (48.1%), Claude 3.7 (49.4%), Gemini 2.5 (50%), ASCO Guidelines Assistant (67.3%), OpenEvidence, MEREDITH, and Google DeepMind AMIE (all $P < .001$; $N = 162$), with gains of 15–47 percentage points. **Conclusions:** Constrained reasoning prioritizing executable pathways outperforms unconstrained LLMs for precision oncology support. Limitations include solid tumor focus and query diversity; diverse population validation planned. GenOnco demonstrates potential for point-of-care integration. Research Sponsor: None.

Comparing oncologists, a GPT-based model, and a SEER-based survival calculator for cancer prognostication.

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Background: Prognostic estimates guide cancer treatment planning and goals-of-care discussions. Clinicians often rely on population-based survival statistics (e.g., SEER), which may not reflect individualized risk. Large language models (LLMs) such as ChatGPT may offer more personalized estimates, but their performance relative to oncologists and population-based tools remains unclear. **Methods:** We conducted a retrospective comparative study of 205 adult cancer patients treated in a safety net cancer clinic. For each patient, one deidentified clinical note from the time of diagnosis was provided to a HIPPA compliant instance of ChatGPT (GPT-4.1) and an oncologist unfamiliar with the patient. Both generated binary (alive/deceased) and probabilistic (0–100%) predictions of survival at 6 months, 1, 2, and 5 years. The primary endpoint was per-patient binary accuracy (0–4 correct timepoints) comparison between ChatGPT and the oncologist. Secondary outcomes (n=189) included Brier scores, and calibration metrics compared with oncologists and a publicly available SEER-based cancer-specific survival calculator (CancerSurvivalRates.com), and subgroup analyses by cancer stage. Significance testing used exact binomial methods for per-patient win–loss comparisons and paired nonparametric tests to compare probabilistic performance across methods. **Results:** Of the 205 patients, 25, 53, 53, and 74 were stages I, II, III, and IV, respectively. Gender was balanced (53% male). All surviving patients had at least 5 years of follow-up. Notes varied in final staging and treatment plans, as some patients were in their initial evaluation. In the primary analysis (N = 205), ChatGPT was numerically, not statistically, superior to the oncologist (52 vs. 41, p=0.299). In secondary analyses (n = 189), ChatGPT had superior overall accuracy with lower Brier scores at 1 year (p < 0.001) and 2 years (p = 0.030). Calibration analyses showed that at 5 years, ChatGPT achieved near-ideal reliability (calibration slope 1.018), whereas oncologists demonstrated overconfidence (slope 0.535). As expected, cancer specific survival by CSR was significantly higher than OS estimates from oncologists or ChatGPT. Stage-stratified analyses revealed oncologist superiority in Stage I disease (p = 0.036), while ChatGPT significantly outperformed oncologists in Stage IV disease at 2- and 5-year horizons (both p < 0.001). **Conclusions:** For a safety-net cancer clinic, using one unstructured note, ChatGPT demonstrated comparable or superior prognostic estimates for clinically relevant time points as compared to oncologists, particularly in long-term outcomes for advanced disease. Future studies should evaluate cancer specific survival and prognosis after or during treatment. Research Sponsor: None.

Machine learning modeling for predicting 60-day prognosis in newly diagnosed advanced solid tumors.

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Background: Accurate mid-term prognosis estimation in patients newly diagnosed with advanced, non-operable or metastatic cancer is critical for evaluation and treatment prioritization and palliative care planning. A 60-day time horizon is clinically meaningful, as major oncologic assessments typically occur at 2–3-month intervals. Existing prognostic tools have shown limited clinical adoption. **Methods:** We conducted a retrospective analysis of patients evaluated at the Sheba Medical Center Oncology Rapid Diagnosis Clinic between 2017 and 2025. Eligible patients had metastatic or locally advanced, non-operable solid tumors. A raw dataset was generated using the MDClone platform (overall 60-day mortality ~18%). A case-enriched training cohort (n=524; 39.3% 60-day mortality) and an independent test cohort (n=343; 19% 60-day mortality) were randomly selected. Seventy-four features were included, encompassing demographics, laboratory values, ECOG performance status, and clinical variables extracted from physician notes using a large language model (LLM). LLM extraction accuracy was validated against expert manual review in 32 randomly selected cases (accuracy 0.91–1.0). Logistic Regression, Random Forest, and XGBoost models were trained with grid-search hyperparameter optimization to predict 60-day survival (y=1) versus death (y=0). Performance was evaluated on the independent test set. Wilson score intervals were used for proportion confidence intervals, and Hanley–McNeil method for AUC confidence intervals. Feature importance for the top-performing model was assessed using SHAP. **Results:** Performance of different ML models is summarized in table 1. Random Forest demonstrated the best overall performance. All models showed high positive predictive value for survival but limited ability to predict short-term mortality. The most influential Random Forest features included INR, CRP, albumin, ECOG status, total protein, LDH, emergency-related hospitalizations, age, neutrophil count, and history of cardiovascular disease. **Conclusions:** A Random Forest-based model accurately identifies patients likely to survive 60 days, supporting timely evaluation and initiation of oncologic treatment. Prediction of short-term mortality remains limited, suggesting intrinsic unpredictability of mid-term outcomes or the need for additional clinical or biological features. Research Sponsor: None.

Metric (95%CI)	Random Forest	Logistic Regression	XGBoost
ROC AUC	0.84 (0.79-0.88)	0.81 (0.76-0.86)	0.80 (0.75-0.85)
Sensitivity	0.89 (0.85-0.92)	0.82 (0.77-0.86)	0.80 (0.75-0.84)
Specificity	0.62 (0.49-0.72)	0.62 (0.49-0.72)	0.63 (0.51-0.74)
PPV	0.91 (0.87-0.94)	0.90 (0.86-0.93)	0.90 (0.86-0.93)
NPV	0.57 (0.45-0.68)	0.45 (0.35-0.55)	0.43 (0.33-0.53)
Accuracy	0.84 (0.80-0.87)	0.78 (0.74-0.82)	0.77 (0.72-0.81)

Evaluation of AI-guided questioning versus standard information delivery in a simulated newly diagnosed breast cancer population.

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Background: Patients newly diagnosed with breast cancer frequently experience information overload and anxiety, which can impair understanding and participation in shared decision-making. Artificial intelligence (AI)-guided educational approaches may support individualized information delivery; however, their impact on patient understanding and emotional response remains incompletely characterized. **Methods:** We conducted a prospective, randomized vignette-based survey study among adults (≥ 18 years) asked to imagine receiving a new diagnosis of early-stage breast cancer. Participants were randomized 1:1 to receive either standard written information or AI-guided questioning that adapted presentation of identical content based on stated preferences and level of detail. Outcomes included a composite breast cancer knowledge score (range 0-20) (primary endpoint), perceived information overload, anxiety, decision confidence, and clarity (all Likert-scale measures, range 1-5). Group comparisons were performed using Welch's two-sample t-test. Exploratory subgroup analyses included educational level and health-related background. **Results:** 102 participants completed the survey (51 per group). Mean knowledge scores were higher in the AI-guided group compared with standard information (17.6 vs 13.2, $p=0.00022$). Participants receiving AI-guided questioning reported lower information overload (2.31 vs 3.35, $p=0.00012$), lower anxiety (3.67 vs 4.16, $p=0.031$), greater decision confidence (4.06 vs 2.84, $p=1.2 \times 10^{-6}$), and higher perceived clarity (4.20 vs 3.18, $p=2.9 \times 10^{-5}$). Exploratory analyses showed greater benefits among participants without graduate education or health-related background (both $p < 0.001$), with smaller, non-significant differences in those with higher education or healthcare experience. **Conclusions:** In a simulated newly diagnosed breast cancer population, AI-guided questioning was associated with improved understanding, reduced information overload and anxiety, and greater decision confidence compared with standard information delivery. Exploratory analyses suggested that benefits were more pronounced among participants without graduate-level education or medical background, supporting a potential role for human-centered AI in equitable patient education. Given exploratory nature and unequal subgroup distributions, confirmation in prospectively stratified studies is needed. Research Sponsor: None.

Outcomes by information delivery approach.

Outcome (range)	Standard information (n=51)	AI-guided questioning (n=51)	p value
Knowledge score (0-20)	13.2	17.6	0.00022
Information overload (1-5) [†]	3.35	2.31	0.00012
Anxiety (1-5) [†]	4.16	3.67	0.031
Decision confidence (1-5) [‡]	2.84	4.06	1.2×10^{-6}
Clarity (1-5) [‡]	3.18	4.20	2.9×10^{-5}

[†]Lower scores indicate better outcome.

[‡]Higher scores indicate better outcome.

Age-dependent pathogenic variant risk in female breast cancer.

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Background: Germline pathogenic and likely pathogenic variants (GPVs) in *BRCA1*, *BRCA2*, and *PALB2* raise female breast cancer risk. Genetic counseling and screening guidelines rely on fixed age estimates. Using two large biobanks, All of Us Research Program (AoURP) and BioVU biobank, we aim to characterize age-dependent breast cancer risk trajectories and associations with family history (FH). **Methods:** In AoURP, we extracted data on female participants with genetic data to identify those with *BRCA1*, *BRCA2*, and *PALB2* GPVs, FH surveys to identify those with first degree breast cancer FH (BCFH), and electronic health records (EHR) to determine presence of breast cancer diagnosis and diagnosis age. Age served as the time scale, with left truncation at first EHR entry and censoring at last EHR event. Gene-specific breast cancer risk was estimated using Cox models with age-dependent genetic effects, adjusted for genetic ancestry (first five principal components) and FH. Analyses in AoURP were stratified by self-reported race and BCFH. We validated results in BioVU using the same methodology excluding FH which was unavailable as discrete data. **Results:** In AoURP, 100,916 women with genetic, FH, and EHR data were available. The majority (67%) were White, based on self-reported race, and 5208 had breast cancer. The sample included 291 *BRCA1* GPVs, 505 *BRCA2* GPVs, and 139 *PALB2* GPVs, with breast cancer diagnosed in 36%, 23%, and 19% respectively. BioVU included 127,147 women, of whom 85.5% were White and 5,664 had breast cancer. The sample had 262 *BRCA1* GPVs, 515 *BRCA2* GPVs, and 210 *PALB2* GPVs, with breast cancer diagnosed in 29%, 22%, and 16% respectively. Across the genes, we observed a bimodal distinct age-dependent breast cancer risk pattern. Bimodal peaks for *BRCA1* in AoURP were at 26 and 36 years, while in BioVU were at 35 and 62 years. The bimodal peaks for *BRCA2* in AoURP were at 32 and 51 years, while in BioVU were at 32 and 55 years. Finally, bimodal peaks for *PALB2* in AoURP were 35 and 51 years, while in BioVU were at 41 and 64 years. Age-specific risk trajectories also varied by FH where risk peaks for participants with BCFH were earlier by 2–7 years compared to those without BCFH. **Conclusions:** We presented population based study providing unbiased estimates of breast cancer risk associated with GPVs in *BRCA1*, *BRCA2*, and *PALB2* in two enrollment-based cohorts. Leveraging these large datasets, we identified novel bimodal age-dependent patterns of breast cancer risk across genes, with consistent peak ages for *BRCA2* and *PALB2* and cohort specific differences for *BRCA1*, highlighting the importance of population context. Replication in BioVU confirmed similar bimodal trends with later peak ages, supporting our finding robustness. Our results show that breast cancer risk in GPVs genes is more dynamic than previously recognized. Integrating age and FH risk estimates into genetic counseling and screening may improve personalized risk assessment and clinical decision making. Research Sponsor: U.S. National Institutes of Health; 5R21MD019103.

Clinical utility analysis of a computational reasoning system on large-scale tumor genomic data.

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Background: Comprehensive tumor molecular testing has become routine in clinical oncology. However, interpretation of complex molecular profiles in clinical practice can be challenging and subjective. The Digital Drug Assignment (DDA) system is a knowledge-graph-based computational method that automates reasoning at the patient level and scores molecularly targeted agents (MTAs) based on the full tumor genome. This approach was predictive of relative benefit of the agents as used in the SHIVA01 trial (NPJ Precis Oncol. 2021 5:59) and in real-world setting (NPJ Precis Oncol. 2025 9:159). Here, we assessed the potential clinical utility of DDA by analyzing large-scale tumor genomic data. **Methods:** Tumor molecular profiles of 20,923 patients of the MSK-CHORD real-world clinicogenomic dataset (Nature. 2024 636:728-36) were processed by DDA. DDA classified all alterations and scored all associated MTAs based on a functional and pharmacological evidence network. Previous research evidenced that high-score MTAs ($1000 \leq$ DDA score) predict increased clinical benefit. Utility of DDA was assessed by the proportion of patients with at least one high-score MTA option associated with their molecular profiles. **Results:** Tumor molecular complexity is evidenced by the number of driver alterations, with an average of 4.6 (range: 1 – 45) drivers per tumor (Table). 75% of all tumors were associated with high-score MTAs, 55% had on-label options. Availability of high-score options was high in all tumor types, with the exception of prostate tumors (24%). Only 3% of pancreatic cancer patients were associated with on-label high-score MTA options. Of the patients with known MTA treatments (n = 14,168), only 37% were administered a high-score MTA during their treatment course (Table). **Conclusions:** Our analysis recapitulates the presence of multiple driver alterations, highlighting the need for methods like DDA that consider the totality of molecular profiles for assigning MTAs, rather than relying on identifying single ‘actionable biomarkers’. The substantial gap between the proportion of patients who did receive and those whose tumor genomes were associated with high-score MTAs indicates a strong potential for improving outcomes in precision oncology. Moreover, the proportion of high-score off-label (i.e., approved in other oncological indications) MTAs highlights the potential of DDA in drug repurposing. Research Sponsor: National Research Development and Innovation Fund, Hungary; 2022-1.1.1-KK-2022-00005.

Tumor site	Mean no. of alterations (±SD)	Mean no. of drivers (±SD)	HS MTAs associated*	HS MTA administered*	HS developmental MTAs associated*	HS off-label MTAs associated*	HS on-label MTAs associated*
All (20,923)	9.9 (11.8)	4.6 (3.9)	75	37	74	71	55
Breast (5,164)	8.1 (8.1)	4.3 (3.4)	90	57	90	89	86
Colorectal (4,565)	13.2 (18.0)	6.0 (5.5)	69	18	67	60	46
Lung (5,932)	11.6 (10.2)	4.6 (3.2)	85	57	83	84	79
Pancreas (2,619)	6.2 (6.0)	3.6 (2.3)	86	2.5	86	86	3
Prostate (2,643)	7.4 (9.5)	3.6 (3.3)	24	6.6	21	11	7

HS: high-score.
*% of patients.

Resolving the ambiguity between genomic rearrangements and gene fusions: An AI-augmented structural framework to define therapeutic eligibility in kinase-driven cancers.

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Background: A critical disconnect exists in precision oncology: clinical guidelines frequently conflate genomic "rearrangements" with functional gene "fusions", utilizing inconsistent terminology that obscures biological reality. While confirmatory RNA sequencing is recommended, it is often clinically infeasible due to tissue exhaustion or poor sample quality. Consequently, clinicians are forced to prescribe targeted therapies based on DNA-level proxies without knowing if a druggable protein actually exists. We addressed this unmet need with VeraFusionDx, an AI-augmented decision support system that moves beyond simple classification to determine therapeutic eligibility. **Methods:** We developed a universal framework integrating AI-driven report parsing with generative molecular modeling, trained on a massive real-world dataset (>10,000 gene fusions and >50,000 rearrangements) from a CAP/CLIA-certified lab. An AI normalization module standardizes heterogeneous inputs (unstructured NGS reports, gene+exon number pairs, or coordinates) into a unified format. Distinct from static database lookups, the core engine performs *de novo* characterization of each patient variant. It computationally reconstructs chimeric sequences and models 3D protein architecture to verify critical druggability criteria, including reading frame alignment and kinase domain integrity. Finally, an AI-literature agent cross-references validated targets with clinical evidence to define definitive therapeutic eligibility (<https://verafusiondx.origimed.com>). **Results:** Analysis using this generative engine revealed a heterogeneous landscape where genomic rearrangement proved a poor proxy for druggability, highlighting the necessity of structural validation. For *NTRK* genes, approximately two-thirds of detected variants were rearrangements rather than actionable fusions, with striking discordance by gene and tumor type. Notably, *NTRK2* rearrangements were 4-fold more common than fusions, and *FGFR1* were 90% rearrangements. Even among canonical partners (*EML4-ALK*, *KIF5B-RET*, *CD74-ROS1*), the analysis identified a persistent 1-2% rate of non-functional mimics. To resolve this complexity, the system generated definitive outputs for each case, including *de novo* chimeric DNA and protein sequences, predicted 3D structural models, therapeutic actionability assessments, and an AI-curated summary of comparable literature evidence. **Conclusions:** Functioning as a comprehensive computational firewall, this framework integrates *de novo* sequence generation, structural modeling, and therapeutic intelligence to definitively filter out inert genomic noise, ensuring that life-altering TKI prescriptions are grounded in verified functional reality rather than ambiguous terminology. Research Sponsor: None.

SMS message sentiment as a predictive indicator of quality of life and program adherence in oncology nutrition.

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Background: A text-message based artificial intelligence nutrition platform called “Ina” was previously developed and shown to be equivalent to human dietitians in providing nutritional recommendations to patients with cancer. Once registered on the platform, patient users exchange conversational texts with and receive tailored dietary recommendations and recipes from Ina. We investigated whether the emotional sentiment of SMS messages can act as a proactive predictor of program-related Quality of Life (QoL) and program adherence. **Methods:** QoL was captured via a 1–5 Likert scale (“Has using Ina improved your quality of life?”) survey, and program adherence was captured by a binary response to a question (“Have you used any of Ina’s suggested tips?”). We extracted SMS messages within a 60-day window prior to each survey and question. Sentiment was measured using the Jockers-Rinker lexicon via the validated sentimentr package; scores were calculated as a weighted average ranging from -1 (negative sentiment) to +1 (positive sentiment). Linear mixed-effects models (LMM) were used to quantify the relationship between pre-survey message sentiment and program QoL/adherence outcomes, adjusting for total number of surveys completed and user’s unique baseline sentiment. **Results:** Between October 2019 and January 2026, 14,700 unique text messages were analyzed from 540 unique patient users of the platform (mean age: 51 ± 20 years; 91% female). Cancer types included breast (40%), ovarian (24%), bladder (16%), lung (13%), and colon (7%); metastases were present among 34%. For every one-point improvement in digital sentiment, users experienced a 14% improvement in subsequent program-related QoL ($\beta = 0.72$, $p < 0.001$). Furthermore, there was a trend toward an association between higher positive digital sentiment and subsequent reported adherence to nutritional recommendations ($\beta = 0.12$, $p = 0.097$). **Conclusions:** Sentiment analysis of unstructured SMS messages successfully identified subtle shifts in digital tone that precede structured assessments. This ‘leading indicator’ of sentiment could enable proactive supportive care and provider escalation for timely triage and intervention. Given rapid symptomatic deterioration in oncology that often leads to non-adherence, text-based sentiment analysis could enable early detection of declining engagement to support improved quality of life and long-term outcomes. Research Sponsor: None.

Toxicity risk calculator for personalised prediction of irAEs in patients with solid tumours receiving ICIs, developed based on a clinical dataset and machine learning approaches.

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Background: Immune checkpoint inhibitors (ICIs) can cause severe (grade 3–4) immune-related adverse events (irAEs), which complicate treatment and require immunosuppressive therapy. To address this, we developed a machine learning (ML)-based tool to predict individual risk. **Aim:** To identify predictors and develop an ML calculator for assessing the risk of grade 3–4 irAEs in patients receiving ICIs for solid tumours. **Methods:** This retrospective study included 1,001 patients (585 men, 415 women; mean age 62.4) treated with ICIs for melanoma, kidney, lung, GI, or cervical cancers. The workflow was implemented in Python using pandas, scikit-learn, and SHAP. The cohort was split 70/30 for training and testing. Only pre-treatment variables were used. Data preprocessing included imputation (median for numeric, most frequent for categorical), one-hot encoding, and standardization. Two classifiers were trained: elastic-net logistic regression and gradient boosting. Hyperparameters were tuned via 5-fold CV. Class imbalance (~7–8% positives) was addressed with `class_weight="balanced"` and SMOTE. Probabilities were calibrated. Performance was assessed by PR-AUC (primary), ROC-AUC, F1, and Brier score. Predictors were selected in a two-stage process: 1) Retention of pre-IO variables, removal of low-variance/high-missingness (>30%) features, and collinearity pruning ($|\text{correlation}| > 0.85$). 2) Model-agnostic ranking using three normalized signals: elastic-net coefficients, permutation importance, and mean absolute SHAP values, combined into a consensus score (weights: 0.5, 0.3, 0.2). Stability was verified by bootstrap resampling. **Results:** The final 10 features maximized cross-validated PR-AUC while maintaining calibration and interpretability. Selected predictors: ICI type/combination; age; haemoglobin; creatinine; treatment regimen (mono/combo); K-RAS/N-RAS mutation status; skeletal muscle index; lymphocyte-to-monocyte ratio; immunotherapy line; T4 level. The model identifies patients at increased risk with calibrated probabilities. Results are presented as probabilities (95% CI) categorized as low (<0.10), moderate (0.10–0.25), and high (≥ 0.25). The colored pictogram visualizes risk distribution for a sample of 100 patients (based on the database; median, quartiles). **Conclusions:** We developed the 'Toxicity Risk Calculator' using 10 clinical factors to assess the probability of severe irAEs. This calculator enables routine assessment of the low, moderate, or high probability of grade 3–4 irAEs, facilitating more effective personalization of cancer immunotherapy in everyday practice. Further prospective studies in real-world clinical settings are needed. Research Sponsor: None.

Fitbit-derived activity and heart-rate patterns for predicting 12-month hospitalization in an NIH All of Us cancer cohort.

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Background: Hospitalizations in oncology are common and diverse, and are often limited in their predictive accuracy with routine variables. Wearable devices capture functional and physiological patterns that may indicate vulnerability. We examined whether Fitbit-derived activity and heart rate features enhance the prediction of all-cause hospitalization beyond demographic and clinical factors like frailty. **Methods:** Using data from the NIH All of Us Research Program, we conducted a retrospective analysis of participants aged ≥ 50 years with a history of cancer, linked electronic health records, and short-term Fitbit data (with imputed missing days). Baseline predictors included demographic variables, clinical factors such as the All of Us frailty index, and indicators of cancer subtype. The outcome was any hospitalization within 12 months of the index date, relative to the last Fitbit data day. Features included step count, step variability, activity distribution, rhythmicity, heart rate, and heart rate variability. Missing data were imputed using predictive mean matching. Models were optimized via nested stratified cross-validation and evaluated with out-of-fold predictions. Discrimination was measured by AUC and average precision with bootstrap confidence intervals. Predictive value for the top 10% at-risk group was also assessed. **Results:** The study cohort consisted of 278 participants (average age 64.6). Twelve percent (35) experienced hospitalization within a year. Time to hospitalization ranged up to 342 days. Hospitalization diagnoses were heterogeneous. Models using demographic and clinical data alone had limited discrimination (AUC 0.41–0.50). Incorporating Fitbit activity features improved logistic performance: average steps yielded an AUC of 0.522, step-pattern quartiles yielded 0.559, and distributional rhythmic features yielded 0.628 (CI 0.520–0.733; average precision 0.283). Heart rate and variability did not materially enhance logistic prediction. Gradient-boosted trees combining activity and heart rate data achieved the highest discrimination (AUC 0.704; CI 0.621–0.786; average precision 0.286). Using the best-performing model, the top 10% predicted-risk group had a hospitalization rate of 28.6% (8/28), compared with the overall cohort hospitalization rate of 12.6%, capturing 8 of 35 events. **Conclusions:** Fitbit-derived activity patterns and heart rate patterns, when modeled using machine learning, improved near-term hospitalization prediction in an NIH cancer cohort beyond demographic and clinical models, supporting their potential for practical risk assessment. Ongoing analyses will address missingness, calibration, and subgroup robustness to inform prospective validation. Research Sponsor: National Institutes of Health (NIH) – All of Us Research Program; Jensen Research Scholars Fund.

Evaluating AI decision support in a rapidly evolving therapeutic landscape: *EGFR*-mutant metastatic NSCLC.

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Background: Large language models (LLM) are increasingly used in oncology, yet may deviate from evidence-based care due to outdated knowledge, hallucinations, and inconsistent confidence calibration. EGFR-mutant metastatic Non small Cell Lung Cancer (NSCLC) treatment sequencing is rapidly evolving following 1L OS benefits from MARIPOSA and FLAURA2 and an expanding 2L landscape. In this study, we evaluate concordance, variability, and expert alignment across artificial intelligence (AI) systems. **Methods:** Twelve expert-curated EGFR-mutant metastatic NSCLC vignettes (6 per 1L and 2L) were evaluated across 4 general-purpose LLMs (ChatGPT, Gemini, Claude, Grok) with deep-research enabled and 2 evidence-based platforms [ASCO AI, OpenEvidence (OpenE)]. Each system simulated percentage-based treatment selections simulating how 100 U.S. med-oncologists might distribute choices across predefined therapies. 5 thoracic oncologists from 3 academic centers established a human reference standard, with unanimous agreement in all but 1 vignette where probability-weighting was applied. Inter-system and expert concordance was assessed using Kendall’s τ , while divergence was quantified using Jensen–Shannon (JS) divergence. **Results:** Guideline-based platforms showed strong agreement (ASCO AI–OpenE $\tau=0.73$). Among LLMs, ChatGPT aligned the most with ASCO AI ($\tau=0.72$), while Claude showed the highest divergence (JS=0.30); the highest inter-LLM concordance was observed between ChatGPT and Gemini ($\tau=0.64$). Although ASCO AI is built on Gemini, agreement was only moderate ($\tau=0.55$), suggesting added guideline constraints enhance consistency. In 1L, all systems demonstrated moderate-to-strong concordance with experts ($\tau>0.50$), with ChatGPT and ASCO AI the highest ($\tau=0.80$). ASCO AI appropriately emphasized guideline-endorsed options, including Osimertinib monotherapy and combination strategies, without preferential commitment. In 2L, concordance declined substantially with ChatGPT demonstrating inverse correlation with experts ($\tau=-0.06$). **Conclusions:** AI systems align with expert decision-making in 1L EGFR-mutant metastatic NSCLC but diverge substantially in 2L, where evidence is evolving. Guideline-constrained platforms show greater consistency than general-purpose LLMs; despite ASCO AI using Gemini as its base model, agreement was only moderate, highlighting the value of guideline constraints. These findings highlight the need for rigorous validation and clinical safeguards when integrating AI into oncology decision-making. Research Sponsor: None.

AI-expert concordance.			
System	1L - Experts (τ , JS)	2L - Experts (τ , JS)	Max Inter-System (τ)
ASCO AI	0.80, 0.14	0.25, 0.39	OpenE (0.73)
ChatGPT	0.80, 0.15	-0.06, 0.36	ASCO AI (0.72)
OpenE	0.67, 0.25	0.27, 0.24	ASCO AI (0.73)
Gemini	0.61, 0.21	0.49, 0.19	ChatGPT (0.64)
Claude	0.59, 0.32	0.27, 0.22	ChatGPT (0.60)
Grok	0.54, 0.26	0.27, 0.25	OpenE (0.64)

Wearable-derived physical activity monitoring with AI-based detection of treatment-related adverse events during neoadjuvant chemotherapy for early breast cancer: TRACK-BC.

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Background: Neoadjuvant chemotherapy (NAC) for early breast cancer (EBC) is commonly delivered in the outpatient setting, yet within-cycle changes in adverse events reduce physical activity (PA). Wearable devices may capture these short-term changes. However, prospective data describing activity patterns during modern regimens, including pembrolizumab (PEMB)-based therapy, are limited. This study evaluated changes in PA using Fitbit-derived digital biomarkers (dBM) and explored associations with patient-reported outcomes (PROs). **Methods:** We conducted a multicenter, prospective observational study in patients (pts) with stage I–IIIA EBC initiating NAC. Eligible pts were ≥ 18 years old, smartphone users, and able to wear a Fitbit daily. Chemotherapy regimens were grouped into weekly, q2w, or q3w cohorts. Fitbits were worn from ≥ 7 days before treatment initiation through four cycles. Total PA (TPA), moderate-to-vigorous PA (MVPA), heart rate, sleep, and other metrics were collected. PRO-CTCAE and HADS were completed weekly electronically (ePROs). The primary outcome was change in TPA and MVPA from baseline to the week following cycle 2. As a secondary endpoint, machine learning approaches extending conventional multivariable regression incorporated multiple wearable-derived parameters to individually predict the worst change in ePRO scores from baseline. Model performance was evaluated by cross-validation, and feature contributions were examined using SHapley Additive exPlanations (SHAP) to enhance clinical interpretability. **Results:** A total of 101 pts were enrolled across the three predefined chemotherapy cohorts. Fitbit use was feasible with high adherence. The primary outcome indicated a consistent decline in PA during NAC. From baseline to the week following cycle 2, mean TPA decreased by 141.4 METS-min/day and MVPA by 33.7 min/day. ePROs revealed worsening symptoms including fatigue, insomnia, appetite loss, and neuropathy. Symptoms varied according to the chemotherapy schedule and generally aligned with changes in PA levels and dBM. The secondary outcomes identified multiple vital signals showing absolute correlations > 0.3 with all PRO and HADS metrics. For fatigue, the best model (ridge regression) yielded mean R^2 0.33 ± 0.20 and RMSE 1.86 ± 0.26 ; SHAP analysis highlighted contributions from nocturnal heart-rate-variability minima and overall variability. **Conclusions:** Continuous wearable monitoring during NAC for EBC was feasible. Objective declines in PA occurred early and paralleled symptom worsening captured by ePROs. AI-based models explained a modest but clinically meaningful proportion of symptom deterioration with acceptable error. These findings support the potential utility of wearable-derived dBM for real-time surveillance of treatment-related toxicities during NAC. Clinical trial information: UMIN000053991. Research Sponsor: Daiichi Sankyo Co., Ltd.

Impact of remote symptom monitoring program on payor-specific healthcare costs.

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Background: Remote symptom monitoring (RSM) programs are currently being implemented across oncology practices nationwide; however, the impact of RSM on costs by payor has been understudied. **Methods:** This is a secondary analysis of a hybrid implementation-effectiveness trial of electronic, patient reported outcome-based RSM for patients with cancer initiating systemic therapy (May 2021-May 2024). Differences in costs for healthcare services for RSM-enrolled patients were compared to historical controls. Outcomes included overall, monthly, payor-, and service-specific costs of care received at 3 and 6 months after RSM-enrollment date or initiation of systemic therapy for controls. Adjusted generalized linear models estimated predicted mean costs, mean cost ratios (MR) and 95% confidence intervals (CIs) for RSM-enrolled patients versus controls. **Results:** Patients receiving RSM (n=968) were 25% Black, 44% privately insured, and 27% living in a highly disadvantaged neighborhood. Historical controls (n=3,488) were demographically similar. Though non-statistically significant, RSM enrolled patients had 5% lower mean costs 3 months post-index date compared to historical controls (MR 0.95, 95% CI 0.78-1.16), translating to an estimated cost savings of \$1,347 per patient (95% CI -\$3,596, \$6,290). Medicare Fee-for-Service (FFS) beneficiaries showed the greatest, though non-statistically significant, cost reductions, with RSM FFS beneficiaries having 10% lower costs than FFS controls (MR 0.90, 95% CI 0.67-1.19) at 3 months post-index date. Though non-statically significant, RSM-enrolled patients had 23% lower costs for radiation, 14% lower inpatient costs, 9% lower costs for labs, scans, or tests, and 2% lower outpatient costs compared to controls at 3 months post-index date. At one-month post-index date, RSM enrolled patients had statistically significantly lower payor costs compared to controls (\$11,849 [95% CI \$9,364-\$14,335] vs. \$15,706 [\$14,291-\$17,121]; p=.004). Costs for RSM enrolled patients and controls were similar two to six-months post-index date. **Conclusions:** We observed payor cost savings of \$1,347 in the 3 months of RSM enrollment compared to controls. As the largest payor cost differences were seen for Medicare FFS beneficiaries, our results suggest RSM may address a gap in the provision of care coordination to patients not offered these services through their insurer. Cost savings were most prominent within the first month of treatment initiation; thus, RSM may aid in reducing acute care needs and optimizing resource utilization for patients with cancer. Our results support future research in potential risk-stratification methods to improve RSM engagement and delivery to reduce costs and improve outcomes for patients with cancer. Research Sponsor: None.

Earlier CRS identification with continuous wearable monitoring in outpatient CAR T-cell therapy.

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Background: CAR-T cell therapy has transformed outcomes of hematologic malignancies and is poised to expand into solid malignancies. However, broader use of CAR-T remains constrained by the need for timely cytokine release syndrome (CRS) detection. Current episodic monitoring may miss early physiologic changes. Wearable digital health technologies (DHTs), offering continuous monitoring and real-time alerts, could enable earlier CRS detection, further support outpatient delivery, and expand access to CAR-T and potentially other immunotherapies associated with CRS. **Methods:** This single-center observational study (NCT05018208) enrolled patients receiving FDA-approved CAR-T products in the outpatient setting at Mayo Clinic, Rochester MN. Management of post-CAR-T complications (e.g. CRS) followed the institution's standard of care. Patients were monitored from day -5 to day +30 post infusion with intermittent remote patient monitoring (SoC) and an arm-worn wearable device for continuous monitoring (DHT). Patients were included in this analysis if DHT data were available for ≥ 5 h of data/day or ≥ 2 h of data/night on ≥ 2 days or nights for baseline and ≥ 1 day or night within 72h prior to CRS, or at least 2h within 4h of CRS onset, or if DHT was available for ≥ 7 days/nights post infusion with no CRS event. CRS detection time by DHT was defined as the onset of pyrexia or threshold-based deviation from an individual's baseline pulse distributions. **Results:** 32 patients were included in this report (median age 64 years, gender 12 F/20 M, diagnoses 18 MM/14 NHL). 25 patients experienced a CRS event, with maximum CRS grades ranging from 1-3 (16 G1, 8 G2, 1 G3). 24/25 patients with CRS required tocilizumab/steroid. Median CRS onset time was 3.4 days (range 0.4-18.4). 12/32 patients had sufficient DHT data (7 CRS, 5 no CRS) for analysis. 5 patients with CRS had a DHT detection time in advance of the SoC by a median of 13h (range 2.8 - 69.2). The DHT prediction of CRS by baseline HR change was earlier than the first episodic fever by a median of 14.5h (range 13-77.5). The remaining 2/7 patients who did not have CRS detected by the DHT had missing DHT data for more than 45h before a treated CRS event. DHT detected CRS in 2/5 patients without CRS according to SoC. One patient had fever caught with intermittent monitoring. The other was treated for neutropenia fever with suspicion of CRS and/or infection. **Conclusions:** These results offer evidence that continuous DHT can identify CRS events earlier than intermittent monitoring (SoC). Despite limitations related to compliance with wearable device use and data missingness, and variability in clinical management of CRS, we highlight the usability of DHT and its potential for future studies with optimized strategies to address these limitations. Clinical trial information: NCT05018208. Research Sponsor: Biofourmis.

Validating a single-item screener for low digital health literacy among surgical oncology patients.

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Background: Digital health literacy (DHL; the ability to find and understand health information using electronic media) may affect surgical oncology patients' ability to navigate patient education and discharge coordination activities that rely on technology. Screening for low DHL can identify patients who may benefit from alternate modalities or additional support. In our prior work, a single item from the validated electronic Health Literacy Scale (eHEALS) had strong sensitivity and specificity for identifying low DHL in the outpatient setting. In this cross sectional, secondary analysis, we explored which sociodemographic and clinical factors were related to low DHL and tested whether the single-item screener could identify patients with low DHL in the surgical oncology setting. **Methods:** Surgical oncology patients were recruited during their post-operative hospitalization for a parent study on health literacy and clinical outcomes. The 8-item eHEALS assessed DHL; total scores ≤ 20 indicate low DHL. Chi-squared, Fisher's exact, or Mann-Whitney tests were used to examine whether DHL varied by patients' sociodemographic (age, sex, race/ethnicity, education, marital status, general health literacy) or clinical characteristics (cancer type, ECOG performance status, comorbidities). Receiver operating characteristic (ROC) curve analysis assessed sensitivity, specificity, and accuracy of eHEALS item 4 ("I know where to find helpful health resources on the Internet") to identify low DHL. **Results:** Participants (N=224) were primarily non-Hispanic White (87%), older (median=68, IQR 61-75 yrs), married (69%), men (59%) with gastrointestinal cancer (60%) who completed at least some college education (76%). On the 8-item eHEALS, 23 patients (10.3%) reported low DHL. Patients with lower general health literacy ($p<0.001$), lower education level ($p=0.007$), and unpartnered marital status ($X^2 = 4.359$, $p=0.039$) were more likely to have low DHL. Other factors were not associated with DHL (p -values >0.299). Older patients were marginally more likely to report low DHL than younger patients ($U=2847$, $p=0.069$). In ROC curve analysis, eHEALS item 4 strongly distinguished low DHL vs. high DHL (AUC=0.989; 95% CI 0.977-0.997). At the optimal threshold (item scores <3 , on a 1-5 Likert scale), item 4 predicted low DHL with an accuracy of 96.9%, sensitivity of 97.0%, and specificity of 95.7%. **Conclusions:** These data suggest a single-item screener (eHEALS item 4) can accurately identify patients with low DHL in the surgical oncology setting, adding support for its ability to detect low DHL in patients with cancer. Among surgical oncology patients, those with lower education, lower general health literacy, and older age may be more likely to experience lower DHL. Future prospective studies with larger samples are warranted to assess utility, acceptability, and feasibility of the screener in clinical practice. Research Sponsor: None.

Conversational AI-assisted exploratory data analysis (CA-EDA): A comparative evaluation of commercial large language models for clinical trial analysis.

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Background: Conventional analysis of clinical trial data requires statistical expertise, time and effort. Previous AI approaches have used structured, pre-processed datasets on specialized platforms. We hypothesized that widely available commercial large language models (LLMs) would perform rapid analysis of raw data. We evaluated three commercial LLM platforms fed identical data, and subsequently validated the outcomes with a formal statistical analysis. We name this approach "Conversational AI-assisted Exploratory Data Analysis" (CA-EDA).

Methods: We used data from a completed phase 2 trial (NCT03323489; Lancet Oncol 2024; 25:1070-9); n=125; 2165 variables) that evaluated the efficacy of celiac plexus radiosurgery in controlling retroperitoneal pain syndrome amongst pancreatic cancer patients. Raw individual patient data was uploaded to three commercial LLMs: Claude Opus 4.1 (Anthropic), ChatGPT 5.2 (OpenAI) in deep research mode, and Gemini 3 Pro (Google). Each LLM received identical inputs: the raw Excel dataset, the codebook, the protocol, and the published manuscript. The prompt requested identification of baseline predictors of pain response and development of a clinical score. Outputs were compared for statistical analyses performed, predictors identified, visualizations generated, and clinical utility. Findings were formally verified using Stata IC/16.1.

Results: Analysis completion time ranged from 10 to 30 minutes across all three platforms. Claude performed a comprehensive statistical analysis, generated a 9-panel visualization dashboard, identified prior exposure to neurotoxic chemotherapy as a novel predictor of response (OR 0.20, $p < 0.001$), and created a 4-variable clinical score predictive of response (AUC 0.71). ChatGPT performed a statistical analysis but missed neurotoxic chemotherapy, creating a 3-variable score. Gemini produced an 8-page narrative with biological insights, but did not perform any statistical analysis. Analysis using Stata confirmed the association between prior exposure to neurotoxic chemotherapy and response (35% with prior exposure vs 75% without, $p < 0.001$). **Conclusions:** Claude Opus 4.1 identified a clinically significant predictor that had not previously been recognized, and developed a helpful clinical score. CA-EDA always requires formal biostatistical verification due to concerns about LLMs' tendency to hallucinate, may analyse only sampled data and potentially implement incorrect Python code. Despite these concerns, here we found CA-EDA of clinical trial data to be rapid, accurate and cost-effective. Financial support for clinical trial: Gateway for Cancer Research, The Israel Cancer Association. Research Sponsor: Gateway for Cancer Research; Israel Cancer Association.

Evaluating the organizational benefits of remote symptom monitoring during injectable outpatient cancer treatment: The final analysis of the randomized OPTIMACURE trial.

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Background: Remote monitoring (RM) to assess whether patients are apt for cancer treatment is already used during standard of care (SOC) in several French centers. Optima RM includes structured phone calls by a nurse, 2–3 days before the planned administration, with the transfer of biological results 48 h before the administration, with a physician's validation the day before administration. Cureety RM, in addition to preparing visit, also monitors symptoms between cures. We aimed to evaluate the organizational benefit of Cureety RM compared to Optima-like RM in patients initiating outpatient injectable cancer treatments. **Methods:** OPTIMACURE was designed as a multicentric, randomized, open-label trial to compare Cureety RM versus Optima-like RM. Patients aged ≥ 18 years, starting an injectable cancer treatment, and capable of using a RM tool were eligible. Patients with dysphonia/difficulties with oral communication were not eligible. Enrolled patients were randomly allocated (2:1) to either Cureety RM or to SOC (with Optima-like RM). Randomization was stratified by type of cancer treatment, ECOG PS, frequency of treatment, and center. Only centers using Optima-like RM participated in the trial. The primary objective was to assess the effectiveness of adding Cureety RM to usual care, in terms of the number of outgoing calls, overall and by reason (preparing visits or for toxicity), within the first 2 months. Secondary outcomes included safety, toxicity-free survival (TFS), and hospitalizations. **Results:** Between April and August 2024, 192 patients were allocated: 127 (66%) to Cureety RM and 65 (34%) to SOC (with Optima-like RM). The trial population was mainly female (73%) and with an ECOG PS 0–1 (96%). Most were being treated with chemotherapy (98%) and less frequently than every 2 weeks (61%). The demographic and disease characteristics were similar in the groups. The mean number of outgoing calls were fewer with Cureety RM, 2.53 (SD: 2.21) versus 3.77 (SD: 2.45). The difference of least-squares means was significantly different in the groups: -1.25 (95% CI: -1.91 to -0.59), $p < 0.0001$. The number of outgoing calls for preparing visit were significantly fewer with Cureety RM, 0.43 (SD: 0.82) versus 3.09 (SD: 2.18), $p < 0.001$. While there were significantly more outgoing calls for toxicity with Cureety RM, 1.68 (SD: 1.89) versus 0.20 (SD: 0.71), $p < 0.001$. No adverse events (AEs) related to RM were reported. The median TFS was significantly shorter with Cureety RM, 10 days versus not reached: driven by early detection of grade ≤ 4 AEs. The number of hospitalizations was similar in the groups. **Conclusions:** Implementing Cureety RM during injectable cancer treatment had an organizational benefit by reducing the number of outgoing calls. More precisely, reducing the outcalls for preparing visit while increasing those for AEs. Clinical trial information: NCT06371911. Research Sponsor: None.

Feasibility and preliminary efficacy of a 12-week remotely delivered exercise program in patients receiving immunotherapy: A phase II randomized controlled trial.

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Background: Patients with advanced cancer receiving immunotherapy experience reduced physical function, increased symptom burden, and poorer health-related quality of life (HRQOL). Limited access to structured exercise programs makes technology-supported interventions a potentially scalable alternative. We assessed the feasibility and preliminary efficacy of a 12-week remote exercise program on HRQOL, symptom burden, and fear of cancer recurrence (FCR), with an exploratory economic evaluation. **Methods:** In this Phase II trial, adult receiving immunotherapy alone or in combination were randomized 1:1 to a remote exercise intervention or usual care (UC). The study was powered to detect a 10-point difference in Functional Assessment of Cancer Therapy-General (FACT-G) scores (80% power, $\alpha=0.05$). The intervention included weekly virtual sessions with an exercise physiologist, individualized Borg-guided exercise prescriptions, video support, and telehealth monitoring 12 weeks (30-45 minutes/day). Outcomes assessed at baseline and 12 weeks included HRQOL (FACT-G), symptom burden (Edmonton Symptom Assessment Scale; ESAS), and FCR (FCR-7). Between-group differences were analyzed using ANCOVA adjusted for baseline values, with effect sizes estimated using Cohen's d. A preliminary provider-perspective cost-consequence analysis estimated cost per one-point FACT-G improvement. **Results:** Seventy patients were randomized (35 per arm); five died before 12 weeks (3 control, 2 intervention). Baseline characteristics were balanced. At 12 weeks, the intervention group had significantly higher FACT-G scores compared than UC (mean difference = 11.1; $p<0.001$; Cohen's $d=1.30$). Symptom burden was lower in the intervention arm ($p<0.001$; Cohen's $d=1.68$), and FCR was reduced ($p=0.014$; Cohen's $d=0.85$). Group assignment remained a significant predictor in adjusted ANCOVA models (all $p<0.01$). Estimated intervention cost was R\$7,023 per participant, or R\$634 per FACT-G point gained. **Conclusions:** A 12-week remote exercise intervention produced a clinically meaningful 11-point improvement in HRQOL at an estimated cost of R\$ 634 per FACT-G point, supporting its economic feasibility and scalability. The program reduced symptom burden and FCR. These findings justify larger trials to confirm effectiveness and further evaluate cost-effectiveness. Research Sponsor: None.

Changes in patient-reported outcomes at 12 weeks.

Outcome (scale)	Group	Baseline Mean $\pm$ SD	12-week Mean $\pm$ SD	Mean Change	P-value	Cohen's d
FACT-G	Control (n=32)	87.3 $\pm$ 9.7	85.9 $\pm$ 10.2	-1.4	0.001	1.30
	Intervention (n=33)	85.2 $\pm$ 9.1	96.9 $\pm$ 6.7	+11.8		
ESAS	Control (n=32)	17.3 $\pm$ 12.1	19.0 $\pm$ 12.8	+1.7	0.001	1.68
	Intervention (n=33)	20.6 $\pm$ 9.6	5.5 $\pm$ 3.7	-15.1		
FCR-7	Control (n=32)	15.0 $\pm$ 6.0	15.4 $\pm$ 6.5	+0.4	0.014	0.85
	Intervention (n=33)	16.2 $\pm$ 6.3	11.3 $\pm$ 3.8	-4.9		

Disparities in receipt of guideline-concordant adjuvant chemotherapy and survival outcomes among immigrant patients with colon cancer: Real-world evidence from Ontario.

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Background: Immigrants comprise a growing proportion of the Canadian population and may face unique barriers to accessing timely and guideline-concordant cancer care. While the “healthy immigrant effect” suggests that immigrants initially experience better health outcomes, it remains unclear whether this advantage extends to cancer treatment and survival. We studied whether disparities exist in the receipt of adjuvant chemotherapy and survival outcomes among recent immigrant patients with stage III colon cancer in Ontario compared with long-standing Ontario residents. **Methods:** A population-based real-world retrospective cohort study was conducted using linked administrative health databases housed at the ICES. Adults diagnosed with stage III colon cancer between 2007 and 2020 who underwent surgery within six months of diagnosis were included. Recent immigrants were defined as individuals with a landing date as a resident within ten years before diagnosis, identified using the Immigration, Refugees and Citizenship Canada database; long-standing residents had no recorded immigration date. The primary outcome was receipt of adjuvant chemotherapy within four months of surgery for their cancer. Secondary outcome was all-cause mortality. **Results:** The cohort included 16,724 patients, of whom 304 were recent immigrants (including 47 refugees). Compared to long-standing residents, recent immigrants were younger, had fewer comorbidities, and were more likely to reside in urban areas. In unadjusted analyses, recent immigrants were more likely to receive adjuvant chemotherapy (RR 1.37; 95% CI 1.23–1.53); however, this association was attenuated in the multivariate analysis (RR 1.08; 95% CI 0.99–1.19). Recent immigrants had significantly lower all-cause mortality, with an adjusted hazard ratio (HR) of 0.70 (95% CI 0.58–0.84). **Conclusions:** In this large population-based study, recent immigrants with stage III colon cancer in Ontario received comparable guideline-concordant adjuvant chemotherapy and had significantly better overall survival than long-standing residents. These findings suggest that, within a universal healthcare system, recent immigrants may not be disadvantaged in colon cancer treatment and perhaps have better outcomes once engaged in care. Further research is needed to assess whether these findings extend to other cancer types and to non-permanent resident populations. Research Sponsor: Department of Medicine, Queen's University and ICES.

Sociodemographic variation in live birth incidence and access to assisted reproductive services among female cancer patients in the United States.

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Background: Sociodemographic variation in fertility outcomes after cancer is not well described. We constructed a novel longitudinal dataset to capture sociodemographic variation in 1) live births and 2) use of assisted reproductive technology (ART) among female cancer patients across the US from 2004–2022. **Methods:** We linked population-based cancer registry data (2004–2018 in 12 states; 2004–2011 in California) with live birth certificates (2004–2022) and the Society for Assisted Reproductive Technology (2004–2022) database, which captures ~90% of ART cycles nationally, to create a dataset integrating oncologic characteristics, obstetric outcomes, and ART use. Patients aged 15–45 at diagnosis of cancer were included. The primary outcome was 5-year cumulative live birth incidence (CLBI) using the Fine and Gray method to account for all-cause death as a competing event and log-rank tests to compare by age, race/ethnicity, insurance, cancer site, cancer stage, and receipt of systemic therapy. Secondary outcome was use of ART after cancer diagnosis, defined as >1 autologous oocyte/embryo cryopreservation or embryo transfer cycles. Patients were categorized by expected fertility detriment, defined as pelvic malignancy and/or receipt of chemotherapy, hormone therapy, or abdominal or pelvic radiation, and covariates compared descriptively. Person-years were accrued from diagnosis date to first post-diagnosis birth/use of ART, death, age 51 (oldest age a post-cancer birth was observed), or December 31, 2022, whichever occurred first. The study was approved by the institutional review board. **Results:** 286,198 female cancer patients were included with 15 live births per 1,000 person-years. 5-year CLBI was 6.14% [6.05, 6.24]. Lower CLBI was observed in Hispanic (4.5% [4.31, 4.76]) and non-Hispanic Black (NHB) (5.23% [4.98, 5.50]) populations compared to non-Hispanic white (NHW) populations (6.75% [6.62, 6.88]) ($p<0.001$). Patients with public insurance also had significantly decreased CLBI (4.68% [4.47, 4.90]) than those with private insurance (6.08% [5.95, 6.20], $p<0.001$). NHB, Hispanic, and patients with public insurance comprise higher proportions of patients with expected fertility detriment versus those without detriment (12.6 vs 8.6%, 18.2 vs 13.1%, and 18.7 vs 13.3%, $p<0.001$) but lower proportion of patients that use ART versus those that do not (5.9 vs 11.4%, 7.6 vs 16.6%, and 4.1 vs 17.1%, $p<0.001$). **Conclusions:** National vital statistics data demonstrates high fertility rates among Hispanic and NHB populations; among cancer patients, however, these trends are flipped, with lower cumulative incidence of live births in these groups. Despite a higher burden of anticipated fertility detriment, NHB, Hispanic, and publicly insured patients were less likely to access fertility care, revealing stark inequities in survivorship care. Research Sponsor: National Institutes for Health; MD017999.

Comorbidity-related medical expenditures and health outcomes in cancer patients.

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Background: Comorbidities are common among adults with cancer and necessitate effective medical management. However, research is scarce on how cancer affects healthcare utilization and expenditures for comorbid conditions. This study used a U.S. database to compare medical expenditures and health outcomes between adults with comorbidities who have cancer and those without. **Methods:** This longitudinal analysis utilized the data from the 2008–2014 Medical Expenditure Panel Survey (Household Component). Participants with one or more of 19 chronic health conditions (ICD-9 coded) relevant to primary care were classified based on self-reported cancer history. Outcomes from the second year of each panel (2009–2015) included comorbidity-specific healthcare utilization, medical expenditures, functional status, HRQoL, and health utility. Cost differences conditional on positive expenditures were analyzed using generalized linear models (gamma regression and log-link), while differences in healthcare utilization were examined using negative binomial regression. All models were adjusted for demographic, socioeconomic, and lifestyle covariates. **Results:** A weighted total of 24,057,137 adults with at least one comorbidity (mean age 58.3 ± 15.8 years; 59% female) were included, of whom 10% ($n=2,393,300$) reported a history of cancer. Compared with non-cancer patients, cancer patients received more comorbidity-specific home health visits (IRR 2.01, 95% CI 1.13–3.57) but had lower total comorbidity-specific expenditures (OR 0.81, 95% CI 0.71–0.92). Cancer patients also incurred lower comorbidity-specific hospitalization costs and out-of-pocket costs for emergency department (ED) visits ($p<0.05$). Specifically, they had reduced total expenditures for arthritis (OR 0.60, 95% CI 0.39–0.93) and stomach problems (OR 0.42, 95% CI 0.22–0.81) and reduced out-of-pocket costs for thyroid problems (OR 0.55, 95% CI 0.36–0.86) and osteoporosis (OR 0.41, 95% CI 0.18–0.92). Among multimorbid patients (≥ 2 conditions; 55.4%), cancer patients incurred lower out-of-pocket costs for ED visits (OR 0.42, 95% CI 0.26–0.68). For health outcomes, cancer patients reported more functional limitations than non-cancer patients in instrumental activities of daily living (10.8% vs 8.5%), role functioning (26.2% vs 20.5%), and cognitive function (13.6% vs 11.2%), all $p<0.05$. Moreover, multimorbid patients with cancer had lower HRQoL and health utilities ($p<0.05$). Similar trends were observed for cancer patients with depression, hypertension, chronic lung disease, osteoporosis, and thyroid problems. **Conclusions:** Cancer patients with comorbidities had greater functional limitations but lower medical expenditures for comorbidity care than non-cancer patients, suggesting inequities in primary care. Healthcare resources should be prioritized for cancer patients with comorbidities and poor functional status. Research Sponsor: None.

Retrospective assessment of Duffy-Null associated neutrophil counts (DANC) status and impact on treatment among patients with and without cancer in an urban academic medical center.

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Background: Duffy-Null Associated Neutrophil Count (DANC) is a non-pathologic state characterized by a low absolute neutrophil count (ANC) without increased risk of infections. Despite this, cancer patients (pts) with DANC have often been excluded from clinical trials due to low ANC and may receive inappropriate dose delays or reductions of standard anticancer therapy. Testing for Duffy-null phenotype is readily available, but no standard of care exists for management of chemotherapy dosing in cancer pts with DANC. In preparation for a prospective study evaluating chemotherapy dose modifications in cancer pts with DANC, we examined characteristics of pts, both with and without cancer, who underwent Duffy antigen testing at our institution, as well as whether results of testing in cancer pts impacted cancer management.

Methods: Pts who received Duffy antigen testing from 05/02/2024–05/01/2025 were identified from the Montefiore Health System pt registry. Baseline characteristics including white blood cell count (WBC), ANC, demographics, and cancer status were obtained and correlated with Duffy status. Reviewed documentation for Duffy-status impact on chemotherapeutic management. **Results:** 523 pts [283 (54.1%) Non-Hispanic Black (NHB), 168 (32.1%) Hispanic (H), 18 (3.4%) Non-Hispanic White (NHW), and 54 (10.3%) Other] were identified. Median age was 56 yrs. Indication for testing was neutropenia in 518 pts (99.0%). 407 (77.8%) pts were found to have DANC and 116 (22.2%) were Duffy-antigen positive. Duffy-null phenotype was seen in 265 (93.6%) pts; 103 (61.3%) H pts, and 4 (22.2%) NHW pts. Race/ethnicity was strongly correlated with Duffy-status ($p < 0.001$). Median baseline WBC and ANC were lower in pts with DANC than in pts without [WBC 3.4 vs 4.4 ($p < 0.001$); ANC 1.1 vs 1.8 ($p < 0.001$)]. 32 (6.4%) pts of the total cohort had cancer [23 (71.9%) NHB, 7 (21.9%) H, 2 (6.3%) other], of which 26 pts (22 NHB, 4 H) had DANC. 13 (40.6%) ordering providers were adult solid tumor oncologists [8 Breast, 4 GYN, 1 GU], 5 (15.4%) pediatric hematologist-oncologists, 6 (18.8%) classical hematologists, 6 (18.8%) hematology/oncology providers, and 2 (6.3%) family medicine providers. Knowledge of Duffy antigen status impacted management in 26 (81.3%) pts with cancer, leading to fewer dose delays and reductions in cancer pts with DANC, while in 6 (18.8%) pts testing did not ($p = 0.31$). **Conclusions:** In our diverse cohort of pts undergoing Duffy antigen testing, predominantly as part of evaluation for neutropenia, almost all NHB pts were found to have Duffy-null phenotype. DANC was also seen in over half of H pts, and in 22% of NHW pts. Among cancer pts, testing for DANC is underutilized, but frequently impacts chemotherapy management, emphasizing the need for prospective evaluation of the utility of Duffy antigen testing in cancer pts receiving chemotherapy. Research Sponsor: None.

Emergency department visits and hospitalizations in cancer survivors with disabilities: A national analysis.

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Background: One in four Americans has a disability. Adults with disabilities are known to have a higher cancer burden than the general U.S. population, but the healthcare utilization patterns and needs of this population remain understudied. We examined factors associated with emergency department (ED) visits and hospitalizations among cancer survivors, with a focus on disability status. **Methods:** We used National Health Interview Survey (NHIS) data from 2022–2024. Adults aged 18+ years who self-reported a diagnosis of breast, prostate, or colon cancer were included. Our key explanatory variable was disability status, defined by receipt of Supplemental Security Income or Social Security Disability Insurance, or a positive designation using the Washington Group Short Set Composite Disability Indicator. The primary outcomes were ED visits and hospitalization in the past 12 months. Logistic regression models adjusted for demographics and health status (e.g., body mass index, self-rated health, and smoking status). All analyses incorporate NHIS survey weights to account for the complex survey design. **Results:** Our sample included 4,179 NHIS respondents with breast, prostate, or colorectal cancer; 999 (23.9%) had a disability. Cancer survivors with disabilities were more likely to have less than a high school education (19.7% vs 9.2%), be enrolled in Medicaid (6.0 vs 2.7%) or Medicare (4.9% vs 44.8%), and report poor health status (22.3% vs 3.6%) compared to those without disabilities. Compared to cancer survivors without disability, those with disability had higher odds of ED visits (aOR 1.59 [95% CI 1.27–1.99], $p<0.001$) and hospitalizations (aOR 1.70 [95% CI 1.30–2.22], $p<0.001$). Other factors associated with increased odds of ED visits in cancer survivors were region (Ref=Northeast, South: aOR 1.33 [95% CI 1.01–1.77], $p=0.046$; West: aOR 1.46 [95% CI 1.09–1.98], $p=0.01$), Medicaid insurance (Ref=no insurance, aOR 1.93 [95% CI 1.01–3.69], $p=0.046$), and poor self-rated health (Ref=excellent, aOR 6.69 [95% CI 4.05–11.07], $p<0.001$). Factors associated with increased odds of hospitalizations in cancer survivors were Medicare (Ref=no insurance, aOR 2.18 [95% CI 1.21–3.92], $p=0.01$), private insurance (Ref=no insurance, aOR 1.83 [95% CI 1.02–3.26], $p=0.04$), multiple insurance (Ref=no insurance, aOR 2.07 [95% CI 1.15–3.74], $p=0.02$), and poor self-rated health (Ref=excellent, aOR 6.96 [95% CI 3.82–12.70], $p<0.001$). **Conclusions:** We observed an independent association between disability and ED visits and hospitalizations among cancer survivors in a national, population-based dataset. Geographic region, insurance, and poor health perception were additional risk factors for acute care utilization in cancer survivors. Our findings highlight the need for targeted interventions to improve ambulatory care access and reduce preventable acute care utilization in this vulnerable population. Research Sponsor: National Cancer Institute; 5R37CA288492.

Healthcare resource use (HCRU) intensity prior to cancer diagnosis and real-world outcomes in early-stage cancers.

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Background: *Choosing Wisely* initiatives aim to reduce futile care by emphasizing the role of clinicians in healthcare decision-making. However, HCRU is strongly shaped by patient preferences with some inherently favoring high-intensity (“maximalist”) care and others preferring low-intensity (“minimalist”) approaches. We hypothesized that HCRU in the years before an early-stage cancer diagnosis may, in part, represent the healthcare seeking preferences of patients rather than strictly reflecting their clinical needs. **Methods:** We conducted a population-based retrospective cohort study of adults diagnosed with stage I-II breast, lung or colon cancer from 2015 to 2020 in Alberta, Canada with follow-up to 2025. Pre-diagnosis HCRU was quantified using ambulatory, emergency, and inpatient encounters. Patients were categorized as high (≥ 75 th percentile) or low (≤ 25 th percentile) users; intermediate users were excluded. Cohorts of high vs. low users were matched based on age, sex, rurality, stage and Charlson Comorbidity Index (CCI) and stratified by tumor site. Outcomes included cancer-specific survival (CSS), overall survival (OS) and post-diagnosis HCRU. **Results:** The matched cohort included 7,384 patients (64% breast, 21% lung, 15% colon) with balance across all covariates. Median age was 67 years, 68% had stage I disease and 95% had CCI ≤ 2 . For all cancer sites, CSS did not differ between high and low users (see Table). High pre-diagnosis HCRU was associated with worse OS in breast (HR 1.34, $p < 0.001$) and colon cancer (HR 1.36, $p = 0.003$), but not in lung cancer (HR 1.02, $p = 0.76$). Importantly, HCRU patterns pre-diagnosis strongly persisted post-diagnosis, with high users continuing to consume significantly more healthcare resources than low users for 4 years after cancer diagnosis ($p < 0.001$). **Conclusions:** In this relatively healthy cohort of early-stage, highly curable cancers, greater pre-diagnosis HCRU was associated with sustained post-diagnosis HCRU intensity without any significant differences in cancer-specific outcomes. Our findings suggest that utilization patterns may reflect patient-level behaviors as much as clinical necessity, thus contributing to volume-driven care that may have limited clinical value. Advancing future *Choosing Wisely* initiatives in oncology must extend beyond clinician stewardship to address patient expectations about their healthcare interactions. This strategy would better align with value-based care and promote health system sustainability. Research Sponsor: None.

CSS based on pre-diagnosis HCRU.

Cancer site	Pre-diagnosis HCRU	10-year CSS (95% CI)	HR for CSS (95% CI)	P value
Breast	Low	89% (87%, 92%)	Reference	0.55
Breast	High	91% (90%, 93%)	0.93 (0.74, 1.18)	
Lung	Low	63% (58%, 69%)	Reference	0.72
Lung	High	68% (64%, 72%)	1.04 (0.85, 1.26)	
Colon	Low	90% (87%, 93%)	Reference	0.39
Colon	High	92% (89%, 95%)	0.82 (0.52, 1.29)	

Reframing access to innovative oncology medicines: The impact of policy and governance reform in a Bismarck-type system in Bosnia and Herzegovina.

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Background: Access to innovative oncology medicines is often assumed to depend primarily on available financial resources. In health systems organized under the Bismarck model, however, access is frequently constrained by structural and policy-related factors, including fragmented governance, rigid reimbursement pathways, and infrequent updating of positive drug lists. These limitations may result in delayed access, restricted indications, and misalignment with contemporary clinical standards, even in the absence of absolute budget shortages. In Bosnia and Herzegovina, such constraints are compounded by complex administrative arrangements, leading to pronounced regional disparities in cancer care. In Sarajevo Canton prolonged waiting times and loss of treatment eligibility underscored that the key barrier was not lack of money, but lack of timely policy action. In October 2024, Sarajevo Canton launched a program shifting financing responsibility locally to improve timely access. **Methods:** We analyzed drug access before and after program initiation in 641 patients, assessing waiting times from indication to treatment approval and the proportion of patients losing indication prior to therapy availability. **Results:** Patients whose indication was established before the program were significantly more likely to remain without therapy compared to those after initiation (23.8% vs. 10.3%, $p < 0.001$). Among 547 patients with available waiting time data, mean waiting time decreased from 251.6 days (SD ≈ 190 ; range 21–910) to 40.4 days (SD ≈ 21 ; range 6–199), representing a >6 -fold reduction. Variability also decreased, making access more predictable and equitable. Levene's test indicated unequal variances ($F = 517.3$, $p < 0.001$), and Welch's t-test confirmed the difference ($t(157.5) = 13.91$, $p < 0.001$; 95% CI 181–241 days), with a very large effect size (Cohen's $d \approx 2.0$). **Conclusions:** This policy intervention dramatically reduced waiting times and improved equity in therapy access. This demonstrates that substantial improvements in oncology drug access can be achieved without increasing overall healthcare spending. The observed gains were the result of a deliberate policy and governance shift—redefining responsibility, prioritization, and accountability—rather than additional financial input. This intervention highlights that, within Bismarck-type systems, access gaps are often policy failures rather than funding failures, and that targeted policy change can serve as a powerful lever to rapidly improve equity and quality of cancer care. Research Sponsor: None.

Association between physician characteristics and likelihood of caring for underserved patients with cancer.

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Background: Despite evidence that a diverse workforce may improve access to care for underserved patients, emerging policies threaten to limit diversity in the physician workforce. We assessed whether nonwhite and foreign-born physicians were more likely than White and US-born physicians to care for underserved (minority race, low-income, rural) Medicare beneficiaries with cancer. **Methods:** Using SEER-Medicare, we analyzed Medicare beneficiaries aged 18+ newly diagnosed with breast, colorectal, lung, or prostate cancer from 2015–2019. We linked patients to cancer physicians (medical, radiation, and surgical oncology) using claims in the 6 months after diagnosis. We assessed physician race/ethnicity (data from Association of American Medical Colleges) and country of birth (American Medical Association). For each physician race and foreign-born status, we calculated the standardized treatment ratio (STR) as the percent of that group's dyads with a given patient characteristic divided by the percent of all dyads with that patient characteristic. Thus, $STR > 1$ indicates physicians in that group are more likely than the average physician to treat patients with the given characteristic. **Results:** We linked 434,923 patients (30% breast, 16% colorectal, 29% lung, 25% prostate) to 35,257 physicians. The patient population (mean age 74.7) was 79% White, 8% Black, 7% Hispanic, 3% Asian, 17% Medicaid dual-eligible, and 16% rural. Black physicians were more likely than expected to care for Black patients (STR 2.55; 95% CI 2.48–2.63; Table) and dual-eligible patients (STR 1.26; 1.22–1.29). Hispanic physicians were more likely to care for Hispanic (1.97; 1.91–2.03) and dual-eligible (1.11; 1.08–1.14) patients. Asian physicians were more likely to care for Asian (1.93; 1.89–1.96) and Hispanic (1.18; 1.16–1.20) patients and less likely to care for rural (0.73; 0.72–0.74) patients. Foreign-born physicians (20.7% of physicians) were more likely to care for Asian (1.36; 1.33–1.39), Hispanic (1.25; 1.23–1.27), and dual-eligible (1.20; 1.18–1.21) patients and less likely to care for rural patients (0.90, 0.89–0.91). **Conclusions:** Nonwhite and foreign-born cancer physicians disproportionately care for nonwhite and low-income patients. Policies restricting entry of minority and foreign-born physicians into the oncology workforce may hinder access to care for underserved cancer patients. Research Sponsor: None.

Standardized treatment ratios (STRs) by physician race, ethnicity and country of birth.

Physician characteristic	Patient Characteristic Asian	Black	Hispanic	White	Dual eligible	Rural
Race & ethnicity						
Asian	1.93	1.00*	1.17	0.95	1.09	0.73
Black	0.60	2.55	1.08	0.85	1.26	1.04
Hispanic	0.79	0.97*	1.97	0.94	1.11	1.01*
White	0.68	0.92	0.81	1.04	0.88	1.09
Foreign born						
No	0.86	0.96	0.89	1.02	0.88	1.04
Yes	1.36	1.05	1.25	0.96	1.20	0.90

*Denotes STRs NOT significantly different from 1.0; all other values are significant ($P < 0.05$).

Racial disparities and nonconcordance with endocrine and HER2 therapy for breast cancer: A sequential mediation analysis of neighborhood deprivation and insurance status.

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Background: Racial disparities in breast cancer treatment persist, but the mechanisms driving inequities may differ by therapy type. We evaluated whether neighborhood racialized economic segregation (mediator 1, M1) and insurance status (M2) sequentially mediate racial disparities in receipt of guideline-concordant endocrine and anti-HER2 therapy. **Methods:** We conducted a retrospective cohort analysis of women diagnosed with breast cancer using the Florida Cancer Data System (2013–2021). Eligible women included those with invasive, nonmetastatic disease with hormone or HER2-receptor-positive tumors. Treatment nonconcordance was defined as failure to receive recommended systemic therapy based on tumor receptor status. M1 was measured by the racial-income version of the Index of Concentration at the Extremes (ICE) at the census tract level and divided into quintiles from the most to least deprived. Insurance status was categorized as insured versus Medicaid/uninsured/unknown (MUU). Simple frequencies were obtained to assess the relationships between race, the mediators, and therapy nonconcordance. Causal mediation analyses using the parametric g-formula quantified natural course risks and the proportion of the racial disparity mediated by ICE and insurance status, while adjusting for confounders (disease stage, molecular subtype [endocrine only], tumor grade, age, region of the state, and marital status). **Results:** There were 71,077 and 3,021 women available for the analysis of endocrine and HER2 therapy, respectively. For nonconcordance with endocrine therapy, disparities were present by race (37.2% vs. 29.0%, Black vs. White), the ICE (37.2% vs. 26.2%, most vs. least deprived), and insurance status (36.1% vs. 29.4%, MUU vs. other). Smaller disparities were present for nonconcordance with HER2 therapy by race (18.1% vs. 12.9%, Black vs. White), the ICE (16.2% vs. 14.2%, most vs. least deprived), and insurance status (18.5% vs. 13.4%, MUU vs. other). In causal mediation analysis for nonconcordance with endocrine therapy, the natural course counterfactual risks showed a 5% absolute disparity by race (34.3% vs. 29.3%); 59% of this disparity was mediated by the ICE and insurance status. For nonconcordance with HER2 therapy, the natural course counterfactual risks showed a 4% absolute disparity by race (17.1% vs. 13.1%); none of this disparity was mediated by the ICE and insurance status. **Conclusions:** Racial disparities in receipt of endocrine therapy are largely mediated by neighborhood deprivation and access to care, whereas these factors played no role in explaining disparities in anti-HER2 therapy. These findings suggest that treatment disparities are therapy-specific and that analyses of aggregate treatment outcomes may obscure distinct mechanisms of inequity. Research Sponsor: University of Central Florida College of Medicine.

Survival outcomes with immune checkpoint inhibitors among patients with cancer from minoritized racial and ethnic groups: A systematic review and meta-analysis.

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Background: Immune checkpoint inhibitors (ICIs) have transformed the treatment landscape across multiple malignancies; however, minoritized racial/ethnic groups remain underrepresented in pivotal trials, limiting the generalizability of efficacy estimates. Whether treatment outcomes with ICIs differ across these groups remains incompletely characterized. Thus, we conducted a systematic review and meta-analysis of published randomized controlled trials (RCTs) to evaluate differences in overall survival (OS) and progression-free survival (PFS) among these groups treated with ICIs. **Methods:** We systematically searched MEDLINE, Embase, Cochrane CENTRAL, and ClinicalTrials.gov for RCTs published through December 31, 2024, that evaluated ICIs in adult patients with cancer and reported OS or PFS by race/ethnicity. Risk of bias was independently assessed using the Cochrane Risk of Bias tool for randomized trials (RoB 2). Hazard ratios (HRs) and 95% confidence intervals (CIs) were extracted. Between-study heterogeneity was quantified using I^2 . Random-effects meta-analyses were performed using Review Manager (RevMan) and stratified by: non-White and White patients; Asian, Black, and White patients; Asian and non-Asian patients; and Hispanic and non-Hispanic patients. Publication bias was evaluated using funnel plots. This review followed Cochrane methodology and PRISMA guidelines and was registered in PROSPERO (CRD420251027941). **Results:** A total of 97 trials comprising 59,949 patients were included. For OS, ICIs were associated with significant benefit in both non-White (HR 0.70, 95% CI 0.63–0.77; $p<0.001$) and White patients (HR 0.75, 95% CI 0.67–0.84; $p<0.001$). Significant OS benefit was also observed in analyses stratified by Asian (HR 0.81, 95% CI 0.76–0.86; $p<0.001$) and White patients (HR 0.86, 95% CI 0.82–0.91; $p<0.001$), and by Asian (HR 0.83, 95% CI 0.76–0.91; $p<0.001$) and non-Asian patients (HR 0.79, 95% CI 0.73–0.86; $p<0.001$). Similar patterns were observed for PFS. Estimates for Black and Hispanic patients were not statistically significant, reflecting limited sample sizes. Heterogeneity ranged from low to substantial (I^2 0–87%), with higher heterogeneity observed in PFS analyses. Only one trial reported race-specific survival outcomes for American Indian/Alaska Native (AI/AN) patients, and none reported outcomes for Native Hawaiian/Pacific Islander (NH/PI) patients, precluding analyses for these groups. **Conclusions:** ICIs were associated with improved OS and PFS across racial/ethnic groups, with no consistent evidence of differential treatment effects. However, the persistent underrepresentation of minoritized populations, particularly AI/AN, Black, Hispanic, and NH/PI patients, limits definitive conclusions and highlights the need for more equitable representation in oncology trials. Research Sponsor: National Institutes of Health, National Cancer Institute; UG3/UH3 CA262602; National Institutes of Health, National Cancer Institute; R01 CA247281; Breast Cancer Research Foundation.

ZIP-code–level distress as a predictor for advanced stage and mortality in female breast cancer across a multiethnic cohort in Hawai‘i.

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Background: Native Hawaiian and Pacific Islander (NHPI) patients experience worse breast cancer outcomes; however, the role of neighborhood-level structural disadvantage remains underexplored. We evaluated whether the Distressed Communities Index (DCI), a ZIP-code–level socioeconomic measure, is associated with stage at diagnosis and survival in a multiethnic breast cancer cohort. **Methods:** We conducted a retrospective cohort study of 10,421 female patients with breast cancer treated at a major tertiary cancer center in Honolulu, Hawai‘i (2000–2024). DCI was assigned by residential ZIP code using the Economic Innovation Group DCI (American Community Survey 5-year estimates, 2019–2023) and dichotomized as low (DCI 1–3) versus high (DCI 4–5). Patients missing ZIP code or stage at diagnosis were excluded. Associations with advanced stage (III/IV) were assessed using logistic regression. Overall survival (OS), defined as time from diagnosis to death from any cause or last follow-up, was evaluated using multivariable Cox regression, adjusting for age, race/ethnicity, insurance, tumor characteristics, and stage. **Results:** The cohort included 1,982 White, 6,206 Asian, 2,067 NHPI, and 166 patients of other races/ethnicities. Baseline DCI distribution differed by race/ethnicity and insurance: NHPI patients were more likely to reside in high-distress communities than non-NHPI patients (38.9% vs 29.3% OR 1.54, $p<0.001$), as were Medicaid/uninsured patients compared with privately insured patients (51.4% vs 27.8%; OR 2.76, $p<0.001$). Advanced stage at diagnosis was more frequent in high-DCI neighborhoods than low-DCI neighborhoods (10.0% vs 6.7%; $p<0.001$) and remained independently associated with high DCI after adjustment (aOR 1.29; $p=0.021$). Higher DCI was also associated with worse survival (aHR 1.16, 95% CI 1.07–1.27; $p<0.001$), demonstrating a dose-response pattern across DCI categories (p for trend <0.001). No significant interaction was observed between DCI and NHPI status ($p=0.493$). Median OS was 247 (234–260) months for White patients, 247 (241–253) months for Asian patients, 227 (215–239) months for NHPI patients (log-rank $p<0.001$). In multivariable analysis, NHPI patients had higher mortality than White patients (HR 1.27, 95% CI 1.12–1.43; $p<0.001$), while Asian patients had improved survival (HR 0.78, 95% CI 0.71–0.87; $p<0.001$). Medicaid/uninsured remained independently associated with higher mortality (HR 2.18, 95% CI 1.85–2.57; $p<0.001$). **Conclusions:** ZIP-code–level socioeconomic distress is independently associated with advanced stage at diagnosis and mortality in breast cancer and disproportionately affects NHPI and Medicaid/uninsured patients. DCI identifies communities at higher risk and provides a scalable, policy-relevant tool to support geographically targeted navigation, screening access, and resource allocation strategies. Research Sponsor: None.

Racial variation in pain medication prescriptions among breast, prostate, and pancreatic cancer patients treated in a large community oncology setting.

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Background: Patients (pts) from racially and ethnically minoritized populations are less likely to receive opioid analgesics for cancer-related pain, raising concern for inequitable symptom management. Although guidelines support opioid therapy within a multimodal approach, large scale evidence on racial differences in pain medication use across cancer types remains limited. This study uses real-world data from a large community oncology network to evaluate prescribing patterns of pain medication among high prevalence and high pain burden cancers by race and cancer type. **Methods:** Electronic medical record data from The US Oncology Network identified pts diagnosed with breast, prostate, or pancreatic cancer between January 2021 and June 2025, followed through December 2025. Pain medication (acetaminophen, NSAID, opioid) prescriptions and median time from cancer diagnosis to pain medication prescription were described. Strong opioids were defined as fentanyl, hydromorphone, morphine, or oxycodone, while general opioid use included hydrocodone and tramadol. **Results:** Among breast cancer patients overall (58,308 White; 7,705 Black; 3,652 Asian), pain treatment was received by 19% of White pts and by 24% of both Black and Asian pts, with median time to first pain medication shortest for White patients (65 d) and longest for Black patients (80 d). Prescriptions for strong opioids for breast cancer were lowest among Asian patients (28%), compared to 32% in Black patients and 35% in White patients. Among prostate cancer overall (19,268 White; 3,385 Black; 469 Asian), where receipt of pain medication was 17%, 20%, and 15%, respectively, Asian pts experienced the longest time to pain medication (86 d) versus the shortest among White patients (50 d). Asian patients had the fewest prescriptions for strong opioids (28%) compared with Black (54%) and White patients (50%). In pancreatic cancer (7,972 White; 1,035 Black; 330 Asian), pain medication prescriptions overall (52%, 55%, 50%, respectively) and for strong opioids (71%, 68%, 73%, respectively) were comparable across racial groups, and median time to pain medication showed minimal variation (18–22 d). **Conclusions:** In this large, nationally representative community oncology population, clinically meaningful racial differences in time to pain medication initiation and strong opioid prescribing were observed for breast and prostate cancer but not pancreatic cancer. Minoritized populations experienced delays in pain management, and Asian patients consistently received fewer strong opioid prescriptions. These results highlight that inequities in pain management vary across malignancies, and categories of pain medication. These findings underscore the need for culturally informed, cancer specific interventions to promote equitable symptom management. Research Sponsor: None.

Racial representation in clinical trials supporting NCCN breast cancer guidelines: A retrospective analysis.

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Background: Racial disparities in breast cancer are well established, with Black women having disproportionately higher mortality rates. The NCCN guidelines are valuable in the management of breast cancer, highlighting the importance of evaluating racial representation and its trends over time within the studies cited in these guidelines. **Methods:** We conducted a retrospective analysis of 735 references cited in NCCN Breast Cancer Guidelines Version 4.2025. All clinical trials were included, while reviews, case reports, and non-clinical references were excluded. The primary outcome of interest was the reporting of racial demographics within each reference. Fisher’s exact test was used to assess statistically significant differences in racial representation across time periods. **Results:** Of 735 references screened, 384 met the inclusion criteria, and 89 (23%) reported racial demographics. Studies reported a total of 87.9% White, 4.5% Black, 4.1% Asian, 0.5% Hispanic, 0.1% American Indian/Alaska Native, 0.0% Native Hawaiian/Pacific Islander, and 0.1% reporting more than one race. Time block 5 had significantly more reported races than blocks 2, 3, and 4 (p-value < 0.05). A statistically significant decrease in percentage reported as White was seen when comparing time blocks 1 to 5 (p = 0.0495), 2 to 5 (p = 0.0336), and 2 to 6 (p = 0.028). Changes in representation among other racial groups were primarily driven by Black and Asian groups, with Asians comprising the largest proportion in time blocks 4 (6.1%) and 6 (17.9%), while the Black race was the largest group in all other time blocks. All other racial groups remained consistently low across time blocks. **Conclusions:** Only 23% of references reported racial data. While the proportion of the White race decreased over time and an increased representation of other racial groups was observed, the overall reporting of these groups remained low across all time periods. This emphasizes the need for standardized reporting of race in clinical trials to ensure that NCCN guidelines accurately reflect the diversity of patients in breast cancer care. Research Sponsor: None.

Race demographics from clinical trials cited in the NCCN breast cancer guidelines.									
Time block	Time Bracket	Percentage of White	Percentage of Non-White	Percentage of Black	Percentage of Asian	Percentage of Hispanic	Percentage of AI/AN	Percentage of NI/PI	Percentage of More than one race
1	1980-1999	95.6%	1.6%	2.8%	0.0%	0.0%	0.0%	0.0%	0.0%
2	2000-2004	92.4%	1.4%	4.6%	0.1%	1.3%	0.0%	0.0%	0.2%
3	2005-2009	86.9%	5.4%	5.2%	1.6%	0.9%	0.0%	0.0%	0.0%
4	2010-2014	88.7%	1.8%	2.8%	6.1%	0.1%	0.0%	0.0%	0.5%
5	2015-2019	87.1%	1.8%	5.7%	4.7%	0.3%	0.3%	0.1%	0.1%
6	2020-2025	78.3%	0.2%	3.1%	17.9%	0.3%	0.1%	0.0%	0.1%
	Total	87.9%	2.7%	4.5%	4.1%	0.5%	0.1%	0.0%	0.1%

AI/AN = American Indian/Alaska Native; NI/PI = Native Hawaiian/Pacific Islander.

Are socio-economic status indicators barriers for enrollment in phase 1 clinical trials?

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Background: Socio-economic Status (SES) indicators create barriers to access Phase 1 clinical trial (Ph1) enrollment, particularly for underrepresented minorities (URM). However, it remains unclear whether they directly affect enrollment after screening, or represent upstream barriers. We evaluated whether SES indicators impacted the enrollment rate in Ph1. **Methods:** All patients were screened for Ph1 at Hackensack University Medical Center (2014–2025). Patient ZIP codes were linked to the U.S. Census data (ACS 2018–2022) to derive neighborhood-level SES indicators: median household income (MHI), educational attainment (Bachelor), poverty rate (PR), unemployment rate (UR), and median home value (MHV). SES indicators were compared to national and state census benchmarks. The primary outcome was enrollment rate by SES indicators. We performed univariate analyses (Mann-Whitney U tests, chi-square), stratified analyses by race/ethnicity and gender, temporal trend analysis, and multivariable logistic regression. **Results:** A total of 1,316 patients were screened for 140 Ph1. Demographics were non-Hispanic White (NHW) 66.2%, Hispanic 19.0%, African American/Black (AA) 7.8%, Asian 6.5%. No SES variable predicted enrollment: median income (enrolled \$62,646 vs not-enrolled \$61,820, $p=0.450$), education (38.3% vs 37.9%, $p=0.598$), poverty (12.9% vs 12.3%, $p=0.416$), unemployment (6.1% vs 6.0%, $p=0.422$), home value (\$277,461 vs \$275,697, $p=0.605$). SES quartile analysis showed no enrollment gradient ($Q_1=61.7\%$, $Q_2=58.1\%$, $Q_3=60.5\%$, $Q_4=63.8\%$; $p=0.491$). Findings were consistent across all racial/ethnic groups (all $p>0.05$), see Table 1, gender (all $p>0.05$), age groups <65 and ≥ 65 years (all $p>0.05$), and time periods 2014–2019 vs 2020–2025. When compared to their respective racial/ethnic groups U.S. Census averages, it demonstrated atypical SES profiles: Hispanic patients had higher education (36.6% vs 20.6%), AA showed higher SES across all indicators, and Asians showed lower SES, suggesting regional selection bias in who reaches Ph1 screening. **Conclusions:** When patients reach Ph1 screening, SES indicators do not predict enrollment, demonstrating that equitable enrollment practices can be achieved at screening. Although there were no visible SES-related barriers at the enrollment point, disparities exist among groups likely suggesting referral patterns prior to screening. Future research should examine how to improve access to Ph1 in URM and upstream inequities. Research Sponsor: None.

SES analysis stratified by race/ethnicity.

Race	SES Variable	p-value
NHW	MHI	0.4476
NHW	Education	0.4585
NHW	PR	0.7483
NHW	UR	0.6957
NHW	MHV	0.4982
Hispanic	MHI	0.8270
Hispanic	Education	0.4104
Hispanic	PR	0.0646
Hispanic	UR	0.2401
Hispanic	MHV	0.9677
AA	MHI	0.9569
AA	Education	0.7355
AA	PR	0.9112
AA	UR	0.3962
AA	MHV	0.3076
Asian	MHI	0.2037
Asian	Education	0.3200
Asian	PR	0.2067
Asian	UR	0.0867
Asian	MHV	0.1677

Early-onset gastrointestinal cancers: Racial disparities in stage and survival from large-scale community oncology data.

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Background: Research on early-onset (EO) gastrointestinal (GI) cancers has focused predominantly on colorectal cancer, leaving knowledge gaps regarding racial variations across other GI malignancies. We used real-world data from a large, nationally representative community oncology network to assess age-of-onset differences in clinical characteristics and survival for colorectal, gastric, and esophageal cancers across key social determinants. **Methods:** This was a retrospective cohort of patients with colorectal, gastric and esophageal cancers treated within the U.S. Oncology Network and non-Network practices from 2000–2025. Patients were categorized as EO (<50 years) or average-onset (AO) ($\geq$ 50 years) at diagnosis. Characteristics including demographics, stage at diagnosis (I–II, III–IV, or unknown), and distress level (NCCN Distress Thermometer) were sourced from iKnowMed. Overall survival (OS) was assessed from diagnosis using Kaplan–Meier methods, stratified by race/ethnicity and stage. **Results:** Among 195,624 patients with GI cancers, 23,244 (11.9%) had EO disease. In the EO cohort, 20,203 (87%) had colorectal, 1,693 (7%) gastric, and 1,348 (6%) esophageal cancers. EO disease occurred in a more racially and ethnically diverse population, with higher representation of Hispanic/Latino (10.3% vs 6.7%), Black (8.2% vs 6.6%), and Indigenous/Native (1.3% vs 0.8%) patients, and higher female representation (46.4% vs 43.9%), versus AO disease. Advanced-stage (III–IV) disease at diagnosis was more common in EO vs AO disease across colorectal (41% vs 32%), esophageal (41% vs 31%), and gastric (37% vs 29%) cancers. Among EO patients, stage III/IV disease at diagnosis was higher in Black (75.3%) and Asian (73.1%) versus White patients (64.9%), whereas among AO patients advanced stage was more balanced across racial groups (66.2%, 64.9%, 62.9%, respectively). Within EO advanced-stage disease, median OS was 8.1 m shorter in Black vs White patients (51.0 vs 59.1 m), compared with only a 1.6 m difference in AO disease (35.0 vs 36.6 m). Among patients with available distress data (N=3,426), distress was higher in EO versus AO patients (median 4 vs 3) but did not differ by race, sex or ethnicity. **Conclusions:** This study represents one of the largest real-world characterizations of EO GI cancers, revealing that EO patients more often present with advanced-stage and higher distress than AO counterparts. While racial disparities in stage were relatively balanced in AO disease, they were exacerbated in EO disease, with Black and Asian patients presenting with substantially higher rates of advanced disease. The resulting survival gap between Black and White EO patients underscores a widening disparity less pronounced in older patients. A precision–public health approach is needed to address biological and socioeconomic drivers of outcomes in young, diverse GI cancer populations. Research Sponsor: None.

Global sex-based disparities in pancreatic cancer clinical trial enrollment: A systematic review and meta-analysis.

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Background: Sex-based disparities in oncology trial enrollment are well recognized, yet their magnitude and consistency in pancreatic cancer clinical trials remain poorly-defined. We conducted a global systematic review and meta-analysis to quantify women's representation in pancreatic cancer trials relative to disease incidence. **Methods:** We identified phase I–III randomized and prospective interventional pancreatic cancer trials published through November 2025 in the top 25 general medicine, oncology, and gastroenterology journals. Women's enrollment was compared with sex-specific pancreatic cancer incidence from Global Burden of Disease estimates. Enrollment disparity difference (EDD) was calculated as the proportion of women enrolled minus the proportion of women in the underlying disease population. Random-effects meta-analyses, subgroup analyses, and temporal meta-regression were performed. **Results:** Among 191 eligible trials including 37,688 participants, 16,393 (43.5%) were women. Overall, women were significantly under-enrolled, with a pooled EDD of -0.050 (95% CI, -0.058 to -0.042). Under-enrollment was observed across all geographic regions, with the largest disparity in European trials (EDD -0.069 ; 95% CI, -0.080 to -0.058). Significant disparities were present across all trial phases except combined phase I/II studies and were most pronounced in trials enrolling fewer than 50 participants (EDD -0.081 ; 95% CI, -0.105 to -0.057). Women remained under-enrolled across chemotherapy, immunotherapy/biologic, vaccine, and multimodal trials, while no significant disparity was observed in radiotherapy studies. Trials with women in leadership roles demonstrated slightly attenuated but persistent under-enrollment (EDD -0.046 vs -0.052). Temporal analyses showed narrowing of disparities between 2016 and 2020, followed by worsening under-enrollment from 2021 to 2025 (EDD -0.033). Sensitivity analyses limited to chemotherapy, immunotherapy/biologic, and phase III trials confirmed consistent patterns of under-representation. **Conclusions:** Women are persistently under-enrolled in pancreatic cancer clinical trials worldwide, with disparities evident across regions, trial phases, and treatment modalities. Recent reversals in progress highlight the need for durable, equity-focused trial design and enrollment strategies. Research Sponsor: None.

Who gets access? National discrepancies in clinical trial enrollment among patients with brain metastases.

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Background: Patients with brain metastases (BM) have historically been underrepresented in clinical trials. Contemporary national data describing clinical trial enrollment (CTE) patterns and sociodemographic predictors in this population remain limited. **Methods:** Using the National Cancer Database, adults (≥ 18 years) diagnosed with BM (2010–2021) from the five most common primary sites (lung, breast, melanoma, colorectal, and renal cell carcinoma) were included. The key outcome was CTE (yes/no). Multivariable logistic regression was used to evaluate associations between enrollment and primary tumor site, age, sex, race/ethnicity, facility type, geographic region, residence, insurance status, area-level education and income, comorbidity burden (Charlson–Deyo score), and time epoch (2010–2013, 2014–2017, 2018–2021). **Results:** The analytic cohort included 238,129 patients with BM (lung $n=206,813$; melanoma $n=10,394$; breast $n=9,915$; renal $n=7,409$; colorectal $n=3,598$). Overall, $<1\%$ of patients ($n=385$) had CTE. In adjusted analyses, compared with patients aged 18–39 years, those aged 40–64 years (aOR: 0.15) and ≥ 65 years (aOR: 0.12) had significantly lower odds of enrollment ($P<0.001$). Female sex was associated with higher enrollment (aOR: 1.30, $P=0.013$), while Hispanic ethnicity was associated with lower enrollment compared with non-Hispanic White patients (aOR: 0.39, $P=0.014$). Higher comorbidity burden (Charlson–Deyo score: 2–3) was associated with lower enrollment (aOR: 0.68, $P=0.04$). Treatment at an academic/research facility had the highest odds of CTE compared with community facilities (aOR: 4.83, $P<0.001$), as well as care within an integrated network (aOR: 1.87, $P=0.001$). CTE increased over time (2014–2017, aOR 1.58, $P=0.002$; 2018–2021, aOR 1.63, $P=0.001$, vs 2010–2013). **Conclusions:** CTE among patients with BM was low across primary tumor sites. Enrollment was higher at academic facilities and among younger patients, while Hispanic patients had lower odds of enrollment. These findings indicate persistent disparities in clinical trial access and support more inclusive enrollment strategies for patients with BM. Research Sponsor: None.

Key predictors of CTE.

Variable	Strata	aOR (95% CI)	P
Sex	Male (Ref)	-	-
	Female	1.30 (1.06–1.60)	0.013*
Race/ethnicity	NH-White (Ref)	-	-
	NH-Black	0.83 (0.57–1.16)	0.292
	Hispanic	0.39 (0.16–0.77)	0.014*
	Asian/Other	0.87 (0.54–1.32)	0.526
Facility type	Community (Ref)	-	-
	Academic/Research	4.83 (3.69–6.39)	$<0.001^*$
	Integrated Network	1.87 (1.31–2.67)	0.001*

*Geographic region, residence, and insurance status were insignificant.

Validation of a 10-item frailty index based on a comprehensive geriatric assessment (FI-CGA-10) for predicting survival in older adults with cancer.

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Background: The FI-CGA-10 is a content- and construct-validated measure for quantifying frailty from a CGA [Oncologist, 26, e1751 (2021)]. For criterion validation, we evaluated the predictive validity of the FI-CGA-10 for survival in older adults with cancer. **Methods:** This prospective cohort study included 1,630 consecutive older adults with cancer who underwent CGA prior to their cancer treatment decision at a geriatric oncology service in Japan from September 2018 through September 2024. Fitness and frailty were evaluated using the FI-CGA-10, which comprises ten domains: cognition, mood, communication, mobility, balance, nutrition, basic and instrumental activities of daily living (ADLs/IADLs), social support, and comorbidity. Deficits in each domain were scored 0 (no problem), 0.5 (minor problem), or 1.0 (major problem). FI-CGA-10 scores were calculated as the sum of domain scores divided by 10 and categorized as fit (<0.20), pre-frail ($0.20-0.35$), and frail (>0.35). The primary outcome was overall survival (OS) at 1 year from the date of CGA. Two Cox proportional hazards models were fitted to predict 1-year overall survival (OS): a base model (age, sex, cancer type, and stage) and the base model plus the FI-CGA-10 as a categorical variable. Model performance was compared using the likelihood ratio test and Harrell's c-index. We also examined associations between each FI-CGA-10 domain and 1-year OS, adjusting for the same covariates. **Results:** Median age was 80 years (range, 51–99); 61% were male, 46% had gastrointestinal cancer, and 41% had distant-stage disease. Overall, 22% were fit, 38% pre-frail, and 40% frail; 29% died within one year. By the likelihood ratio test, adding the FI-CGA-10 significantly improved model fit compared with the base model ($\text{LR } \chi^2 = 140.7$; $P < .001$). Adding the FI-CGA-10 also significantly improved discrimination (c-index 0.70 vs 0.76; $P < .001$). Kaplan–Meier curves for the three groups showed clear separation, demonstrating the FI-CGA-10's discriminatory ability (log-rank $P < .001$). After adjustment for covariates, pre-frail (HR 2.26; 95% CI 1.61–3.19) and frail (HR 5.06; 95% CI 3.64–7.04) patients had higher hazards of death versus fit patients. Estimated 1-year OS probabilities were 90% (fit), 78% (pre-frail), and 58% (frail). In multivariable analyses adjusted for age, sex, cancer type, and stage, major problems in all domains—and minor problems in cognition, mobility, balance, nutrition, IADL, and comorbidity—were significantly associated with worse survival compared with no problems. **Conclusions:** These findings support the predictive validity of the FI-CGA-10 for 1-year OS in older adults with cancer. Together with prior work demonstrating its content and construct validity, the FI-CGA-10 satisfies core components of measurement validation that can help clinicians care for older cancer patients. Research Sponsor: JSPS KAKENHI; 20K16540 (T.F.N.) and 25K20897 (T.F.N.).

Use of parsimonious Fitbit step metrics to improve frailty classification in adults ≥ 50 with cancer in NIH All of Us.

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Background: Frailty predicts treatment intolerance and adverse outcomes in older adults with cancer, yet scalable screening remains limited. Scalable frailty screening is particularly relevant for treatment selection and risk stratification in routine oncology care. We tested whether routine Fitbit step metrics improve frailty classification beyond basic variables and whether high-dimensional step-pattern features add benefit. **Methods:** Retrospective cross-sectional study in the NIH All of Us Research Program including adults ≥ 50 years with cancer history and Fitbit step data ($N=378$). Frailty was defined by a 33-item All of Us deficit frailty index (fit <0.15 , vulnerable $0.15-0.25$, frail >0.25); primary endpoint was frail vs not frail (fit+vulnerable). Valid wear day required ≥ 10 hours with activity or heart-rate evidence. Missing days were imputed for daily totals and minute-level profiles reconstructed using within-person donor days or weekday/weekend templates. Prespecified feature tiers were: basic (9), basic+average steps (10), and high-dimensional step-pattern features (108; minute-level intensity, variability, and frequency-domain summaries). Class-weighted elastic-net logistic regression, random forest, and gradient-boosted trees were tuned and evaluated with nested 5×5 cross-validation. Discrimination was pooled out-of-fold area under the receiver operating characteristic curve (AUC) with stratified bootstrap 95% confidence intervals (CI); incremental value used paired bootstrap Δ AUC. **Results:** Participants were 64.8 ± 8.6 years; 67.7% were female. Frailty categories were fit 43.7%, vulnerable 40.7%, and frail 15.6% (59/378). Mean daily steps were lower in frail vs not frail participants (5505 vs 7648 steps/day). Elastic-net logistic regression with step features achieved the highest AUC (0.713, 95% CI 0.636–0.783) vs the basic model (0.644, 95% CI 0.567–0.720; Δ AUC 0.068, paired bootstrap 95% CI 0.002–0.133). At $\geq 90\%$ specificity, sensitivity increased from 25.4% (15/59) to 39.0% (23/59). In secondary analyses predicting not-fit status (vulnerable/frail vs fit), adding step features improved AUC from 0.551 (95% CI 0.493–0.609) to 0.635 (95% CI 0.580–0.694). High-dimensional step features did not improve AUC. **Conclusions:** In adults ≥ 50 with cancer, a parsimonious step-based metric improved frailty classification and increased sensitivity at high specificity, while complex feature sets and models did not add benefit. These findings support low-burden step metrics as scalable adjuncts to frailty screening in oncology; external validation is needed. Research Sponsor: National Institutes of Health (NIH) All of Us Research Program.

GRACE: A conversational AI platform for geriatric oncology risk and capability evaluation.

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Background: Comprehensive geriatric assessment (CGA) is a multidimensional evaluation of health in older adults and endorsed by the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN) for improved outcomes in geriatric cancer patients. However, CGA is underutilized due to time constraints and staffing shortages. Artificial intelligence (AI) can provide autonomous geriatric assessments (GA) but require validation. **Methods:** GRACE, an AI platform for GA via natural language interaction, was tested against manual GA. 70 adults aged ≥ 65 were enrolled from UCLA using the portal MyChart and at affiliated active senior living centers. 15 clinicians contributed qualitative perspectives. Concordance was evaluated using sensitivity, specificity, predictive values, and agreement (Cohen's κ , Gwet's AC1). Usability was measured with the System Usability Scale (SUS), and patient and provider interviews were thematically analyzed. **Results:** GRACE showed high diagnostic performance (sensitivity 0.73, specificity 0.94, $\kappa=0.63$, AC1=0.82) with highest agreement in polypharmacy ($\kappa \approx 0.97$; AC1=0.98). Usability was high (SUS >80th percentile) and 84% of participants reported confidence using GRACE. Clinicians endorsed GRACE as a practical pre-visit intake tool that integrates with electronic health records and facilitates timely referrals. **Conclusions:** GRACE demonstrates that conversational AI can replicate key elements of clinician-administered GA while reducing burden on oncology teams. Larger multi-site studies are warranted to evaluate clinical impact and integration into routine oncology practice. Research Sponsor: None.

Performance of GRACE versus manual geriatric assessment.

Domain	Sensitivity (CI)	Specificity (CI)	PPV (CI)	NPV (CI)	Cohen's Kappa (CI)	Gwet's AC1 (CI)
General Health	0.872 (0.748, 0.940)	0.931 (0.891, 0.957)	0.719 (0.592, 0.819)	0.973 (0.943, 0.988)	0.741 (0.637, 0.845)	0.887 (0.839, 0.935)
Physical	0.859 (0.760, 0.922)	0.971 (0.956, 0.981)	0.753 (0.649, 0.834)	0.985 (0.973, 0.992)	0.781 (0.704, 0.858)	0.953 (0.935, 0.970)
Functional	0.563 (0.332, 0.769)	0.985 (0.971, 0.993)	0.529 (0.310, 0.738)	0.987 (0.974, 0.994)	0.532 (0.298, 0.765)	0.972 (0.957, 0.986)
Social Support	0.629 (0.530, 0.718)	0.873 (0.839, 0.900)	0.508 (0.420, 0.596)	0.918 (0.889, 0.940)	0.458 (0.359, 0.558)	0.753 (0.702, 0.805)
Psychological	0.570 (0.460, 0.673)	0.920 (0.894, 0.940)	0.506 (0.404, 0.607)	0.937 (0.913, 0.955)	0.465 (0.353, 0.576)	0.839 (0.802, 0.876)
Comorbidity	0.641 (0.484, 0.773)	0.996 (0.989, 0.998)	0.862 (0.694, 0.945)	0.985 (0.975, 0.991)	0.726 (0.601, 0.851)	0.980 (0.971, 0.989)
Polypharmacy	0.974 (0.865, 0.995)	1.000 (0.893, 1.000)	1.000 (0.906, 1.000)	0.970 (0.847, 0.995)	0.971 (0.915, 1.027)	0.972 (0.916, 1.027)
Overall	0.721 (0.674, 0.763)	0.956 (0.949, 0.963)	0.649 (0.603, 0.692)	0.968 (0.962, 0.974)	0.645 (0.604, 0.687)	0.917 (0.907, 0.927)

Development of a composite risk score for chemotherapy toxicity and unplanned hospitalization in older adults with cancer: A prospective cohort study.

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Background: Older adults receiving chemotherapy are at high risk for severe treatment-related toxicities, which may compromise treatment completion and lead to unplanned hospitalizations. We developed a composite risk score integrating the components of Cancer and Aging Research Group (CARG) chemotherapy toxicity score and proved clinical predictors to enhance prediction of grade 3–5 (G3–5) chemotherapy-related toxicities, treatment tolerance, and unplanned hospitalization. **Methods:** Patients aged ≥ 70 years with solid tumors initiating chemotherapy were enrolled between December 2024 and August 2025 at a tertiary hospital in Shanghai, China. The primary endpoint was the occurrence of any G3–5 chemotherapy-related toxicity; secondary endpoints included chemotherapy incompleteness and unplanned hospitalization. Baseline characteristics included the CARG score, tumor- and treatment-related characteristics, and laboratory parameters. Toxicities (graded using CTCAE v5.0), treatment completion, and unplanned hospitalizations were assessed at each cycle for up to 6 months or until completion of the planned treatment course. Predictors of G3–5 toxicities were screened by LASSO-penalized multivariable logistic regression, and model discrimination was evaluated by receiver operating characteristic curve. **Results:** Among 242 patients (median age 74 years; range 70–88), 71.9% were male, 64.5% had gastrointestinal malignancies, and 73.1% had stage IV disease. Overall, 164 patients (67.8%) experienced G3–5 toxicities, and 63 (26.0%) had unplanned hospitalizations. The score system included cancer type, hemoglobin, estimated glomerular filtration rate, falls within 6 months, medication management ability, C-reactive protein/albumin, MAX2 index, walking ability, and social activity level. The median score was 10 (range 6–14). Each one-point increase in score was associated with higher risk of any G3–5 toxicity (OR 1.21, 95% CI 1.14–1.30; AUC 0.75) and non-hematologic G3–5 toxicity (OR 1.19, 95% CI 1.12–1.27; AUC 0.73). The score was also positively associated with unplanned hospitalization (OR 1.07, 95% CI 1.01–1.13; AUC 0.62), but was inversely associated with chemotherapy incompleteness (OR 0.93, $p=0.019$), suggesting more proactive treatment modifications in high-risk patients. In this cohort, the new score showed superior discrimination for any G3–5 toxicity, with a higher AUC than the CARG score (0.75 vs. 0.63). The optimal cutoff point of any G3–5 toxicity was 7.5 with relatively good specificity (72%) and sensitivity (65%). **Conclusions:** The composite score may help predict G3–5 toxicity, non-hematologic G3–5 toxicities, and unplanned hospitalization, potentially outperforming the CARG score. External validation and evaluation of clinical utility are warranted. Research Sponsor: None.

Practice patterns and outcomes by genomic risk in octogenarians with high-risk localized prostate cancer: A national real-world data analysis.

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Background: Chronologic age and traditional clinical-pathologic prostate cancer (PCa) risk factors (e.g. PSA, Gleason Score) are useful but incomplete predictors of prognosis. While some octogenarians may benefit from watchful waiting for clinically high risk (HR) and very high risk (VHR) PCa due to competing risks, others may survive more than a decade with curative prostate-directed treatment. We examined real-world data (RWD) on practice patterns and outcomes for octogenarians with HR PCa stratified by genomic classifier (GC) scores. **Methods:** A retrospective cohort study was conducted using a national database of clinical-genomic linkage of Decipher GC with longitudinal RWD (Veracyte, South San Francisco, CA). The cohort included 1,519 patients, ≥ 80 -years-old with HR/VHR PCa who underwent GC testing with >1 year of follow-up. Patients were stratified by low (GC-Low) compared to intermediate or high (GC-High/Int) GC scores. Observational management was determined by absence of treatment with evidence of prostate cancer-related services (e.g. GC-High/Int-Obs). Freedom from distant metastases (FFDM), metastasis-free survival (MFS), and overall survival (OS) were modeled using Kaplan-Meier analysis and log-rank tests. **Results:** Most patients (88%, $n=1,341$) had GC-High/Int. The rate of observational management was significantly lower in the GC-High/Int compared to GC-Low cohorts (26% vs 38%, $p=0.001$). Among treated patients, there were similar rates of ADT only use (52% GC-Low vs 54% GC-High/Int) but amongst those who were treated with radiotherapy, concurrent ADT use was lower in GC-Low compared to GC-High/Int (55% vs 69%, OR 0.83, 95% CI 0.73-0.95, $p=0.007$). There were significant differences between groups for FFDM ($p=0.003$), MFS ($p<0.001$), and OS ($p<0.001$) (Table). Among observed patients, GC-Low had significantly better FFDM than GC-High/Int (HR 0.11, 95% CI 0.02-0.80; $p=0.03$). **Conclusions:** Geriatric patients with aggressive, localized PCa decide between potentially morbid, curative treatments and heterogeneous risk of distant metastases in the setting of limited life expectancy. We present RWD that patients ≥ 80 years old with NCCN HR/VHR PCa with low GC scores have $<5\%$ rate of metastatic disease within 5 years with observation alone. This hypothesis generating data suggests GC score may be a useful prognostic tool in addition to standard clinical-pathologic factors for elderly patients. Patient-specific risk calculators for cancer and non-cancer specific mortality may help this underserved but growing population. Research Sponsor: Veracyte Inc.

	NCCN HR (%)	NCCN VHR (%)	FFDM Hazard Ratio (95% CI)	5-yr FFDM	5-yr MFS	5-yr OS
GC-Low-Obs	58 (85%)	10 (15%)	0.11 (0.02-0.80)	98%	70%	71%
GC-Low-Treat	90 (82%)	20 (18%)	0.76 (0.36-1.59)	82%	75%	91%
GC-High/Int-Obs	250 (71%)	104 (29%)	Reference	83%	37%	43%
GC-High/Int-Treat	633 (64%)	354 (36%)	1.35 (0.93-1.98)	81%	59%	64%

Evaluation of a co-designed nurse-led geriatric oncology multidisciplinary model in treatment-naïve older adults with solid cancers.

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Background: Integration of geriatric assessment into cancer care improves outcomes for older adults but remains limited by resource intensity and reliance on physician time, hence restricting scalability. We evaluated the implementation of a co-created multidisciplinary (MDT) nurse-led geriatric oncology (GO) model developed to address these barriers. **Methods:** Implementation evaluation was conducted across two tertiary cancer centers. Older adults (≥ 65 years) with solid cancers underwent nurse-led structured geriatric assessment and MDT review involving medical oncology and geriatric medicine prior to oncology consultation. MDT recommendations addressed identified vulnerabilities, with referral for geriatrician-led CGA reserved for complex cases. Outcomes included G8 screening, referral for CGA, SACT delivery, treatment modification due to frailty, treatment discontinuation, delays, dose modification due to toxicity, and health service utilization (ED, SURC and unplanned hospital admissions within 12 weeks). Demographic and clinical characteristics were summarized using descriptive statistics. Associations with health service use were determined using logistic regression analyses. **Results:** Of 431 eligible pts, 204 (47.3%) participated in the GO assessment. Median age was 76 years. Most pts had lung cancer (73.1%), followed by GU (14.8%) and upper GI cancers (8.6%). Disease stage did not differ between groups; GO pts were more likely to have ECOG PS 1–2 and 81.4% scored ≤ 14 on the G8 screening tool. Half (50.7%) were referred for CGA and 67.1% of this cohort received SACT while 32.4% of the cohort not referred for a CGA received SACT. Upfront treatment modification due to frailty was numerically higher in GO pts compared to non-participants (21.1% vs 13.1%, $p=0.076$). GO participation was associated with higher receipt of SACT (70.6% vs 59.7%, $p=0.019$), increased use of monotherapy (22.5% vs 13.7%, $p=0.016$), and lower rates of BSC alone (41.0% vs 59.0%, $p=0.033$). There were no differences between groups in treatment discontinuation ($p=0.64$), delays ($p=0.074$), or dose modifications due to toxicity ($p=0.42$). GO pts were more likely to be admitted to hospital within 12 weeks of initial oncology consultation. **Conclusions:** GO assessment supported detailed evaluation of older pts with borderline ECOG PS and increased access to SACT, particularly monotherapy, without increasing treatment-related toxicity. Higher hospitalization rates likely reflect appropriate escalation of care following identification of frailty-related needs. Research Sponsor: None.

GO vs no GO.			
	GO (n=204)	No GO (n=227)	p-value
Age median (range)	76.0 (72.0, 81.0)	76.0 (71.0, 81.0)	0.77
Monotherapy	46 (22.5%)	31 (13.7%)	0.016
Doublet, or more therapy	98 (48%)	101 (44.5%)	0.46
ED presentation	93 (45.6%)	86 (37.9%)	0.11
SURC use	43 (21.1%)	49 (21.6%)	0.90
Inpatient admission	74 (36.3%)	62 (27.3%)	0.046

Outcomes of mortality and health care utilization in frail older patients with cancer receiving target therapies and/or immunotherapy.

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Background: ASCO & NCCN guidelines recommend geriatric assessment for cancer patients aged 65+ to identify vulnerabilities missed on standard evaluations. Patients with G8 ≤ 14 (High risk) are potentially frail and at risk for chemotherapy toxicity, early mortality and ED visits/hospitalizations. However, there is currently limited evidence regarding the impact of a high-risk G8 score on outcomes among older frail patients receiving immunotherapy or targeted therapies. **Methods:** G8 screening was done at initial oncology consultation. Data was analyzed for individuals aged 65 and above referred between January 2021 and December 2024. Outcomes were measured 180 days after referral. A chi-square test assessed the relationship between demographic or outcome variables and G8 score. Multivariate regression and survival models predicted outcomes using age, sex, ethnicity, cancer type, and risk score. **Results:** This study included 1,671 patients receiving targeted therapy and/or immunotherapy. Participants ranged in age from 65 to 102 (median 75). Higher risk scores were linked to lower BMI (underweight: 92%, healthy: 74%, overweight/obese: 57%, $p < .0001$), older age ($p < .0001$), and female sex (73% vs 62%, $p < .0001$). Ethnicity was not related to risk scores. High risk patients receiving target and/or immunotherapy had over 3x higher mortality rates at 180 days than low risk ones ($p < 0.0001$). They were also 1.4x as likely to have an ED Visit or hospitalization, 2x as likely to be referred to palliative care, and 5x as likely to be referred to hospice ($p < 0.0001$). Multivariate analysis showed patients with upper GI and thoracic cancers were 1.4x more likely to be admitted and had over 2.7x mortality rate compared to those with breast cancer ($p < .0001 - 0.0188$). A total of 515 patients underwent only immunotherapy. Outcome trends and the association between risk score and demographics were similar to the combined target therapy and/or immunotherapy study. **Conclusions:** A high-risk G8 score (≤ 14) is linked to higher mortality and more emergency visits or hospitalizations in older cancer patients receiving immunotherapy or targeted therapies. It is recommended that oncologists integrate geriatric assessment results into treatment decisions involving immunotherapy and targeted therapies. Research Sponsor: None.

Outcomes of patients by risk score and treatment type 180 days after referral.

Risk Score/Treatment Type	Mortality	ED Visits or Hospitalizations	Palliative Care Referral	Hospice Referral
High risk G8-Combined target/Immunotherapy	15.3%	51.1%	33.0%	12.1%
Low risk G8 - Combined Target/Immunotherapy	3.7%	29.2%	14.8%	2.3%
p-value	<0.0001	<0.0001	<0.0001	<0.0001
High risk G8 - Immunotherapy alone	26.5%	61.5%	40.1%	22.3%
Low risk G8 - Immunotherapy alone	8.7%	43.5%	19.6%	5.1%
p-value	<0.0001	0.001	<0.0001	<0.0001

G8 screening-defined geriatric vulnerability as a predictor of survival and quality of life in older patients with advanced cancer treated with novel therapies.

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Background: Older patients with advanced cancer are a highly heterogeneous population, in whom geriatric vulnerability may significantly influence survival, treatment tolerance, and patient-reported outcomes. The G8 screening tool is a validated instrument designed to identify geriatric vulnerability and select patients for comprehensive geriatric assessment; however, its prognostic and longitudinal impact on quality of life in patients receiving novel anticancer therapies remains poorly explored. **Methods:** The ONC-OLD study prospectively enrolled patients aged ≥ 70 years with advanced cancer treated with novel therapies across six referral centers. The primary objective was to assess the prognostic impact of baseline G8-defined geriatric vulnerability on overall survival (OS). Geriatric vulnerability was assessed at baseline using the G8 screening tool (≤ 14 vs > 14). Health-related quality of life (HRQoL) was assessed using the EORTC QLQ-C30 and QLQ-ELD14 at baseline, after 3 months, and at disease progression. Baseline associations were analyzed using multivariable regression models, while longitudinal HRQoL changes were assessed using ANCOVA adjusted for baseline scores and relevant clinical covariates. **Results:** A total of 143 patients were included (median age 78 years, IQR 75–82); 78% had ECOG performance status (PS) 0–1, and 73% had G8 ≤ 14 . Treatments consisted mainly of immunotherapy, either as monotherapy (31%) or in combination (36%), and targeted therapy (30%). At baseline, patients with G8 ≤ 14 were older (≥ 80 years: 46% vs 20%, $p=0.019$), more frequently female (42% vs 16%, $p=0.016$), and had worse ECOG PS (PS ≥ 2 : 25% vs 0%, $p=0.005$) compared with those with G8 > 14 , with a different distribution of primary tumor types (lung cancer: 67% vs 29%, $p=0.001$). Median OS was 16.1 months (95% CI, 13.4–not reached) and was significantly shorter in patients with G8 ≤ 14 compared with those with G8 > 14 (14.2 vs not reached; $p=0.019$). G8 ≤ 14 was independently associated with an increased risk of death (HR 2.71, 95% CI 1.01–7.24; $p=0.047$), after adjustment for ECOG PS, number of metastatic sites, treatment line and type. G8 ≤ 14 was associated with a trend toward a higher risk of grade ≥ 3 adverse events (OR 2.00, 95% CI 0.69–7.25; $p=0.23$), without specific treatment-related safety signals. At baseline, patients with impaired G8 reported worse global health, physical and role functioning, fatigue, pain, and mobility (all $p \leq 0.01$). In longitudinal analyses adjusted for baseline HRQoL and clinical covariates (ECOG PS, age, treatment), G8 remained significantly associated with higher fatigue (+12.6 points; $p=0.039$). **Conclusions:** Baseline G8 impairment is associated with poorer survival, worse baseline HRQoL, and a higher risk of severe toxicity, supporting the clinical value of G8 screening in older patients treated with novel therapies. Research Sponsor: PNRR - M4C2-I1.3 Project PE_00000019 "HEAL ITALIA"; CUP J33C22002920006.

Age-related efficacy of antibody-drug conjugates in solid tumors: A meta-analysis.

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Background: Antibody–drug conjugates (ADC) have revolutionized cancer therapeutics, with various ADC improving clinical outcomes across solid tumors and several now approved as standard of care. Older adults with cancer are historically underrepresented in trials. As therapies with ADC are shifting to earlier lines of therapy, investigating whether clinical outcomes differ from those of younger patients with cancer is of interest. **Methods:** We searched PubMed, Embase, and the CENTRAL databases from inception through Dec 2025 for phase III randomized controlled trials (RCTs) that included adult patients with metastatic solid tumors treated with ADC and reported survival outcomes stratified by age group: elderly (>65 years) and younger (<65 years). The co-primary endpoints were progression-free survival (PFS) and overall survival (OS) across these age subgroups. Pre-specified subgroup analyses were performed according to ADC drug, target, and cancer types. Time-to-event outcomes were pooled as hazard ratios (HR) using the inverse-variance method with random-effects models. Heterogeneity was assessed using the I^2 . PROSPERO: CRD4202612924710. **Results:** Of 2194 records, 17 RCTs (phase 3) met eligibility, including 9,929 patients, spanning breast (n=12), lung (n=2), urothelial (n=1), ovarian (n=1), and gastric cancer (n=1). ADCs were stratified by payloads: topoisomerase I inhibitors (TOPO1i; 65%), microtubule inhibitors (MMAE; 29%), alkylating agents (6%); and targets: TROP-2 (53%), HER2 (41%), and FR α (6%). Elderly pts treated with ADC exhibited significant improvement in PFS with a HR of 0.57 (95% CI 0.46–0.71; $p < 0.01$; $I^2 = 62\%$). Similarly, younger pts exhibited longer PFS, with a HR of 0.55 (95% CI 0.45–0.67; $p < 0.01$; $I^2 = 86\%$). Likewise, elderly patients exhibited significantly greater OS with a HR of 0.78 (95% CI 0.66–0.91; $p < 0.01$; $I^2 = 41\%$), comparable to that observed in younger pts (HR 0.74; 95% CI 0.65–0.85; $p < 0.01$; $I^2 = 63\%$). Specifically, in elderly patients with breast cancer treated with ADC (n=7,213), significant improvements were seen with an HR of 0.49 (95% CI 0.36–0.67; $p < 0.01$) and 0.65 (95% CI 0.48–0.87; $p < 0.01$; $I^2 = 39\%$) for PFS and OS, respectively. Similar improvements in survival outcomes were seen in younger pts (HR of 0.53; 95% CI 0.42–0.67 and HR of 0.66; 95% CI 0.57–0.77, for PFS and OS, respectively. Pre-specified subgroup analyses according to ADC payloads showed no differences in pts treated with ADC plus TOPO1i (HR 0.76 and 0.70, $p < 0.01$). Notably, ADCs with MMAE payloads were associated with benefit only in the elderly (HR 0.77, $p < 0.01$), with no significant benefit in younger patients (HR 0.82, $p = 0.11$). **Conclusions:** In this pooled analysis, including 5,111 pts treated with ADC under phase III RCTs, survival outcomes with ADC therapies were similar regardless of age. As the number of ADCs approved for the standard of care setting is expected to increase, age should not be an exclusion criteria. Research Sponsor: None.

Integrating objective sarcopenia assessment into geriatric screening as a predictor of treatment tolerance.

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Background: Geriatric assessment (GA)–based screening tools, including the G8 screening tool, the Korean Cancer Study Group Geriatric Score (KG-7), and the Cancer and Aging Research Group (CARG) toxicity score, are widely used to guide treatment decisions in older patients with cancer. However, these tools incompletely capture biological reserve and show limited accuracy in predicting treatment tolerance, particularly in patients with indeterminate risk. We evaluated whether incorporating objective sarcopenia assessment could improve risk stratification.

Methods: We retrospectively analyzed 97 elderly patients with cancer (age ≥ 70 years) who underwent GA screening prior to treatment decision-making at a single tertiary center between May 2024 and December 2025. In addition to standard GA tools (G8, KG-7, and CARG toxicity score), skeletal muscle index (SMI) and functional frailty were assessed. SMI was measured using the DYPHI body water analysis (BWA) system, which estimates appendicular lean mass through multi-frequency bioelectrical impedance analysis. Functional frailty was evaluated using the Short Physical Performance Battery (SPPB). Treatment intolerance was defined as grade 3–5 toxicity, unplanned hospitalization, emergency room visit, or treatment discontinuation. Multivariable logistic regression and subgroup analyses were performed. **Results:** The median age was 76 years (range, 61–87), and 77 patients (79.4%) were male. Most patients had advanced-stage disease (72.2%), and 55.7% received palliative treatment. Initial dose reduction ($<100\%$) occurred in 63.9%. GA tools, sarcopenia, and frailty showed modest concordance. Among GA tools, G8 demonstrated the strongest association with treatment intolerance (odds ratio [OR] per point increase 0.86, 95% confidence interval [CI] 0.74–0.99; $p=0.03$; area under the curve [AUC] 0.64). Sarcopenia was independently associated with treatment intolerance (OR 2.45, 95% CI 1.02–5.87; $p=0.045$) and improved discrimination across G8, KG-7, and CARG tools (Δ AUC up to +0.12). The benefit of sarcopenia was greatest in borderline or intermediate GA risk groups (Δ AUC approximately +0.10–0.12), with minimal improvement in low- or high-risk groups (Δ AUC ≤ 0.02). A minimal model incorporating G8, sarcopenia, and Eastern Cooperative Oncology Group (ECOG) performance status achieved the best performance (cross-validated AUC 0.68). **Conclusions:** Incorporation of objective sarcopenia assessment using the DYPHI BWA system significantly improves prediction of treatment tolerance beyond established GA tools, particularly in intermediate-risk subgroups. A pragmatic model combining G8, sarcopenia, and ECOG performance status may refine risk stratification and personalize treatment decisions in geriatric oncology. Research Sponsor: None.

Online peer support for breast cancer survivors: A decentralized multicenter non-blinded parallel-group pilot randomized controlled trial (HOPE-BC study).

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Background: Peer support effectiveness for breast cancer survivors has reportedly varied, and no study has examined patient–supporter matching. This decentralized, multicenter, non-blinded pilot randomized controlled trial aimed to assess online peer support effectiveness and explore factors for a matching algorithm. **Methods:** Breast cancer survivors within three years of completing initial treatment were recruited and provided electronic informed consent. Based on the sample size estimation, the target sample size was set at 50. Participants were randomly assigned either to the peer support group, which scheduled an online peer support session immediately after registration, or to the waitlist group, which scheduled their session two weeks later. Participants could choose their preferred time and date through a web-based scheduling system. Peer support sessions were conducted online by two trained peer supporters. The primary outcome was the UCLA Loneliness Scale score, assessed one week after the session in the peer support group and at the end of the 2-week waiting period in the waitlist group. Secondary outcomes included satisfaction with peer support and other psychosocial measures, all collected through an electronic patient-reported outcome system. Effect sizes for outcomes were calculated to inform sample size estimation for future trials. Analyses were performed to explore factors associated with satisfaction. The study protocol was registered in the UMIN Clinical Trials Registry (UMIN000056741). **Results:** From February to July 2025, 54 participants enrolled and 52 individuals completed the study (27 peer support group, 25 waitlist group). At the primary endpoint, the mean (standard deviation) UCLA Loneliness Scale scores were 38.4 (11.2) in the peer support group and 41.3 (13.3) in the waitlist group (Cohen's $d = 0.24$; t -test, $P = 0.40$). The change from baseline corresponded to a Cohen's $d = 0.32$. Among the secondary outcomes, the changes in Generalized Anxiety Disorder-7 scores differed between groups (mean difference [MD] = -1.3 ; 95% CI = -2.5 to -0.1), and the changes in Patient Health Questionnaire-9 scores tended to be greater in the peer support group (MD = -1.2 ; 95% CI = -2.5 to 0.1). The global health status on EORTC QLQ-C30 did not differ between groups (MD = 1.0 ; 95% CI = -6.6 to 8.7). The median (IQR) satisfaction score was 46 (41.5, 50) on a 50-point scale. A linear mixed-effects model indicated that sharing ≥ 1 topic and age proximity between the participant and peer supporter were significantly associated with higher satisfaction. **Conclusions:** Results demonstrate the feasibility of future decentralized randomized trials on online peer support and provide effect size estimates to guide sample size planning. Shared topics and age proximity between participants and peer supporters may be considered when scheduling sessions. Research Sponsor: None.

Evaluation of a remote electronic assessment of survivors with tailored follow-up recommendations and survivorship messaging (REASSURE) to improve the delivery of follow-up for low-risk breast cancer survivors.

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Background: Current follow-up care for the 2 million+ low-risk breast cancer survivors fails to adequately address survivors' needs and burdens survivors and oncology teams. We evaluated a novel approach to follow-up that comprehensively assesses survivors' symptoms and concerns and uses that information to tailor follow-up frequency. **Methods:** We conducted a randomized trial at an academic and community breast clinic. Eligible survivors had a history of stage I breast cancer that was ER or PR +/Her2-, were 6-36 months from diagnosis, and did not receive chemotherapy. Survivors were randomized 1:1 to REASSURE versus usual care and followed for 18-months. REASSURE was developed through stakeholder engagement and comprises three components integrated around follow-up visits: 1) Online patient-reported symptoms and concerns (PRO), 2) Tailored follow-up visit recommendations based on the PRO, and 3) Survivorship messaging. The primary outcome was survivors' preparedness for survivorship and confidence about follow-up, measured at 18-months by the Preparing for Life as a (New) Survivor (PLANS) scale. Secondary outcomes included number of oncology follow-up visits, proportion of reported symptoms that were discussed, and acceptability of REASSURE. Continuous variables were analyzed using t-tests or Wilcoxon tests. The proportion of symptoms discussed was analyzed using a generalized linear mixed model for binomial data. **Results:** Of the 104 consented patients, 3 did not complete any study activities and 1 withdrew (n=100). The median age was 63 (range 36-86), most were White (98%), and 19% resided in a rural locale. Preparedness for survivorship and confidence did not differ between REASSURE and usual care (Table). Symptoms or concerns were reported on 50.4% of PRO assessments. In the REASSURE arm, 80% of survivors accepted the recommendation to forgo a visit. Fewer follow-up visits were observed with REASSURE (M=2.1, SD 1.0) than usual care (M=2.6, SD 1.0), p=0.007. There was no difference in likelihood of discussing symptoms. REASSURE was acceptable to survivors, with 78% saying they would recommend REASSURE to others. **Conclusions:** In this implementation of a novel tailored approach to follow-up for low-risk breast cancer survivors, we did not find improvement in preparedness for survivorship. However, we demonstrated a decrease in number of follow-up visits with strong survivor support for this approach. Further research will focus on implementing REASSURE in more diverse clinical settings. Clinical trial information: NCT05609435. Research Sponsor: Wisconsin Partnership Program.

	REASSURE M (SD) or %	Usual Care M (SD) or %	P value
PRIMARY OUTCOMES			
Preparedness	29.3 (1.7)	28.9 (2.1)	0.36
Confidence	24.0 (14.4)	18.7 (13.6)	0.08
SECONDARY OUTCOMES			
# of follow-up visits	2.1 (1.0)	2.6 (1.0)	0.007
% of symptoms discussed	89.3%	83.0%	0.29
% of survivors who would recommend REASSURE	78%	NA	

The Engage program for childhood cancer survivors: Results from a multidisciplinary, distance-delivered intervention.

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Background: As the growing number of childhood cancer survivors exceeds follow-up care capacity, scalable models to improve access and support self-management are needed. We evaluated the effectiveness of the 'Engage' survivorship program (primary outcomes: self-efficacy and health-related quality of life; HRQoL). **Methods:** Engage is a multidisciplinary program comprising a treatment summary; online health/lifestyle assessment; telehealth nurse consultations; multidisciplinary review; tailored survivorship recommendations for survivors and their nominated primary-care physician. Survivors treated at two Australian hospitals were eligible if diagnosed <18years, >5 years post-diagnosis, and completed treatment. Mixed-effects models examined change over time (baseline, 1-, 6-, 12-month) and differences by diagnosis (brain cancer vs other), adjusting for sex and age at diagnosis. **Results:** Of 138 consenting survivors 92% completed the health assessment and 89.1% completed the whole program (n=123). Median age was 24 years; median time since diagnosis was 15 years; 28% lived in rural/remote/regional areas; and 53% were brain cancer survivors. Program acceptability was high, with >80% of survivors reporting Engage was helpful, improved knowledge and confidence, and was easy to access. Health-related self-efficacy improved over 12 months ($\chi^2(3)=146.52, p<.001$), with no evidence of differences in change between diagnostic groups (time $\times$ group; $p=.97$). HRQoL (EQ-5D index) improved modestly by 12 months (0.77 to 0.82; $p=.011$); brain cancer survivors reported lower baseline scores, with similar patterns of change over time. Satisfaction with care improved over time ($\chi^2=35.59, p<.001$), with higher satisfaction among non-brain cancer survivors ($\chi^2=4.03, p=.045$) but not over time (time $\times$ group $p=.75$). Among health behaviours, alcohol consumption decreased over time ($\chi^2=16.20, p=.001$) and was higher overall among non-brain survivors ($\chi^2=5.97, p=.015$), with no time $\times$ group interaction ($p=.94$). Adherence to personalised healthcare recommendations >50%, with greater adherence if discussed briefly during a follow-up nurse consult. **Conclusions:** Engage was associated with sustained improvements in survivors' self-efficacy and satisfaction with care and modest improvements in HRQoL at 12-months follow-up. Similar trajectories across diagnosis groups suggest telehealth survivorship models can also support survivors with higher risk profiles (e.g., brain cancer survivors). Clinical trial information: ACTRN12621000590864. Research Sponsor: None.

Survivorship-focused content at the American Society of Clinical Oncology (ASCO) 2022-2024 annual meetings.

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Background: Survivorship is a core component of comprehensive cancer care yet its representation in major oncology scientific meetings remains unclear. This study systematically evaluated survivorship-focused content presented over three years at the ASCO Annual Meetings for prevalence, characteristics, and thematic patterns. **Methods:** All abstracts presented at the ASCO Annual Meeting from 2022–2024 were obtained (N=8,928). Abstracts containing the root word “survivor” (e.g., survivor, survivors, survivorship) in the title, text, or submission category “Symptoms and Survivorship” were identified using an automated data-extraction tool. Each extracted abstract underwent structured review to determine relevance to survivorship and then mapped to domains of the Quality of Cancer Survivorship Framework. Two independent reviewers evaluated each abstract, with discrepancies resolved by consensus. Descriptive statistics were used to summarize abstract content. **Results:** A total of 568 abstracts from 2022–2024 contained the root word “survivor” in the title, text or the submission category, representing 6.4% of all presented abstracts. Prevalence of survivorship-focused abstracts increased modestly from 2.2% in 2022 to 4.1% in 2024. Reviewers identified 63.8% of the extracted abstracts as relevant to the survivorship care framework and abstracts most frequently addressed the survivorship domains of physical effects (28.3%) and contextual factors (14.6%). Additional analyses examined cancer type and stage studied (36.6% mixed, 19.5% breast; 55.2% cancer stage not specified), survivorship stage (45% not specified, 19.3% in curative treatment), study design (65.9% observational), and healthcare setting (58.2%). **Conclusions:** Despite a rapidly growing population of cancer survivors, survivorship-focused content at the ASCO Annual Meeting remained largely static between 2022 and 2024, highlighting a gap between emerging survivorship needs and representation within oncology research programming. Further, abstracts frequently failed to specify the study population or context, or reference specific implications to survivorship domains. This study establishes a reproducible benchmark for monitoring survivorship content and provides a scalable methodology for ongoing surveillance of future meeting abstracts. The abstraction method may have excluded relevant survivorship-focused content. These findings could guide ASCO educational planning committees as they refine strategies to strengthen and advance survivorship-focused content in future meetings, ensuring alignment with the evolving needs of the survivor community. Research Sponsor: Rush University Medical Center.

Impact of medically tailored meals plus nutrition counseling on treatment adherence in vulnerable lung cancer patients: Results from NutriCare randomized controlled trial.

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Background: This study aims to evaluate the impact of a Food is Medicine intervention on reducing treatment interruptions among vulnerable patients with lung cancer in a multi-site randomized controlled trial (RCT). **Methods:** Newly diagnosed stage I-IV lung cancer patients (n=249) enrolled from four cancer centers (MD Anderson Cancer Center, The Ohio State University Comprehensive Cancer Center, Fox Chase Cancer Center, and Tufts Medical Center) were randomized to the NutriCare (intervention; n=134) or NutriTool (control; n=115) arm in a 1:1 ratio. Patients on NutriTool received a nutrition toolkit for cancer survivors and monthly nutrition information and recipes. Patients on NutriCare additionally received 6-8 months (mo) of tapered home-delivered medically tailored meals (initially 21 meals/week) plus remote nutrition counseling provided by registered dietitians. Treatment interruptions, including overall interruptions and those due to treatment toxicities, were assessed using the relative dose intensity (RDI) and number of treatment cycles with dose delay or reduction among patients receiving curative or first-line palliative treatment. The primary analysis was intention-to-treat, comparing treatment interruptions between arms using Poisson regression models. **Results:** The mean (SD) of RDI was 0.84 (0.26) and 0.81 (0.26) for patients on NutriCare and NutriTool, respectively (p=0.24), with approximately 31% of the NutriCare patients having RDI reduction of 15% or more compared to 38% of the NutriTool patients (p=0.36). After restricting the analyses to treatment interruptions due to toxicities, 14.4% of NutriCare versus 25.4% of NutriTool patients experienced RDI reduction of 15% or more (p=0.08). After multivariable adjustments, NutriCare patients had 16% lower risk of having RDI reduction of 15% or more (relative risk [RR]=0.84, 95% confidence interval [CI]: 0.47-1.47) and 41% lower risk of having toxicity-related RDI reduction of 15% or more (RR=0.59, 95% CI: 0.28-1.24) than NutriTool patients. For dose delays, NutriCare patients had 35% lower risk of having any dose delay (RR = 0.65, 95% CI: 0.28-1.49) and 44% lower risk of having toxicity-related dose delay (RR=0.56, 95% CI: 0.16-1.97) compared to NutriTool patients. For dose reduction, NutriCare patients had 19% lower risk of having any dose reduction (RR=0.81, 95% CI: 0.49-1.34) and 35% lower risk of having toxicity-related dose reduction (RR=0.65, 95% CI: 0.35-1.22) compared to NutriTool patients. None of the differences reached statistical significance. **Conclusions:** Findings suggest that a Food is Medicine intervention comprising medically tailored meals and nutrition counseling may reduce treatment interruptions among vulnerable patients with lung cancer undergoing treatment. Clinical trial information: NCT04986670. Research Sponsor: Bristol Myers Squibb Foundation.

Performance of ChatGPT in generating patient-facing cancer survivorship care plans.

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Background: Survivorship care plans (SCPs) summarize cancer treatments and provide evidence-based recommendations for surveillance, screening, and management of treatment-related complications. Despite the availability of guidelines and templates, SCPs remain underutilized in routine practice due to the time-intensive and error-prone nature of manual creation. Empowering cancer survivors to use publicly available large language models (LLM)-based chatbots, such as ChatGPT, may offer a feasible solution to this problem.

Methods: Standardized patient profiles were developed for six common cancers: breast, colorectal, non-small cell lung, small cell lung, prostate cancer, and diffuse large B-cell lymphoma. Profiles were reviewed by a primary care physician and an oncologist to ensure clinical accuracy and representativeness of common survivorship scenarios. Using lay language to simulate real-world patient input, ChatGPT (version 5.2, publicly available at the time of the study) was prompted with each profile using the question, "What follow-up care do I need?" Common survivorship symptoms for each cancer were also tested. Responses were evaluated across five domains: medical accuracy (concordance with current ASCO or NCCN guidelines), thoroughness, patient safety and risk framing, clarity and patient comprehension, and actionability. Five-point Likert scales were used (1 = not at all; 5 = very much). Scores were averaged across two independent physician raters. Readability was assessed using the Flesch Reading Ease Score. **Results:** ChatGPT-generated SCPs demonstrated high medical accuracy (mean score 4.25/5), with no factual errors or hallucinations identified on manual review. Patient safety and risk framing scored 3.75/5; symptom red flags and care escalation guidance were appropriately stated in most scenarios. Thoroughness was moderate (3.50/5), with key survivorship elements, such as smoking cessation counseling or genetic risk considerations; sometimes omitted unless explicitly prompted. Readability was limited, with a mean Flesch Reading Ease Score of 40.5, corresponding to a college reading level and exceeding recommended readability standards for patient education materials. Clarity (3.38/5) and actionability (3.38/5) were similarly constrained due to dense medical language. **Conclusions:** ChatGPT demonstrated high medical accuracy in generating survivorship care plans across six common cancers, supporting the feasibility of using publicly available LLMs to guide survivorship care. However, improvements in comprehensiveness, readability, and patient-centered actionability are necessary before such tools can be safely integrated into clinical survivorship workflows. Research Sponsor: None.

Temporal trends and sociodemographic differences in influenza vaccination among U.S. cancer survivors, 2005-2024.

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Background: Given the increased risk of complications and adverse outcomes associated with influenza infection among individuals with cancer, even in the post-treatment setting, clinical oncology guidelines support annual vaccination in cancer survivors. Few studies have investigated long-term trends and potential disparities in the prevalence of influenza vaccination among individuals with a history of cancer. Therefore, we examined temporal trends in and factors associated with influenza vaccination in a nationally representative sample of cancer survivors in the United States. **Methods:** Using data from 20 survey years (2005-2024) of the National Health Interview Survey, we included adults aged ≥ 18 years with a self-reported history of cancer and complete data on influenza vaccination. The primary outcome was self-reported influenza vaccination in the past 12 months. Crude annual prevalence estimates were calculated overall and by select sociodemographic characteristics using survey-weighted logistic regression models. Temporal trends were quantified using annual percent change (APC) estimates. **Results:** Among 43,932 adults with a history of cancer (median age: 65.7 years), representing approximately 15.0 million U.S. cancer survivors annually, crude influenza vaccination prevalence increased from 45.5% (95% CI: 43.0-48.1) in 2005 to 63.3% (95% CI: 61.2-65.4) in 2024, corresponding to an absolute change of 17.8 percentage points (pp; 95% CI: 14.5-21.1) and an APC of +0.79 pp/year (95% CI: 0.52-1.06). Younger survivors aged 18-44 years experienced a particularly large absolute change over the 20-year study period (+32.4 pp; APC: +1.32 pp/year), yet fewer than half were vaccinated in 2024 (46.4%), compared to 77.4% of those aged ≥ 75 years. Cancer survivors without insurance (change: +24.7 pp; APC: +0.83 pp/year) had a 2024 vaccination prevalence of 32.0%, compared to insured survivors (63.8%). Survivors without a usual source of care (change: +31.0 pp; APC: +1.63 pp/year) had a 2024 vaccination prevalence of 39.9%, compared to those with a usual source of care (63.8%). Hispanic survivors (change: +25.3 pp; APC: +1.30 pp/year) had a 2024 vaccination prevalence of 51.9%, compared to non-Hispanic White survivors (64.9%). **Conclusions:** Influenza vaccination prevalence among U.S. cancer survivors increased substantially over the past two decades; however, more than one-third were unvaccinated in 2024. Despite overall gains, vaccination coverage remained particularly low among younger survivors, uninsured individuals, and those without a usual source of care, with persistent differences across racial and ethnic groups. Targeted clinical and public health strategies are needed to address these gaps and improve guideline-endorsed uptake of seasonal influenza vaccination among cancer survivors. Research Sponsor: None.

Rethinking MRI surveillance after breast cancer in the context of persistent racial disparities in mortality.

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Background: Detection of asymptomatic breast cancer recurrence by imaging is associated with improved survival compared to detection after symptoms develop. Currently, both the American Cancer Society and ASCO recommend against routine MRI for patients with a history of breast cancer and no clinical findings, unless they meet specific high-risk criteria. The American College of Radiology Appropriateness Criteria similarly characterizes surveillance MRI as conditionally appropriate, supporting its use only when additional risk factors are present. Since randomized trials to address surveillance strategies in diverse populations are unlikely to be feasible, we performed an observational study comparing MRI performance in intermediate and high-risk screening populations, and women with a history of breast cancer, stratified by race. **Methods:** We retrospectively analyzed 41,041 breast MRI exams performed in an urban health system from 1/2/2014 to 10/29/2025. In Pennsylvania, insurance covers supplemental MRI for women with dense breasts, and in our network, screening MRI is generally performed in asymptomatic patients current with mammography. Exams were categorized as high-risk screening (n=15,682, 38%), supplemental (n=10,905, 27%), or surveillance for a personal history of breast cancer (n=11,476, 28%). Logistic regression was used to estimate odds ratio for true and false positives by indication adjusted for age and race. **Results:** Cancer detection rates were higher in the surveillance group compared with high risk screening (true positive [TP] rate 21.0, n=241 vs 12.4, n=194), a 53% difference after adjusting for age and race (OR 1.53 [1.26–1.86], p<0.001), with similar false-positive rates (7.5%, n=857 vs 8.7%, n=1,359; OR 1.02 [0.93–1.11], p=0.7). MRI cancer detection rate was higher for supplemental than high-risk screening (OR 1.35 [1.24–1.46], p<0.001). Notably, in a subset comparison of screening MRI in Black vs. white women (n=37,383), TP rates were higher among Black women than white women across all MRI indications. The highest TP rate was observed in Black women undergoing surveillance MRI (31.9 vs. 20.5; OR 1.62 [1.11, 2.31], p=0.010), followed by supplemental (25.6 vs. 14.5; OR 1.84 [1.17, 2.77], p=0.005), and high-risk (21.6 vs. 11.4; OR 1.97 [1.22, 3.03], p=0.003). The TP rate remained higher for Black compared with white women for first MRI as well as subsequent MRI for surveillance, high-risk, and supplemental screening. **Conclusions:** Black women in the U.S. have 40% higher breast cancer mortality compared to non-Hispanic white women, and early detection offers the best chance for optimal survival. Our findings suggest surveillance MRI identifies a higher burden of clinically occult cancer than high-risk screening MRI, especially among Black women. Expanding access to surveillance MRI may help address persistent racial disparities in breast cancer outcomes. Research Sponsor: Pennsylvania Breast Cancer Coalition; American Cancer Society; PASD-22-1003156-01 & RSG-23-1038098-01-HOPS.

CTNow pilot study: A multilevel clinical trial education and clinical trial referral coordination intervention for rural oncology providers and patients with cancer.

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Background: Enhancing patient access to cancer clinical trials is an ASCO and NCI priority. Major barriers to clinical trial access in rural areas include limited awareness and knowledge of available cancer clinical trials among both rural oncology providers and patients with cancer. Our preliminary research found that only 9% of rural cancer patients have knowledge of clinical trials, and many providers lack the time or resources to discuss them in clinical settings. Hawai'i's geographic isolation presents persistent barriers to clinical trial access, particularly for residents of the five rural neighbor islands of Hawai'i. Expanding clinical trial access requires not only increasing infrastructure and trial availability; enhancing provider and patient awareness and knowledge is a critical step toward improving access to trials in rural communities. A coordinated, culturally informed, and statewide approach is urgently needed to build trust, increase literacy on clinical research participation, and ensure that clinical trials become an equitable part of standard cancer care for all communities in Hawai'i. This pilot trial evaluates the preliminary efficacy of *CTNow*, a novel multilevel, multicomponent clinical trial education and clinical trial referral coordination intervention designed for rural oncology providers and patients with cancer. **Methods:** This multi-site pilot trial is currently open in three rural counties in Hawai'i. The multilevel *CTNow* intervention includes: 1) two interactive webinar sessions for rural oncology providers; 2) a tablet-based multimedia education program for patients; and 3) referral resources for providers and an optional video chat feature for patients to connect with clinical trials staff for questions and/or referrals to trials. The study team developed intervention components that provide rural-specific provider clinical trial information, along with evidence-based patient education materials adapted for varying levels of health literacy. Key patient inclusion criteria include patient self-report of cancer diagnosis, current/past/planned treatment, and residency in rural areas. Provider participants include rural-based oncologists and advanced practice providers not currently involved in clinical trials. Planned enrollment includes 30 patients with any cancer type and 5 oncology providers practicing in rural Hawaii. The primary endpoint is within-patient and within-provider changes in knowledge of cancer clinical trials from baseline. Secondary endpoints include changes in attitudes toward clinical trials and self-efficacy related to trial participation, and utilization of video chat sessions. Enrollment began in March 2025. To date, 80% of patients and 100% of planned providers have been enrolled. Clinical trial information: NCT06237816. Research Sponsor: Agency for Healthcare Research and Quality.

Genetic testing uptake through an enhanced oncology nurse–led intervention in patients with solid tumors (GENESIS): A pilot study.

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Background: Identification of pathogenic germline variants (PGV) in patients with solid tumors is critical for directing targeted therapies, surveillance, and cascade testing for family members. Despite established National Comprehensive Cancer Network (NCCN) guidelines, uptake of genetic counseling and testing (GCT) remains suboptimal, with recent data suggesting <7% utilization in some cancer populations. Barriers are pronounced in community oncology settings due to limited access to genetic counselors and reliance on physician-initiated referrals. Oncology nurses routinely provide education during systemic therapy initiation, presenting a unique, underutilized touchpoint to bridge this gap. The GENESIS study (NCT06436157) evaluates the feasibility and impact of a novel, nurse-led "enhanced education" intervention on GCT uptake. **Methods:** This is a single-center, prospective, randomized (1:1) pilot trial conducted at a community cancer center. Eligible participants are adults (≥ 18 years) with solid tumors (breast, ovarian, prostate, pancreatic, colorectal, and others per NCCN guidelines) who are starting or switching systemic therapy, meet NCCN criteria for GCT, and have no prior germline testing. The study plans to accrue 60 patients. Participants are randomized to the Usual Care arm (standard therapy education; clinician-initiated referral) or the Enhanced Education Intervention arm. In the intervention arm, trained oncology nurses integrate a specific GCT educational module into the standard chemotherapy teaching session. For eligible/agreeable patients, the nurse directly places the GCT referral order and executes a follow-up "nudge" to referral coordinators within one week. The primary endpoint is the percentage of patients proceeding to GCT consultation. Secondary endpoints include GCT referral rates, time from order to consultation, time to testing completion, and implementation feasibility assessed via the Acceptability of Intervention Measure (AIM) and retention rates. Clinical trial information: NCT06436157. Research Sponsor: Robert A. Winn Excellence in Clinical Trials Awards Program (Winn Awards).

Patient preference for subcutaneous vs. intravenous immune therapy (PSI-Immune).

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Background: Immune checkpoint blockade (ICB) has improved outcomes for patients (pts) with advanced solid tumors. Conventional intravenous (IV) route of administration (RoA) requires repeated, time-intensive infusions involving cannulation, monitoring, pharmacy preparation, and chair time, increasing treatment burden and constraining infusion center capacity, staffing, and scalability as ICB use expands. Subcutaneous (SC) formulations of pembrolizumab and nivolumab—two widely used PD-1 inhibitors—have recently been approved across multiple indications. PD-1 ICB SC formulations contain the same active drug as IV formulations and have demonstrated comparable PK exposure, efficacy and safety profiles (CheckMate 8KX; 3475A-D77). Beyond pt convenience, SC RoA may enable more scalable delivery by reducing infusion chair utilization, nursing time, and workflow bottlenecks, supporting access across high-volume cancer networks. Real-world pt preference and perceived health-system impact of SC versus IV PD-1 ICB remain incompletely characterized. We therefore designed a distributed, real-world clinical trial to evaluate patient preference and health-system implications of PD-1 ICB RoA across a large integrated cancer network (>70 sites across 4 states). **Methods:** PSI-Immune is a randomized, phase II, open-label, crossover study evaluating pt preference for SC versus IV RoA of PD-1 ICB in pts with locally advanced (LA) or advanced/metastatic (A/M) solid tumors pending initiation PD-1-based therapy, either as monotherapy or in combination. The primary endpoint is pt preference for ICB RoA, assessed using a validated pt preference questionnaire (PPQ). Key secondary endpoints include pt-reported treatment satisfaction (TASQ), HCP-reported time and resource utilization, pt-reported health-related quality of life (HRQoL), and time to next therapy (TTNT). A subcohort permits enrollment of pts who are already on IV PD-1 ICB. Eligible pts must have an FDA-approved indication for SC pembrolizumab or nivolumab singly or in combination with other FDA-approved agents and a planned duration of PD-1-based therapy exceeding six months. Patients are randomized 1:1 to receive either SC therapy for three cycles followed by IV therapy for three cycles, or the reverse sequence (crossover phase). Subsequently, pts select their preferred route of administration (continuation phase). Treatment regimen is identical across cohorts and differs only by ICB RoA. Randomization is stratified by disease setting (LA vs A/M) and ICB regimen (monotherapy vs combination). The planned sample size is 280 patients. Assuming equal allocation and up to 10% attrition, the exact 95% confidence interval for the proportion of patients preferring SC administration will exclude 50% if the observed preference rate is at least 60%. This study is open and enrolling across the entire UPMC Hillman Cancer Center Network (NCT07223424). Clinical trial information: NCT07223424. Research Sponsor: None.

Cancer CARE (Connected Access and Remote Expertise) beyond walls: Pilot, phase 2 clinical trial to evaluate administration of cancer-directed therapy in the patient's homes versus in clinic in the Florida Panhandle and surrounding areas.

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Background: Cancer care in the United States remains highly centralized, imposing substantial time, caregiver, and financial burdens on patients, particularly those residing in rural and medically underserved regions. While international experience supports the feasibility of home-based cancer therapy delivery, prospective U.S. clinical trial data are limited. The Cancer CARE Beyond Walls (CCBW) program was developed to address these gaps through a decentralized cancer care model integrating virtual oversight, remote monitoring, mobile clinical services, and community-based nursing partners. The study evaluates the feasibility, safety, and patient-centered impact of delivering cancer-directed therapy in patients' homes or near-home mobile units in the Florida Panhandle, a region characterized by long travel distances to tertiary centers and limited oncology infrastructure. **Methods:** This is a phase 2, single-arm clinical trial evaluating the delivery of standard-of-care cancer-directed therapy outside of traditional infusion centers. Eligible adult patients (ECOG 0–3) with histologically confirmed malignancies receiving guideline-supported or FDA-approved systemic cancer therapy must demonstrate tolerability of at least one prior in-clinic treatment cycle. Following registration, patients transition to home-based or near-home mobile unit administration for a minimum of 12 weeks, with an option to continue up to 24 weeks. Care delivery is coordinated through a virtual command center providing real-time virtual oversight, remote monitoring, and escalation pathways. Treatment administration is performed by trained local home health nurses, medication shipping, and digital interaction with the electronic health record. A fully equipped mobile unit extends access to rural areas not covered by home health agencies. The primary endpoint is patient preference for treatment location at week 12. Secondary endpoints include safety, avoidable acute care utilization, patient-reported function and global health/quality of life, patient-reported symptoms, and satisfaction with care. Exploratory endpoints assess travel burden, patient perceptions of caregiver experience, and patient perceptions of home versus mobile unit care. Enrollment of 27 patients will provide 80% power to reject a 50% null rate (2-sided exact test, $\alpha=0.10$), assuming 75% prefer decentralized care or express no preference. This investigator-initiated trial is open to accrual and is supported by a grant from the Florida Cancer Innovation Fund. Clinical trial information: NCT07285044. Research Sponsor: Mayo Clinic.

Making telehealth delivery of cancer care at home effective and safe: A pragmatic cluster randomized trial.

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Background: Telehealth (TH) use for cancer care has rapidly expanded, both during and following the COVID-19 pandemic. However, evidence regarding safety, feasibility, effectiveness, equity, stakeholder satisfaction, and implementation of telehealth-enabled oncology care remains limited. We seek to assess the impact of TH on these outcomes in breast and prostate cancer patients. **Methods:** The MATCH-UP pragmatic cluster randomized trial is being conducted at Memorial Sloan Kettering Cancer Center to compare alternate models of TH use in oncology practice. Sixty-two physician practice clusters in breast and prostate medical oncology are randomized 1:1 to enhanced telehealth (ET) or usual practice (UP), stratified by disease type and clinic volume. ET emphasizes TH with expanded home services designed to deliver as many components of care as desired in patients' homes. Usual care involves routine practice with TH visits at the discretion of the patient and MD or APP. Eligible patients have ≥ 3 prior medical oncology visits and are not enrolled on a therapeutic trial. Automated enrollment is triggered by a routine oncology visit with waiver of informed consent. The ET intervention includes EHR-enabled telehealth scheduling defaults for routine follow-up visits, optional home phlebotomy, structured support for home administration of select injectable medications, and digital support for patients with TH access barriers. The primary endpoint is the proportion of routine medical oncology visits conducted in person among all routine medical oncology visits over 1 year. Secondary outcomes include healthcare utilization, no-show and late cancellation rates, and overall survival. Patient-reported outcomes include: quality of life, healthcare costs, experience of care, and preferences for use of TH at future visits. Clinician-reported outcomes include: experience of care and preferences for TH use at future visits. For patients in the ET arm only, telehealth accessibility, intervention uptake and efficiency, and implementation outcomes, including acceptability, appropriateness, and feasibility, are also being collected. The primary endpoint will be analyzed using generalized linear mixed models with a logistic link, accounting for repeated visits within patients and clustering within randomized practice units and adjusting for stratification factors. Enrollment will continue through March 2026 with follow-up for 12 months. To date, 7256 patients have been enrolled, with 3641 patients assigned to ET, (n=2437 [67%] breast cancer; n=1204 [33%] prostate cancer) and 3,615 assigned to UP (n=2252 [62%] breast cancer; n=1363 [38%] prostate cancer). MATCH-UP will generate pragmatic evidence on the effectiveness, patient-centeredness, implementation, and equity-relevant barriers of a scalable, EHR-embedded enhanced telehealth model for breast and prostate oncology care. Clinical trial information: NCT06954337. Research Sponsor: NIH/; NCI/NIH P50 CA271357; National Cancer Institute/U.S. National Institutes of Health; NCI/NIH P30 CA008748.

Implementation of a cancer-oriented geriatric assessment (COGA) clinic to promote age-friendly cancer care: A type III hybrid implementation–effectiveness method in community practice.

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Background: Cancer incidence increases with age, and adults aged ≥ 65 years account for the majority of new cancer diagnoses. Standard oncology assessments often fail to identify age-related vulnerabilities such as frailty, cognitive impairment, and functional decline (Hurria et al., JCO 2011). The American Society of Clinical Oncology (ASCO) recommends routine geriatric assessment–guided management for older adults receiving systemic cancer therapy to inform treatment decisions and reduce treatment–related toxicity (Mohile et al., JCO 2018). In alignment with these goals, we established a Cancer–Oriented Geriatric Assessment (COGA) clinic within an academic cancer center. **Methods:** We implemented a Type III hybrid implementation–effectiveness design to integrate Cancer–Oriented Geriatric Assessment (COGA) into routine oncology practice using the 5M framework (Mind, Mobility, Medications, Matters Most, and Multicomplexity). The Eleanor N. Dana Cancer Center is part of a large academic health system in Northwest Ohio, serving a predominantly rural and suburban population across Ohio and Southeast Michigan. Eligibility included oncology patients aged ≥ 65 years with a positive G8 screen (≤ 14), consistent with ASCO and European Society for Medical Oncology (ESMO) recommendations for comprehensive geriatric assessment. A tiered workflow was implemented on January 15, 2026, in which medical assistants obtained vital signs, performed medication reconciliation, and completed standardized screenings for cognition, mood, and nutrition, followed by a geriatrician–led assessment of frailty, fall risk, mobility, and functional status. The medication domain emphasized deprescribing of potentially inappropriate medications, while the Matters Most domain addressed goals of care, advance directives, and social support. Additional geriatric syndromes—including sensory impairment, sleep disturbances, incontinence, and fatigue—were systematically assessed and managed. Risk stratification was guided by validated tools, including the Cancer and Aging Research Group (CARG) toxicity tool and the Schonberg Index, to estimate non–cancer mortality. Primary implementation outcomes included reach (the proportion of eligible patients receiving COGA), adoption (use of COGA by oncology teams), and fidelity (completion of the core 5M domains as intended). Secondary effectiveness outcomes included patient–centered outcomes and unplanned hospitalizations. This scalable, real–world implementation model enables systematic integration of geriatric assessment into oncology practice, with the potential to improve outcomes for older adults with cancer and support broad dissemination across diverse cancer care settings. Research Sponsor: None.

An EHR-embedded SmartForm (OncAssessment) paired with ePROs to enable real-time structured documentation of key oncologic data during routine cancer care: A pragmatic implementation study.

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Background: Real-world evidence generation in oncology is often limited by inconsistent and unstructured documentation within electronic health records (EHRs). Key clinical variables including disease status, performance status, and treatment change rationale are frequently embedded in free text, requiring retrospective manual abstraction that is inefficient and error-prone. As a result, clinically meaningful real-world endpoints, such as time to treatment change and real-world progression-free survival (rwPFS), are inconsistently captured. To address these gaps, the University of Pennsylvania developed OncAssessment (OA), an EHR-embedded SmartForm integrated directly into routine oncology clinical documentation. Unlike post hoc abstraction or standalone registries, OA enables prospective, structured data capture of key oncologic variables at the point of care by treating clinicians, and is paired alongside with electronic patient-reported outcomes (ePROs). This approach aligns clinician decision-making with patient-reported experience within routine workflows, enabling timely, scalable, and higher-fidelity real-world data (RWD) capture. **Methods:** This pragmatic implementation study, developed by the University of Pennsylvania in collaboration with Gilead Sciences, evaluates OA and ePRO implementation in standard clinical practice. Adult patients with stage IIIB-IV unresectable non-small cell lung cancer (NSCLC) initiating standard-of-care immunotherapy with or without chemotherapy (Cohort I) and adult breast cancer patients receiving systemic infusional therapy (Cohort II) are identified via the EHR. 200 patients per cohort are planned for enrollment over 2 years. Enrollment began July 22, 2025. For identified patients, clinicians are prompted to complete OA at each visit: documenting clinical status, tumor status, treatment changes, and rationale. ePROs are automatically distributed through the EHR to Cohort I patients prior to their visits. Structured data from OA, ePROs, and other EHR sources are auto-extracted. Primary objectives for Cohort I include OA utilization, time to treatment change decision (TTCd), comparison of TTCd with time to treatment change (TTC) derived from EHR reporting, ePRO completion rates, and concordance between patient- and clinician-assessed clinical status. Secondary objectives include rwPFS captured via OA, comparison with rwPFS determined by manual chart and radiology review, characterization of patient experience via ePROs, and exploratory analyses of discordance and factors associated with treatment change. The primary objective for Cohort II is OA utilization. Follow-up continues until progression, treatment change, or 2 years for Cohort I and 12 months for Cohort II. Research Sponsor: Gilead Sciences.

MATCHES-NOVEL: A randomized controlled trial in progress of hospital-at-home (HaH) versus inpatient hospitalization for post tarlatamab monitoring.

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Background: Tarlatamab is a bispecific T-cell engager (BiTE) therapy approved for the treatment of extensive-stage small cell lung cancer (ES-SCLC) and is the first BiTE therapy approved for a solid tumor. Due to the risk of cytokine release syndrome, patients are routinely hospitalized for ≥ 24 hours following each of the first two doses. These hospitalizations can pose substantial logistical, financial, and psychosocial challenges, particularly for patients in rural communities or with caregiver or employment constraints. HaH is an emerging care delivery model that provides hospital-level care in patients' homes and has been associated with reduced readmission rates, improved patient experience, and lower cost in other populations. Whether HaH can safely and efficiently replace inpatient hospitalization for post-tarlatamab monitoring is unknown. The MAKing Telehealth Delivery of Cancer Care at Home Effective and Safe (MATCHES)-Novel trial evaluates a HaH model compared with standard inpatient hospitalization following tarlatamab administration. **Methods:** MATCHES-Novel is an active, single-center, prospective randomized controlled trial comparing HaH with standard inpatient hospitalization for post-administration monitoring of tarlatamab in patients with ES-SCLC. Eligible patients have an ECOG performance status of 0-2, are initiating tarlatamab for an FDA-approved indication, reside within a 60-minute response catchment area, and have an available in-home caregiver. Participants are randomized 1:1 to HaH or standard inpatient monitoring following drug administration, with monitoring duration and discharge criteria aligned with institutional standards. The HaH intervention includes scheduled in-home community paramedic assessments on the day of and the day after infusion, home phlebotomy, telehealth physician oversight, patient and caregiver education, and 24/7 care escalation pathways. The primary objective is to compare efficiency, measured by the number of inpatient hospital days during the two 7-day periods after each infusion. Assuming a mean number of 4 inpatient hospital days in the control arm, enrollment of 70 patients provides $\geq 80\%$ power to detect a statistically significant difference if the mean inpatient days per patient in the HaH arm is ≤ 2.8 . Secondary objectives include safety outcomes (transfers from home to inpatient care, clinician adjudicated toxicity events) and patient, caregiver and physician reported experiences and preferences, assessed through prespecified surveys and interviews. These findings may inform future care-delivery models for administering innovative cancer therapies outside the inpatient setting, potentially improving access. The trial opened to accrual in April 2025, and 16 of the planned 70 patients have been enrolled. Clinical trial information: NCI-2025-03406. Research Sponsor: National Cancer Institute; P50 CA271357; National Institutes of Health and National Cancer Institute Cancer; P30 CA008748; Amgen.