Pharmacist-led medication reconciliation televisit (MRT) for phase 1 oncology clinical trials: A telemedicine model.

Sarah O'Neill, Shannon Lerro, Kennevie Aquino, Nitasha Sanil, Elke Backman; Massachusetts General Hospital Cancer Center, Boston, MA

Background: Accurate medication reconciliation is critical in oncology trials to mitigate drugdrug interactions (DDIs), address eligibility and enhance patient safety. Cancer patients often experience polypharmacy (\geq 5 medications), increasing the risk of additive toxicities when investigational agents are introduced. Medication lists in Electronic Medical Records (EMRs) are often incomplete or outdated, complicating eligibility evaluations. To streamline screening for Phase 1 trials, a pharmacist-led medication reconciliation televisit (MRT) model was implemented to improve baseline medication list accuracy and reduce in-clinic time. Methods: From December 2022 to January 2025, one MRT was scheduled for each patient screening for Phase 1 trials (≥18 years, English-speaking or with interpreter support), after trial consent but before registration. Pharmacists reviewed EMRs and dispense histories, then conducted structured phone interviews with patients to review prescription (RX), over-thecounter (OTC), herbal and cannabis product usage, including name, strength, dose, frequency, start dates, indications and ingredients. Inactive medications were discontinued, allergies were updated, patient concerns and medication details were documented in the EMR. Results: A total of 525 MRTs across 82 trials had a median turnaround time of 2 days. Patients (median age 61 years) reported a median of 12 medications (range 2-41) and a median total time spent of 45 minutes (range 5–330) including documentation. 4.8% of patients required interpreter support. Primary cancer types (12 total) included gastrointestinal (32%), breast (20%) and head and neck (11%). Table 1 summarizes MRTs April 2024 and later which captured additional data: 64% required an EMR-prompted outside source reconciliation, 32% modified allergies, a median of 3 medications were added (range 0-37), 2 were changed (range 0-13), 3 were discontinued (range 0-18) and the median call time was 18 minutes. Conclusions: Pharmacist-led MRTs provided substantial value for investigators and research nurses, enabling them to focus on patient care. Flexible scheduling of remote MRTs supported presence of caregivers and medications, reducing list omissions and hospital chair time for patients. Sponsors and study teams gained more accurate baseline records, lowering the risk of unknown prohibited medications. This scalable telemedicine model offers potential for broader use in oncology trials, improving efficiency and patient safety. Research Sponsor: None.

MRT identification of previously undocumented medications with DDI potential (n=235).								
> 1 medication on EMR categorized as:	Before MRT n (%)	After MRT n (%)	Absolute Change	% Increase				
RX OTC Non-herbal OTC Herbal Antacid/H2 Blocker/PPI Cannabis	208 (98%) 179 (84%) 26 (12%) 81 (38%) 11 (5%)	232 (99%) 224 (95%) 46 (20%) 107 (46%) 66 (28%)	+24 +45 +20 +26 +55	+12% +25% +77% +32% +500%				

Remote clinical pharmacist impact on reducing total cost of care in Enhancing Oncology Model-enrolled oncology practices.

Daniel Kendzierski, Alexa Basilio, Morgan Cantley, Andrea Roman, Meredith Keisler, Shannon Hough; McKesson Specialty Health, The US Oncology Network, The Woodlands, TX; McKesson Specialty Health, The Woodlands, TX; McKesson, The US Oncology Network, The Woodlands, TX

Background: The national cost of cancer care is estimated to exceed \$245 billion by 2030, primarily due to the high cost of cancer drugs. The Enhancing Oncology Model (EOM) is a voluntary 6-month, 2-sided, risk-based payment model implemented by the Centers for Medicare and Medicaid Services (CMS) to improve cancer care while simultaneously reducing the total cost of care (TCOC). The US Oncology Network (The Network) comprises approximately 50% of all providers participating in EOM nationwide across twelve practice sites. In The Network, drug costs represented an average of 63% of a patient's TCOC. This study aims to demonstrate the impact of a pharmacist in reducing TCOC in the EOM model. Methods: Medication initiatives were clinically evaluated and adopted at an individual practice level and included: monoclonal antibody (moAB) dose rounding, pembrolizumab dose banding, biosimilar therapeutic interchange (TIC) to preferred products, use of a preferred PD-1 agent in metastatic NSCLC, decreased upfront usage of long-acting growth factor (GF) in metastatic cancer, and preferred use of zoledronic acid over alternatives. ClinReview pharmacists (CRP) remotely reviewed oncology treatment orders for cost-savings opportunities. CRPs updated eligible treatments per practice protocols or reviewed with the treating oncologist. Interventions were submitted by the CRP into a tracking system and marked as an EOM-related intervention. TCOC reduction was calculated using the difference between the CMS allowable for the original treatment ordered and the new order. Results: From July 1, 2023, to December 31, 2024, seven CRPs within five of The Network's EOM participating practices evaluated over 5,600 patients for medication initiatives. A total of 1,271 interventions were identified, with 1,180 accepted. The sum of TCOC reduction amounted to 8,982,235. Further breakdown of each initiative and average TCOC reduction per intervention are shown in Table 1. In addition to the six initiatives, the CRP contributed an additional 1,201,326 in medication savings associated with drug selection. Conclusions: CRP's medication initiatives within The Network's EOM participation reduced TCOC by nearly \$9 million across five practices. Key initiatives such as pembrolizumab dose banding and preferred use of zoledronic acid were the largest contributors. These findings demonstrate the potential for pharmacist-driven interventions to lower costs and drive the success of value-based care models in oncology practices. Research Sponsor: None.

EOM Initiative	n (%)	TCOC Reduction, \$	Average TCOC Reduction per intervention, \$
moAB dose rounding	443 (35)	1,537,273	3,470
Pembrolizumab dose banding	106 (8)	1,962,105	18,510
TIC	356 (<u>2</u> 8́)	1,510,945	4,244
Preferred PD-1 agent for NSCLC	26 (2)	153,117	5,889
Decrease GF use	37 (3)	109,822	2,968
Zoledronic acid use	181 (Ì́14)	2,157,895	11,992

Video-based genetic counseling to reduce physician workload and enhance consulter understanding: A prospective randomized clinical trial.

Georg Pfeiler, Muy-Kheng Tea, Michael Seifert, Florian Heinzl, Christian F. Singer, Daphne Gschwantler-Kaulich, Carmen Leser, Selina Ebner, Ella Asseryanis, Christine Deutschmann; Department of Obstetrics and Gynecology and Center for Breast Health, Comprehensive Cancer Center, Medical University of Vienna and Austrian Breast and Colorectal Cancer Study Group, Vienna, Austria; Zailab Pharmaceuticals, San Francisco, CA; Medizinische Universitaet Wien, Wien, Austria; Medical University of Vienna, Vienna, Austria; Department of Obstetrics and Gynecology and Center for Breast Health, Comprehensive Cancer Center, Medical University of Vienna, Vienna, Austria

Background: Genetic counseling is an essential part of germline genetic testing, which is reccomended for use of PARP inhibitors in breast cancer treatment. Despite its importance, only about 40-60% of breast cancer patients receive genetic counseling. A video tool has been developed to provide genetic counseling, aiming to reduce the physician's workload and improve the patient's understanding. Methods: Advice seekers at increased risk for hereditary breast and ovarian cancer as well as breast and ovarian cancer patients were included in the trial. They were randomly assigned 1:1 to either standard of care (physician only, PO) or video based followed by physician genetic counseling (VPO). A 15-minute video tool was created for VPO participants, who watched it on an iPad and answered 6 comprehension questions online. The physician then clarified any misunderstood topics. In both groups, counseling time was measured from conversation start to blood donation. Afterwards, participants completed a questionnaire with 9 comprehension questions (16 points total). Data analysis included Bernard's and Pearson's tests for categorical data, Kendall's test for correlations, and ordinal logistic regression for multivariable analysis. Results: A total of 110 participants with a median age of 47 years were randomized into two groups: PO counseling (55 participants, 50%) and VPO counseling (55 participants, 50%). Among them, 29% (32 participants) received therapeutic counseling for breast/ovarian cancer, while 71% (78 participants) received predictive counseling with no cancer diagnosis. Participant characteristics were well balanced between groups, with no significant differences in age, indication for counseling, sex (90% female), level of education, or German-speaking proficiency. Participants reported their sources of genetics knowledge as previous knowledge (30%) and physician counseling (70%) in the PO group, and as previous knowledge (20%), physician counseling (30%), and the video tool (45%) in the VPO group. The video significantly improved comprehension scores from 62.5% (10 points, PO group) to 81.3% (13 points, VPO group) (p < 0.0001). Additionally, the video tool significantly reduced the time physicians spent on counseling from 6.6 minutes to 2.4 minutes (p < 0.0001). According to the logistic regression model, both the level of education (estimate -1.34, p = 0.002) and German language comprehension level (estimate 1.62, p = 0.001) significantly influenced the genetic counseling comprehension score. Conclusions: In this prospective randomized trial, video genetic counseling improved comprehension and reduced physician counseling time. The genetic video tool, which can be translated into various languages, facilitates genetic counseling by decreasing the workload for physicians, which may increase the genetic counseling rate in the clinic. Research Sponsor: None.

Electronic patient-reported outcome-based weight management versus usual care during induction chemotherapy followed by concurrent chemoradiotherapy in nasopharyngeal carcinoma: A phase II randomized controlled trial.

Qiu-Yan Chen, Jing Jin, Shan-Shan Guo, Hai-Qiang Mai, Lingquan Tang, Li-Ting Liu, Jin-Hao Yang, Dongxiang Wen, Jie-Yi Lin, Si-Qi Liu, Guo-Dong Jia, Pan Wang, Ru Li, Dong-Mei Li, Ying-Hua Jiang; Department of Nasopharyngeal Carcinoma, Sun Yat-Sen University Cancer Centre, Guangzhou, China; Department of Nasopharyngeal Carcinoma, Sun Yat-Sen University Cancer Center, State Key Laboratory of Oncology in South China, Guangdong Key Laboratory of Nasopharyngeal Carcinoma Diagnosis and Therapy, Guangdong Provincial Clinical Research Center, Guangzhou, China; Sun Yat-sen University Cancer Center, Guangzhou, China

Background: Nearly almost patients with nasopharyngeal carcinoma (NPC) experience weight loss (WL) and malnutrition during treatment. However, effective patients' weight management remains a challenge, as no standardized approach currently exists. This study aimed to evaluate the feasibility and efficacy of an electronic patient-reported outcome (ePRO) based weight management in mitigating WL and malnutrition in patients with locally advanced NPC (LA-NPC) receiving induction chemotherapy (IC) followed by concurrent chemoradiotherapy (CCRT). Methods: In this phase II randomized controlled trial, eligible patients aged 18 to 70 years with stage III-IVa (AJCC⁸th) NPC were randomly assigned in a 1:1 ratio to either ePRObased weight management (ePRO group) or usual care (UC group). Body weight, NRS2002, PG-SGA, EORTC QLQ-C30 and hematological indicators were collected at six timepoints during treatment. Patients in ePRO group used the ePRO weight management system (ePRO-WMS). When predefined e-alert were triggered (e.g., WL > 5%), the MDT promptly communicated and responded with patients. Patients in UC group did not use the ePRO-WMS and had no e-alerts. The primary outcome was the proportion of patients experiencing WL > 10% at one month after completing CCRT (Post-1m). The secondary outcomes included WL > 10% and WL > 20% at the end of CCRT (W7-CCRT), as well as comparisons of NRS2002, PG-SGA, EORTC QLQ-C30, and hematological indicators. WL was compared using the χ^2 test, while other secondary outcomes were analyzed with linear mixed-effects models (ClinicalTrials.gov, NCT05834712). Results: From May 2022 to August 2023, 112 patients were enrolled in each group (76.8% male, 86.6% with \geq junior high school education). 110 patients (UC group) and 109 patients (ePRO group) completed IC+CCRT. Among ePRO group, 107 patients successfully completed the ePRO-WMS, generating 561 e-alerts. Compared to UC group, ePRO group had significantly fewer patients with WL > 10% at Post-1m (37.5% vs. 57.1%, P = 0.003) and W7-CCRT (22.3% vs. 38.4%, P < 0.001). Additionally, ePRO group showed improved nutritional status (Retinol Binding Protein, 38.3 vs. 34.8, P = 0.011) and quality of life. Notably, reductions in inflammation (C-reactive protein, 10.4 vs. 15.9, P = 0.027) and immune suppression (CD4⁺CD25⁺ regulatory T cells, 20.1 vs. 22.2, P = 0.034) were also observed. No significant differences were found between groups for acute adverse and progression-free survival (median follow-up time: 16 months). However, 2 cases of nasopharyngeal necrosis were observed in the UC group during follow-up. Conclusions: Compared to usual care, ePRO-based weight management in LA-NPC patients mitigated weight loss, alleviated inflammation, and significantly improved nutritional status and quality of life. Clinical trial information: NCT05834712. Research Sponsor: None.

A novel virtual reality supportive care intervention (BMT-VR) for patients undergoing hematopoietic stem cell transplantation (HSCT): A pilot randomized clinical trial.

Hermioni L. Amonoo, Richard Newcomb, Lara Traeger, Ashley Nelson, Anna Barata, Karl Lorenz, Sid Desai, Nik Vassev, Joseph Greer, Jennifer S. Temel, Zachariah Michael DeFilipp, Yi-Bin Albert Chen, Areej El-Jawahri; Department of Supportive Oncology, Dana-Farber Cancer Institute; Department of Psychiatry, Mass General Brigham; Harvard Medical School, Boston, MA; Division of Hematology and Oncology, Department of Medicine, Massachusetts General Hospital; Harvard Medical School, Boston, MA; Department of Psychology, University of Miami, Miami, FL; Department of Psychiatry, Mass General Brigham; Harvard Medical School, Boston, MA; Stanford School of Medicine; VA Palliative Care Quality Improvement Resource Center (QuIRC), Stanford, CA; Novobeing, Boston, MA; Massachusetts General Hospital, Boston, MA

Background: Patients with hematologic malignancies undergoing HSCT experience immense physical and psychological symptom burden during their extended transplant hospitalization. Interventions that help manage patients' psychological distress and improve their quality of life (QOL) during this inpatient stay are limited. Virtual reality (VR), with its three-dimension capabilities for user engagement, offers a novel delivery modality for scalable, targeted, and patient-centered supportive care interventions aiming to address the persistent unmet psychosocial needs of these patients. Methods: We conducted a pilot randomized clinical trial (RCT) of a VR supportive care intervention (BMT-VR). Patients undergoing HSCT were randomly assigned to BMT-VR or usual care during their 3-4-week hospitalization. BMT-VR consisted of five self-directed modules addressing 1) supportive psychoeducation and managing expectations during HSCT; 2) effective coping; and 3) acceptance and gratitude while dealing with uncertainty. The primary endpoint was feasibility ($\geq 60\%$ of eligible patients enrolling, and \geq 60% of BMT-VR participants completing \geq 3/5 modules). To assess BMT-VR's acceptability, we used the System Usability Scale (> 80 = excellent acceptability). We assessed psychological distress (Hospital Anxiety and Depression Scale), QOL (Functional Assessment of Cancer Therapy-BMT), post-traumatic stress symptoms (PTSD-Checklist), coping (Measure of Current Status-A), and self-efficacy (Cancer Self-Efficacy Scale) at baseline (i.e., 3 days post-HSCT) and 4-, 12-, and 24-weeks post-HSCT. We used analysis of covariance (ANCOVA) to explore the preliminary effects of BMT-VR on outcomes. Results: We enrolled 58.3% (81/139) of eligible patients (BMT-VR (n = 40); usual care (n = 41)) with a mean age of 57.9 (SD = 14.7) and 51.9% women. 74.4% of BMT-VR participants completed \geq 3/5 modules and 65.1% completed 5/5 modules, with median acceptability score = 81.2. At 4-weeks, BMT-VR vs. usual care participants reported improved anxiety (5.3 vs. 3.6, P = 0.016), QOL (108.2 vs. 96.8, P = 0.014), coping (36.6 vs. 32.4, P = 0.023), and self-efficacy (144.6 vs. 131.9, P = 0.019). Although BMT-VR vs. usual care participants reported sustained improvements in QOL (B = 3.8, P = (0.002), coping (B = 1.8, P = 0.011), and self-efficacy (B = 4.5, P = 0.017), BMT-VR effects became more pronounced for depression (B = -0.5, P < 0.001), and PTSD (B = -1.7, P < 0.001) symptoms longitudinally across all time points. **Conclusions:** A novel VR-delivered supportive care intervention tailored to the psychosocial needs of HSCT recipients is feasible and acceptable and demonstrated preliminary efficacy for improving psychological distress and QOL. A subsequent multi-site RCT will evaluate BMT-VR's efficacy for improving outcomes in diverse HSCT settings. Clinical trial information: NCT05629676. Research Sponsor: Doris Duke Charitable Foundation; Clinician Scientist Development Award; National Cancer Institute; K08CA251654.

Geriatric assessment and management with a question prompt list using a webbased application to reduce treatment toxicity in older patients with cancer: A randomized controlled trial (J-SUPPORT 2101 study).

Ayumu Matsuoka, Maiko Fujimori, Narikazu Boku, Atsuo Takashima, Takuji Okusaka, Ken Kato, Yuta Maruki, Akihiro Ohba, Hidekazu Hirano, Keita Mori, Tatsuo Akechi, Yukari Tsubata, Tomohiro F. Nishijima, Taichi Shimazu, Tempei Miyaji, Yoshiyuki Majima, Takayo Sakiyama, Kyoko Obama, Fumio Nagashima, Yosuke Uchitomi; Division of Survivorship Research, National Cancer Center Institute for Cancer Control, National Cancer Center, Tokyo, Japan; Department of Oncology and General Medicine, IMSUT Hospital, Institute of Medical Science, University of Tokyo, Tokyo, Japan; Department of Gastrointestinal Medical Oncology, National Cancer Center Hospital, Tokyo, Japan; Department of Hepatobiliary and Pancreatic Oncology, National Cancer Center Hospital, Tokyo, Japan; Department of Hepatobiliary and Pancreatic Oncology, National Cancer Center Hospital, Tokyo, Japan; Department of Hepatobiliary and Pancreatic Oncology, National Cancer Center Hospital, Tokyo, Japan; Department of Gastrointestinal Oncology, Shizuoka Cancer Center, Sunto-Gun, Japan; Clinical Trial Coordination Office, Shizuoka Cancer Center, Shizuoka, Japan; Department of Psychiatry and Cognitive-Behavioral Medicine, Nagoya City University Graduate School of Medical Sciences, Nagoya, Japan; Department of Internal Medicine, Division of Medical Oncology & Respiratory Medicine, Shimane University Faculty of Medicine, Izumo, Japan; Geriatric Oncology Service, NHO Kyushu Cancer Center, Fukuoka, Japan; Division of Behavioral Sciences, National Cancer Center Institute for Cancer Control, National Cancer Center, Tokyo, Japan; NPO Pancreatic Cancer Action Network Japan; Department of Cancer Survivorship and Digital Medicine, The Jikei University School of Medicine, Tokyo, Japan

Background: Older adults with cancer experience aging-related physical, psychosocial and cognitive challenges that require comprehensive communication with their oncologists. Geriatric assessment (GA) can assess these aging-related problems and guide management. Communication support may further facilitate the implementation of GA-guided management (GAM). We report secondary outcomes of a single-blind, parallel-group, multicenter, randomized controlled trial evaluating the efficacy of a program combining GAM recommendations and communication support to facilitate aging-related communication between older Japanese patients with cancer and their oncologists. Methods: This study included patients aged \geq 70 years with advanced or recurrent gastrointestinal cancers who were scheduled to receive first- or second-line systemic therapy and had impairment in at least one GA domain as assessed with a web-based application at baseline. In the intervention group, GAM recommendations and a question prompt list were given to patients by trained intervention providers to be shared with their oncologists at the first outpatient visit after randomization. During 5 months after the initial intervention, the implementation of the GAM recommendations was reviewed monthly by the intervention providers with the patients and their oncologists. The control group received usual care. Secondary outcomes included the incidence of grade 3-5 adverse events (National Cancer Institute Common Terminology Criteria for Adverse Events, ver. 5.0), dose modifications, early treatment discontinuation, unplanned hospital utilization during 3 months, overall survival rate at 6 months, and health-related quality of life and patient satisfaction at 3 and 6 months. Results: Between September 2021 and September 2023, 215 patients (99 women, 116 men; median age 75 [range 70-88] years) were randomized (n=108/ 107 in the intervention/control group). No differences were found between the groups in patient background characteristics. The incidence of any grade 3-5 adverse event was significantly lower in the intervention group than in the control group (50.9% vs. 66.4%, P<0.05); the incidence of hematologic toxicities was significantly reduced (37.0% vs 55.1%, P<0.01), while that of non-hematologic toxicities remained similar (29.6% vs 36.4%, P=0.31). Early treatment discontinuation was also significantly lower in the intervention group than in the control group (26.9% vs. 43.0%, P<0.05). No significances were found in other secondary outcomes including overall survival rate at 6 months (77.7% vs 78.7%, P=0.88) Conclusions: Our program combining GAM recommendations with communication support significantly reduced severe treatment toxicity without compromising survival in older patients with cancer. Clinical trial information: UMIN000045428. Research Sponsor: Japan Agency for Medical Research and Development.

A technology-enabled clinical trial program's impact on patient screening and trial enrollment in 2024.

Samantha Mallahan, Danielle Skelly, Michelle Huang, Allison Madera, Sarah Salzman, Li-Pang Huang, Ajeet Gajra, Ayed Ayed, Ralph J. Hauke, Jay Carlson, James Lloyd Wade III, Syeda Bushra Ahesam, Sristee Niraula, Charles H. Redfern, Jijun Liu, Janelle Marie Meyer, Amol Rao, Benjamin Maurice Solomon, Nihal Essa Abdulla, Chelsea Kendall Osterman; Tempus AI, Inc., Chicago, IL; Tempus AI., Inc, Chicago, IL; Tempus AI, Inc, Chicago, IL; Hematology Oncology Associates of CNY, East Syracuse, NY; Cancer Specialists of North Florida, Jacksonville, FL; Nebraska Cancer Specialists, Omaha, NE; Mercy Hospital St. Louis, Springfield, MO; Cancer Care Specialists of Illinois, Decatur, IL; Cayuga Hematology Oncology Associates, Ithaca, NY; Cayuga Medical Center At Ithaca, Inc., Ithaca, NY; Oncology Associates of San Diego, CA; Illinois CancerCare, Peoria, IL; Oregon Oncology Specialists, Salem, OR; MemorialCare Cancer Institute, Fountain Valley, CA; Avera Cancer Institute, Sioux Falls, SD; Cancer and Blood Specialty Clinic, Los Alamitos, CA

Background: Typical workflows for clinical trial start-up and screening are time- and resource-intensive. The Tempus AI TIME program offers a novel clinical trial solution, collaborating with clinical sites to increase trial access and alleviate site burden by streamlining study activation and screening methods. Methods: The TIME program consists of an algorithmic trial screening platform (TApp), team of oncology nurses, diverse trial portfolio, and rapid study activation processes. Patient-level clinical information is centralized within the TIME database and includes structured and unstructured data generated from Electronic Medical Record integration, next generation sequencing results, and natural language processing models. The TApp used this data combined with trial eligibility criteria to algorithmically match patients to TIME trials. TApp searches were triggered by changes to study criteria and/or updates to clinical data. Algorithmic matches were filtered based on site capabilities, site interest in the trial, and trial lookback criteria, which defined the required recency of a patient's latest clinical document or encounter. Qualifying matches were then reviewed by a Tempus nurse and sent to sites if confirmed eligible. Trial activations followed TIME's streamlined operational methods using a pre-negotiated rate card for site reimbursement of all clinical trial activities, standardized clinical trial agreement, and central IRB. Trials could be activated prospectively before the first eligible patient was identified, or in a "just-in-time" (JIT) manner if a patient was ready to consent. Data collected included TIME network information, TApp and nurse screening results, activation timelines, and enrollments across all active TIME sites and trials from 01/01/2024 - 12/31/2024. Results: During 2024, the TIME network consisted of 87 sites (79 Community, 8 Academic) and 98 trials. The TApp completed 1,323,259,353 searches across 1,281,676 patients resulting in 2,251,505 potential TApp trial matches. After applying site capability and trial lookback filters, TIME nurses screened 35,912 of these matches with 5,034 confirmed. These matches led to 186 activations (82 JIT, 104 prospective) and 573 consents. Conclusions: The Tempus AI TIME program facilitated the screening of 1.28M+ patients for over 95 clinical trials, averaging 1.57 consents per day over 1 year. Future trial matching strategies should utilize algorithmic screening and rapid activation processes to improve patient access and trial success. Research Sponsor: Tempus AI, Inc.

2024 patient screening and consents.	
Patient Population	1,281,676
TIME Trials	98
TApp Searches	1,323,259,353
Algorithmic Matches	2,251,505
Matches Screened	35,912
Matches Confirmed	5,034
Interventional Consents	225
Observational Consents	348
Total Activations	JIT: 82, Prospective: 104
Avg Activation Time (business days)	JIT: 16.1, Prospective: 39.6

Effect of human-AI teams on oncology prescreening: Final analysis of a randomized trial.

Ravi Bharat Parikh, Likhitha Kolla, Elizabeth Beothy, William J. Ferrell, Brenda Laventure, Matthew Guido, Anthony Girard, Yang Li, Jinbo Chen, Ezekiel J. Emanuel; Emory University, Atlanta, GA; University of Pennsylvania Perelman School of Medicine, Philadelphia, PA; University of Pennsylvania, Philadelphia, PA; Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA

Background: Eligibility assessment for oncology clinical trials – "prescreening" – relies on manual review of unstructured clinical notes, which is error-prone and time-consuming. Artificial intelligence (AI) language models that merge deep learning with oncologistderived rules (neurosymbolic AI) can enhance prescreening by automating eligibility extraction from longitudinal electronic health records (EHRs), yet real-world evaluations are limited. We compared the accuracy and efficiency of traditional vs. AI-augmented (Human+AI) prescreening. Methods: In this randomized non-inferiority trial, two research coordinators (RCs) abstracted 12 common trial eligibility criteria from complete EHRs from patients with advanced non-small cell lung cancer (NSCLC) or colorectal cancer (CrC) treated in a community oncology practice. Before the trial, gold-standard abstraction was performed by 3 independent oncologist reviewers. Charts were randomized in blocks of 20 to be viewed alone (Human-alone) or augmented by a pretrained neurosymbolic model (Human+AI) in a paired design, such that each RC reviewed each patient chart. The primary aim was to evaluate noninferiority (margin \pm 5%) and subsequent superiority of chart-level accuracy (proportion of correctly abstracted elements per chart relative to gold standard) between Human+AI vs. Human-alone. Secondary outcomes were criterion-level accuracy (proportion of correctly abstracted elements across charts for each eligibility criterion), and efficiency (median abstraction time per chart). Paired t-tests and Wilcoxon rank-sum tests assessed differences between Human+AI vs. Humanalone. We descriptively compared accuracy of both arms vs. the AI algorithm (AI-alone). Results: Among 356 charts (196 NSCLC, 160 CrC), Human+AI had noninferior and superior accuracy than Human-alone (76.1% vs. 71.5%, p < 0.001); both Human arms were superior to AI-alone (59.9%). Human+AI had greatest criterion-level accuracy for 7 of 12 criteria. Efficiency was similar between Human arms (32.1 vs. 31.8 min, p = 0.51). Conclusions: AIaugmented prescreening was more accurate than RC or AI prescreening alone. Human+AI teaming most improved accuracy for biomarker, staging, and response criteria. While Human+AI did not save time, efficiency gains may be realized as RCs become more familiar with AI eligibility models. AI language models can enhance CRC prescreening and identification of trial-eligible patients. Clinical trial information: NCT06561217. Research Sponsor: Mendel AI.

Accuracy ac	cross arms.				
		Ad	curacy (%)		
	Criteria	Human- Alone	Human+Al	AI-Alone	p-value
	Overall	71.5	76.1	59.9	< 0.001
Neoplasm	Cancer Type	86.9	86.4	73.3	0.80
•	Stage Group	71.7	73.4	57.0	0.57
	M Stage	43.9	57.0*	60.2	< 0.001
	N Stage	50.5	66.3*	52.6	< 0.001
	T Stage	56.3	71.6*	54.3	< 0.001
Biomarker	Biomarker Tested?	84.6	93.2**	88.1	< 0.001
	Biomarker Result	67.9	79.0*	32.5	< 0.001
	Biomarker Result Interpretation	80.8	91.3*	35.7	< 0.001
Other	Outcome	23.7	35.9*	55.2	0.004
	Response	47.1	51.7	60.4	0.20
	EĊOG	84.7**	78.1	34.4	0.10
	Medications	89.0	89.1	59.4	0.92

Bold indicates arm with greatest accuracy for a given criterion. *>10% accuracy difference between Human+AI vs Human-alone. **5-10% accuracy difference between Human+AI vs Human-alone.

Disparities in pediatric oncology outcomes in the occupied Palestinian territories: A retrospective study from Augusta Victoria Hospital.

Ru'a Rimawi, Kendall Carpenter, Wesam Bader, Navid Madani, Leslie Lehmann, Hani Saleh; Dana-Farber Cancer Institute, Boston, MA; Boston Children's Hospital, Boston, MA; Augusta-Victoria Hospital, East Jerusalem, Palestinian Territories (West Bank and Gaza)

Background: Childhood cancer survival rates exceed 80% in high-income countries, but over 80% of the global burden occurs in low- and middle-income countries, where survival rates are significantly lower. The occupied Palestinian territories (OPT)—comprising the West Bank, Gaza, and East Jerusalem—face additional and location-specific challenges, including political instability, movement restrictions, and fragmented healthcare, that would be expected to further negatively impact care. The aim of our study is to report on outcomes of children treated at the only specialized pediatric oncology cancer center, Augusta Victoria Hospital (AVH), located in East Jerusalem. Methods: This was a retrospective IRB approved study conducted by Dana-Farber Cancer Institute and AVH. Chart review was performed to obtain diagnoses, treatments and outcomes of all pediatric oncology patients with histologically confirmed cancer admitted at AVH from January 2018 to June 2024. Results: A total of 424 patients were included, with a median age at diagnosis of 6.95 years (IQR, 3.35–11.2). Of these, 51.2% were male. Patients resided in the West Bank (51.2%), Gaza (43.4%), and East Jerusalem (3.8%). The median diagnostic delay, defined as date of symptom onset to date of diagnosis, was 24.5 days (IQR, 10-45), with significant variation by gender (males: 30 days; females: 20 days, p = 0.018), age group (<5 years: 14 days; \geq 5 years: 30 days, p = 0.003), and oncology diagnosis (leukemia: 14 days, lymphoma and solid tumors: 30 days, p = 0.014). Treatment delays, defined as the time form diagnosis to treatment initiation, was 14 days (IQR, 4-30), with the shortest duration for leukemia (2 days) and the longest for solid tumors (30 days, p = 0.008). There were no significant differences in time to treatment by region. The majority of patients lost to followup were living in Gaza (15/21, 71%). Among the 13% deaths, 15.4% were treatment-related, primarily due to infection, and most of these treatment-related deaths (65%) occurred in patients living in Gaza. The 3-year overall survival (OS) rate was 76.31%, and event-free survival (EFS) rate was 62.36%. Gaza patients had the lowest 3-year EFS rate (37.12%) compared to the West Bank (70.37%) and East Jerusalem (77.78%; p < 0.0001). Conclusions: This study is the first to report on outcomes of pediatric oncology patients treated at the only specialized center in the OPT. Males and patients older than 5 years experienced longer diagnostic delays, while patients with solid tumors faced treatment delays 15 times longer than those with leukemia. Gaza patients had higher lost to follow-up rates and treatment-related deaths with significantly inferior EFS. Research Sponsor: None.

Analysis of evidence in NCCN harmonized guidelines for sub-Saharan Africa.

Scott Swartz, Gwynn Spielman, Samrawit Agezew, Ayo Samuel Falade, Rebecca Jane DeBoer, Mary Jue Xu, Glory Frank Makupa, Eulade Rugengamanzi, Courtney Chau, Kathy Jung, Rohan Luhar, Pariswi Tewari, Alita Mrema, Katherine Van Loon, Geoffrey Buckle; Department of Medicine, University of California, San Francisco, San Francisco, CA; UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA; University of California, San Francisco School of Medicine, San Francisco; Department of Medicine, Mayo Clinic, Rochester, MN; Department of Medicine, Division of Hematology/Oncology, University of California, San Francisco, San Francisco, CA; Department of Otolaryngology - Head and Neck Surgery, University of California, San Francisco, San Francisco, CA; Kilimanjaro Christian Medical University College, Dar Es Salaam, Tanzania; Butaro Cancer Center of Excellence, Butaro, Rwanda; Icahn School of Medicine at Mount Sinai, New York, NY; Johns Hopkins University School of Medicine, Baltimore, MD; Rush University Medical College, Chicago, IL; University of California, San Francisco School of Medicine, San Francisco, CA; Ocean Road Cancer Institute, Dar Es Salaam, Tanzania

Background: The National Comprehensive Cancer Network (NCCN) Harmonized Guidelines for Sub-Saharan Africa (SSA) have emerged as leading cancer treatment guidelines in SSA. The NCCN-SSA guidelines, derived by adapting NCCN guidelines for the SSA context, offer standardized recommendations to guide cancer care and shape policy in SSA. This study examines the evidence cited in support of the NCCN-SSA guidelines, with a focus on population characteristics and generalizability to SSA. Methods: Two reviewers independently examined the NCCN-SSA guidelines for the eight most common cancers in SSA to identify all studies cited in support of treatment/management recommendations. Study selection discrepancies were resolved by discussion. Full-text articles were reviewed and data on age, sex, race, and recruitment geography were abstracted. Descriptive analyses were performed using R statistical software. Results: Overall, 4,589 citations were reviewed, and 2,938 (64.0%) studies with individual-level data were included, representing >10.4 million study participants. Of the 2,061 studies reporting geographic information (70%), 50 (2.4%) recruited in SSA; of these, 39 (83.0%) recruited from South Africa. Three studies (0.2%) recruited exclusively in SSA. Most studies (95.3%) recruited exclusively from high or upper-middle income countries. Only 29.2% of studies with race data included >10% Black study participants. **Conclusions:** Most studies cited in the NCCN-SSA guidelines were conducted in high-income countries outside SSA. A small minority of all study participants were Black. Our findings underscore potential limitations in the generalizability of the NCCN-SSA guidelines to SSA and highlight a pressing need to generate and incorporate context-specific data to guide care and inform policy. Research Sponsor: UCSF Helen Diller Family Comprehensive Cancer Center.

Cancer type	# (%) stud- ies report- ing geography	# (%) studies by recruitment re- gion*: Americas	# (%) studies by recruitment region*: Europe	# (%) studies by recruitment re- gion*: Sub-Sah. Africa	% partici- pants, White	% partici- pants, Black	% partici- pants, Other race	# (%) studies representing only HMIC (per World Bank)
Overall	2061 (70%)	1177 (57%)	921 (45%)	50 (2%)	79%	9%	11%	1964 (95%)
B-cell	325 (57%)	173 (53%)	178 (55%)	5 (2%)	82%	7%	10%	`307´ (94%)
Breast	206 (44%)	123 (60%)	124 (60%)	12 (6%)	80%	9%	11%	179 (87%)
Cervical	163 (90%)	100 (61 %)	44 (27%)	3 (2%)	64%	14%	22%	158 (97%)
Colorectal	584 (82%)	278 (48%)	292 (50%)	11 (2%)	80%	10%	10%	571 (98%)
Hepato- cellular	`183´ (74%)	80 (44%)	68 (37%)	0 (0%)	69%	9%	22%	`169´ (92 %)
Kaposi sarcoma	`51´ (80%)	25 (49%)	`19´ (37%)	`5´ (10%)	38%	51%	10%	44 (86%)
Ovarian	115 (56%)	76 (66%)	35 (30%)	0 (0%)	83%	4%	13%	115 (100%)
Prostate	434 (88 %)	322 (74 %)	161 (37%)	14 (3%)	79%	9%	12%	421 (97%)

HMIC = high and upper-middle income countries.

*Percent of studies includes as the denominator only the number of studies with reported geographies

Integrated health system for resolving breast cancer screening actions: Multicenter randomized clinical study—Itaberaí randomized trial, ReBEC, RBR-39vm2nd.

Ruffo Freitas-Junior, Danielle Cristina Netto Rodrigues, Rosangela da Silveira Corrêa, Douglas Euclides da Silva, Paola Ferreira Germek, Luana Vieira Martins, Christina Souto Cavalcante Costa, Flavia Vidal Cabero, Priscila Dias Watanabe, Leonardo Ribeiro Soares; CORA – Advanced Center for Diagnosis of Breast Diseases Federal University of Goias, Goiania, Goias, Brazil; CORA - Centro Avançado de Diagnóstico da Mama do Hospital das Clinicas da Universidade Federal de Goias, Goiania, Goias, Brazil; Secretaria Municipal de Saude de Itaberai, Itaberai, Goias, Brazil; Federal University of Goias, Goiânia, Goias, Brazil

Background: The ITABERAÍ Project involves an intervention through training of Community Health Workers (CHW), based on evidence from clinical breast examinations (CBE) screening. It is a randomized, prospective, phase III, multicenter clinical study. The target population is divided into a Control Group (CG) and an Intervention Group (IG), where the CG receives the Brazilian Ministry of Health's (MS) recommendations for breast cancer screening, The IG, in addition to the MS recommendations, receives the CBE. Among the stages of the project are the training of CHW and the development of tools for data collection. Objective: This study aims to evaluate the functioning of the integrated system as a tool for the resolution of breast cancer screening actions, according to the ITABERAÍ Project. Methods: Information stored in the integrated system database developed for the project, from 2022 to 2024, was analyzed. The system comprises a set of services and applications that integrates actions from the registration of participants to the diagnosis and treatment of altered cases. It involves the integration of the App Rosa with the Web System (RosaWatch). The App Rosa was created for exclusive use by the CHW to collect data from participants who agree to participate in the study, while RosaWatch is for use by the Family Health Team (FHT), specialist doctors, nurse navigators, and researchers, and was created to collect information on the follow-up of altered cases. To evaluate the functioning of the system, data on the completeness of the information stored according to the Study Group and the follow-up of cancer cases were checked. Results: At the end of 3 years of project implementation, data from 3,670 randomized women were reported, of which 92% (3,359) were active in the project, out of this 1,780 (53%) in the CG and 1,579 (47%) in the IG (p < 0.05). Regarding the completeness of the information, by the end of 2024, it was found that 2,984 (88.8%) had consistent data. Stratifying by year of data collection, a significant increase in completeness was observed: in 2022, of the 425 records, 278 (65%) were compliant; in 2023, of the 2,255 records, 2,117 (94%) were compliant; and in 2024, of the 679 records, 654 (96%) were compliant. During the study period, 3,143 breast exams were performed by the CHW of the IG, with 594 (19%) altered cases. Of these, after screening at the Family Health Units (ESF), 90 (15%) participants received care from a specialist doctor (mastologist), and 10 had a confirmed breast cancer. In the CG, ESF doctors referred 33 women for specialist consultations, and six diagnoses were confirmed. Conclusion: The integrated system proved to be effective in monitoring the actions of the ITABERAÍ Project. Additionally, it contributed to the adherence of the CHW and the quality standard of the information, facilitating better data monitoring. Clinical trial information: RBR-39vm2nd. Research Sponsor: None.

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Anesthesia type during surgery for treatment of biologically aggressive cancers: Results of the GA-CARES randomized, multicenter trial.

Elliott Bennett Guerrero, Jamie Romeiser, Samuel DeMaria Jr., Jacob Nadler, Timothy Quinn, Sanjeev Ponnappan, Samuel Stanley III, Dongliang Wang, Aaron R. Sasson; Stony Brook University School of Medicine, Stony Brook, NY; Department of Public Health & Preventive Medicine, Syracuse, NY; Department of Anesthesiology, Perioperative and Pain Medicine, New York, NY; University of Rochester Medical Center, Rochester, NY; Roswell Park Cancer Institute, Buffalo, NY; Long Island Jewish Medical Center, Northwell Health, New Hyde Park, NY; State University of New York Upstate Medical University, Syracuse, NY; Stony Brook School of Medicine, Stony Brook, NY

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, 2025, issue of the *Journal of Clinical Oncology*.

General practitioner-led vs surgeon-led colon cancer survivorship care: A randomized clinical trial.

Julien Vos, Laura Duineveld, Thijs Wieldraaijer, Jan Wind, Wim Busschers, Edanur Sert, Irma Verdonck-De Leeuw, Henk van Weert, Kristel M. van Asselt; Amsterdam UMC, Amsterdam, Netherlands

Background: The role of general practitioners (GPs) in providing survivorship care for cancer patients remains debated. In 2015, the randomized I CARE trial was initiated to evaluate the impact of GP-led vs. surgeon-led survivorship care on quality of life (QoL) and assess the effect of the eHealth application Oncokompas. An interim analysis after 12 months revealed no clinically relevant differences in QoL changes. However, patients continued to have followup consultations for up to 60 months after treatment. This study addressed the long-term QoL outcomes of the trial. Methods: The I CARE trial was a pragmatic, 2x2 factorial, open-label, randomized controlled trial. The trial was conducted in 8 hospitals and 225 general practices across the Netherlands. The trial included patients who underwent primary surgical treatment for stage I-III colon cancer or rectosigmoid carcinoma, and who were eligible for routine follow-up according to national guidelines. Inclusion lasted from March 26, 2015, to Nov 21, 2018. Patients were randomized using variable block randomization, stratified by age and tumor stage, into four groups (1:1:1:1): usual surgeon-led care, surgeon-led care with Oncokompas, GP-led care, and GP-led care with Oncokompas. The primary outcome was QoL at 5 years, as measured by the change from baseline in the EORTC QLQ-C30 summary score (range 0-100). Generic and disease-specific QoL were measured at baseline, 3, 6, and 12 months, and annually up to 60 months post-treatment. Differences in QoL changes were analyzed using piecewise linear mixed-effects models with a knot at 24 months to capture potential deviations in QoL recovery. A 10-point difference was considered clinically relevant (superiority design with α = 0.05, power of 80%, and 15% dropout). The trial is registered with the Netherlands Trial Register (NTR4860). Results: In total 303 patients were enrolled; 79 were randomized to surgeon-led care, 83 to surgeon-led care with Oncokompas, 73 to GP-led care, and 68 to GP-led care with Oncokompas. Patients were male (67%) with a mean age of 68.0 years (SD 8.4). Of the 151 patients assigned to Oncokompas, 51 (36%) reported using the app at least once in the first year. Baseline QoL was high in all groups. No clinically meaningful differences in QoL were observed between GP-led and surgeon-led groups at 24 months (difference of -0.5 [95% CI -1.6 to 0.5]) and 60 months (-0.01 [-0.8 to 0.8]). Oncokompas also had no meaningful effect (difference of 0.8 [0.0 to 1.6] at 60 months). Conclusions: In this pragmatic, randomized controlled trial conducted in the Netherlands, GP-led survivorship care did not improve longterm QoL compared to traditional surgeon-led care among non-metastatic colorectal cancer survivors. Due to low usage rates, the impact of Oncokompas is inconclusive. Survivorship care models can be tailored to fit individual preferences. Clinical trial information: NTR4860. Research Sponsor: Dutch Cancer Society; grant BMA 5954.

Effect of post-discharge symptom monitoring on hospital readmissions: A randomized trial.

Robert Michael Daly, Jun J. Mao, Jennifer R. Cracchiolo, Jessie C. Holland, Jennie Huang, AnnMarie Mazzella Ebstein, Chasity Walters, Jill Ackerman, Nitya Prabhakar Raj, Rachel Ann Sanford, Mark Andrew Dickson, Alison J. Moskowitz, Raajit Rampal, Alexander Noor Shoushtari, William P. Tew, Martin H Voss, Raymond E Baser, Peter D. Stetson, Katherine Panageas, Deb Schrag; Memorial Sloan Kettering Cancer Center, New York, NY; Memorial Sloan Kettering Cancer Center and Weill Medical College, New York, NY

Background: There is growing interest to improve patient care transitions from hospital to home and to prevent readmissions but effective interventions are lacking. Methods: We conducted a randomized clinical trial among patients with cancer discharged after an unplanned hospital admission at a specialty cancer center. Hospitalized patients on medical oncology services were randomized at discharge to receive either a digital symptom monitoring and management intervention or to usual care. Patients randomized to the intervention received a daily electronic symptom assessment for 10 days post-discharge, consisting of 9 common symptoms from the National Cancer Institute Patient Reported Outcomes version of the Common Terminology Criteria for Adverse Events and an open-ended question to allow for patients to provide further symptom context and for two-way engagement with their clinical team. Patients also received customized self-management education delivered through the patient portal based on their reported symptoms. Primary oncologists received alerts through the portal for moderate and severe symptoms. Usual care consisted of symptom monitoring at the discretion of the primary clinical team, generally comprising an oncologist and an office practice nurse. The primary outcome was the 30-day readmission rate, analyzed using cumulative incidence functions and Gray's test with death as a competing risk. Secondary endpoints included 90-day readmission rate and 30-day emergency room visit without admission rate. Results: Between 04/19 and 09/19/2024, 1,713 patients were randomized with median age 66 years (range: 19 – 99), 66% white, 12% African American, 11% Asian, and 11% Hispanic with 53% female. The most common cancer diagnoses were gastrointestinal (26%), thoracic (11%), genitourinary (10%), gynecologic (10%), leukemia (9%), and lymphoma (9%). In the intervention group, the most frequently reported moderate and severe symptoms were fatigue and pain. The two arms had roughly similar proportions of patients who died before a hospital readmission. The 30-day readmission rate was 30% in the intervention group compared to 37% in the usual care group (p = 0.001). The decrease in readmission rate was maintained at 90 days (45% vs. 52%, p = 0.002). Emergency room visits without admission at 30 days were also lower in the intervention group (12% vs. 17%, p = 0.007). Conclusions: Digital post-discharge symptom monitoring and customized patient self-management education for 10 days post discharge reduced hospital readmissions in patients with cancer. Further research is necessary to identify the precise mechanisms that contribute to the success of this intervention. Research Sponsor: National Cancer Institute; Emerson Collective Digital Oncology Care.

SNF-CLIMEDIN: A HECOG prospective randomized trial of digital support and intervention in patients with advanced non-small cell lung cancer (NSCLC)—Final results.

Paris A. Kosmidis, Thanos Kosmidis, Kyriaki Papadopoulou, Nikolaos Korfiatis, Athanassios Vozikis, Sofia Lampaki, Amanda Psyrri, Elena Fountzilas, Athina Christopoulou, Epaminondas Samantas, Anastasios Vagionas, Giannis Socrates Mountzios, Georgios Gkoumas, Nikolaos Tsoukalas, Ilias Athanasiadis, Dimitrios Bafaloukos, Chris G. Panopoulos, Margarita Ioanna Koufaki, George Fountzilas, Helena Linardou; Department of Medical Oncology, Hygeia Hospital, Athens, Greece; Care Across, London, United Kingdom; Molecular Oncology Laboratory, Hellenic Foundation for Cancer Research, Thessaloniki, Greece; Faculty of Social Sciences, University of East Anglia, Norwich, United Kingdom; Laboratory of Health Economics and Management (LabHEM), University of Piraeus, Piraeus, Greece; Pulmonary Department, Lung Cancer Oncology Unit, Aristotle University of Thessaloniki, G. Papanicolaou Hospital, Thessaloniki, Greece; Section of Medical Oncology, Department of Internal Medicine, Attikon University Hospital, Faculty of Medicine, National and Kapodistrian University of Athens, School of Medicine, Athens, Greece; Oncology Department, General Hospital of Patras St. Andrews, Patras, Greece; Second Oncology Department, Metropolitan Hospital, Piraeus, Greece; Department of Medical Oncology, Agioi Anargyri Cancer Hospital, Athens, Greece; 401 General Military Hospital of Athens, Oncology Department, Athens, Greece; Department of Medical Oncology, Mitera Hospital, Athens, Greece; First Oncology Department, Metropolitan Hospital, Piraeus, Greece; Department of Medical Oncology, Mitera Hospital, Athens, Greece; First Oncology Department, Metropolitan Hospital, Piraeus, Greece; Department of Medical Oncology, Mitera Hospital, Athens, Greece; First Oncology Department, Metropolitan Hospital, Piraeus, Greece; Department of Medical Oncology, Mitera Hospital, Athens, Greece; First Oncology Department, Metropolitan Hospital, Piraeus, Greece; Department of Medical Oncology, Mitera Hospital, Athens, Greece; First Oncology Department, Metropolitan Hosp

Background: This trial aims to investigate the feasibility and effectiveness of online digital intervention to NSCLC patients in terms of adverse events (AEs), guality of life (QoL), cost, and the interrelation with clinical and molecular characteristics. Methods: This prospective randomized trial recruited 200 advanced NSCLC patients (3/22-10/23). Final analysis was undertaken in 12/24. All had NGS tissue analysis for 161 genes, and received standard treatment (predominantly immuno-chemotherapy). Through the CareAcross online platform, they received information about their disease and treatment, and periodically reported any of the 22 preplanned AEs. Patients were randomized 1:1 in the Intervention (A) and Control (B) arm; patients in arm A received digitally, additionally, evidence-based guidance for the reported AEs. The study was designed to assess AE improvement (measured per patient as reduction of AEs reported at last contact, compared to those previously reported) and QoL. EQ5D-5L scores were collected. Patient-case level hospitalization data were collected and costs were estimated based on reimbursed cost as defined by the Ministry of Health. Results were correlated with patients' clinical and molecular characteristics. Results: Clinical and molecular characteristics will be presented during ASCO Congress. Comparing arms A vs B: ORR: 42.1% vs 41.7%; Median PFS: 11m (8.0-15) vs 10m (7.0-13), 1-year PFS: 43% (31%-54%) vs 42% (31%-53%) (p = 0.4). Median OS: 15m (12-20) vs 16m (12-21), 1-year OS: 59% (48%-68%) for both arms (p = 0.9). PFS and OS were improved for those with best responses (p < 0.001). Patients with EGFR mutations had better OS (p = 0.05). The most common AEs reported in both arms were fatigue, cough, anorexia, nausea. More AEs were reported online vs to clinicians (89% vs 68% of patients; p < 0.01). Baseline EQ5D-5L was similar for both arms; when compared with data at best response, Anxiety/Depression showed the biggest difference in improvement for arm A vs B. Among the 22 AEs, 17 improved more in arm A, 1 improved equally, and 4 improved more in Arm B. The comparative improvements of rash and stomatitis in arm A vs B were statistically significant (p = 0.0073 & p = 0.0447). The mean hospitalization cost (arm A vs B, in Euros) was 455.4 (95%CI: 91.9-941.5) vs 779.5 (346.6-1328.5) (p < 0.001); the mean diagnostics cost was 20.3 (0.5-50.8) vs 73.3 (1.3-186.1) (p < 0.001). Conclusions: Digital oncology is feasible, costeffective by reducing hospitalizations and tends to improve QoL (especially anxiety and depression) and most AEs of NSCLC patients regardless of clinical and molecular status. Patients report, digitally, more informative AEs for clinical and research analysis. Through the digital transformation of healthcare, digital oncology can be a complementary tool to the Oncology team and warrants further exploration. Clinical trial information: NCT05372081. Research Sponsor: Stavros Niarchos Foundation.

Breast cancer diagnosis, management, and outcomes in transgender, nonbinary, and gender-diverse individuals: A multicenter cohort.

Chandler Scott Cortina, Ruta Brazauskas, Meghan Rose Flanagan, Kathie-Ann P. Joseph, Rita Mukhtar, Olga Kantor, Kristen M. Rezak, Laura Horst Rosenberger, Sumanas Jordan, Rachel Jimenez, Katherine A. Kopkash, Tasha Hughes, Meeghan A. Lautner, Emily L. Siegel, Zahraa Alhilli, Michael Ryan Cassidy, Rachel L. McCaffrey, Marie Catherine Lee, Anna Weiss, Melinda Stolley; Division of Surgical Oncology, Department of Surgery, Medical College of Wisconsin & MCW Cancer Center, Milwaukee, WI; Division of Biostatistics, Institute for Health and Equity, Medical College of Wisconsin, Milwaukee, WI; University of Washington/Fred Hutchinson Cancer Center, Seattle, WA; NYU Grossman School of Medicine, NYU Langone Health, New York, NY; Division of Surgical Oncology, Department of Surgery, University of California, San Francisco, San Francisco, CA; Brigham & Women's Hospital and Harvard Medical School, Boston, MA; Division of Plastic, Maxillofacial, and Oral Surgery, Duke University Medical Center, Durham, NC; Department of Surgery, Duke Cancer Institute, Duke University Medical Center, Durham, NC; Division of Plastic & Reconstructive Surgery, Department of Surgery, Northwestern University, Chicago, IL; Department of Radiation Oncology, Harvard Medical School and Harvard Radiation Oncology Program, Boston, MA; Department of Surgery, Northshore University HealthSystem and University of Chicago Pritzker School of Medicine, Evanston, IL; Department of Surgery, University of Michigan, Ann Arbor, MI; Division of Surgical Oncology, Department of Surgery, University of Wisconsin School of Medicine and Public Health, Madison, WI; Department of Surgery, University of Southern California, Los Angeles, CA; Breast Center, Integrated Surgical Institute, Cleveland Clinic Foundation, Cleveland, OH; Boston University School of Medicine, Boston, MA; Division of Surgical Oncology, Department of Surgery, Vanderbilt University Medical Center, Nashville, TN; Comprehensive Breast Program, Moffitt Cancer Center, Tampa, FL; Department of Surgery, Unive

Background: Paucity of data on breast cancer (BC) in transgender, nonbinary, and genderdiverse (TGD) individuals leads to suboptimal screening and treatment algorithms. We developed a national multicenter retrospective cohort to describe demographic, clinicopathologic, and treatment characteristics of TGD individuals with BC and report outcomes. **Methods:** The cohort included TGD persons age \geq 18yrs with stage 0–IV BC treated at 22 US centers from 1990–2023. Demographic and clinicopathologic characteristics were evaluated and compared to BC patients in the SEER 2016–21 dataset. Wilcoxon rank sum tests, χ^2 tests, and KM analysis were used to compare variables and estimate 5-yr BC-specific survival (BCSS). Results: 112 TGD persons with 113 BCs were included. Median age at diagnosis was 42.5yrs (IQR 36.5-51), 92.9% were female sex at birth (FSAB), 73.2% were NH-White, and 38.4% used gender-affirming hormones pre-BC. Of those FSAB (n=104), 61.5% were premenopausal and 11.5% had undergone gender-affirming top surgery (GATS) pre-BC. Most BCs (51.8%) were self-detected, 27.7% were screen-detected (48.2% underwent screening pre-BC), 13.4% were incidentally found on GATS pathology, 3.6% were provider-detected, and 2.7% were incidentally found on other imaging. Of 84 (75%) tested patients, 16/84 (19%) had a pathogenic germline variant, with BRCA2 (25%) and BRCA1 (18.8%) being most common. Most tumors were HR+ (85.7%) and early stage (25.7% DCIS and 45.1% stage I). Regarding local treatment, most (61.6%) underwent mastectomy, with 63.8% omitting reconstruction; after lumpectomy, 29% omitted radiation (RT). 41.1% received systemic chemotherapy and while endocrine therapy (ET) was recommended for 79, only 81% (64/79) received ET. There was no difference in surgery type (p = 0.22) or ET receipt (p = 0.32) by SAB. Compared to patients in SEER (N = 401,311), the TGD cohort was younger (median age 42.5 vs 62yrs), more frequently NH-White (75.2% vs 65.1%), more often had PR+ disease (79.5% vs 70.7%), and had a higher proportion of males (MSAB) (7.1% vs 0.8%) (p < 0.01 for all); but there was no difference in disease stage (p = 0.39). At 38 months median follow-up: 12 (10.7%) had a locoregional recurrence (LRR), and 2 died of metastatic BC. 5-yr BCSS probability was 96.2% (95% CI 85.3–99.0%). Conclusions: The first multicenter cohort study of TGD individuals with BC identified they were younger and had a higher proportion MSAB compared to BC patients in SEER. Most tumors were selfdetected, and the pathogenic germline variant rate was high – suggesting a possible role for earlier screening in high-risk TGD persons regardless of SAB. The elevated LRR rate along with low ET and RT uptake indicates opportunities to improve adherence to guideline concordant care. Findings underscore the necessity for prospective research to inform gender-inclusive evidence-based BC screening and treatment guidelines. Research Sponsor: National Cancer Institute.

Inclusion of people living with HIV in Food and Drug Administration (FDA) oncology pivotal registration trials from 2020 to 2024.

Alberto Giovanni Leone, Mark Lythgoe, Jeremy Lyle Warner, Claudia A.M. Fulgenzi, Marlie Smith, David Joseph Benjamin, Jonathan Krell, Mark Nelson, Margherita Bracchi, Adam Temple, Marta Boffito, Filippo Pietrantonio, Pascal Migaud, Dario Trapani, David James Pinato, Alessia Dalla Pria, Mark Bower; Department of Oncology and National Centre for HIV Malignancy, Chelsea and Westminster Hospital, London, United Kingdom; Imperial College Healthcare NHS Trust, London, United Kingdom; Brown University, Providence, RI; Department of Surgery and Cancer, Imperial College, Hammersmith Hospital, London, United Kingdom; Hoag Family Cancer Institute, Newport Beach, CA; Department of Infectious Disease, Imperial College London, London, United Kingdom; Department of HIV and Sexual Health, Chelsea and Westminster Healthcare NHS Trust, London, United Kingdom; Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy; Department of Infectious Diseases, St. Joseph Hospital, Berlin, Germany; European Institute of Oncology IRCCS, Milan, Milan, Italy; Department of Surgery and Cancer, Imperial, Italy; Department of Surgery, Intervention, Intervention, Intervention, Italy; Department of Surgery, Intervention, Intervention, Italy; Department of Surgery, Intervention, Italy; Department of Surgery, Intervention, Intervention, Imperial, Italy; Department of Surgery, Intervention, Intervention, Intervention, Imperial, Italy; Department of Surgery, Intervention, Inte

Background: People living with HIV (PLWH) have an increased risk of developing cancers compared to the population without HIV, with cancer being the leading cause of death for this population in high-income countries. Previous research by the ASCO-led HIV working group found only 11% of clinical trials supporting FDA cancer therapy approvals from 2010-2014 allowed for inclusion of PLWH, leading to clinical uncertainty in the efficacy-safety profile of new cancer treatments in this group. To address this gap, ASCO (2017) and FDA (2020) issued guidelines encouraging inclusion of PLWH in cancer clinical trials. To explore their impact, we examined inclusion of PLWH in pivotal cancer trials post-guidelines release. Methods: We reviewed all new FDA-approved indications of the past five years (Jan/2020-Nov/2024). For each new approval, two authors independently assessed the inclusion/exclusion criteria outlined in the primary protocol of each pivotal trial. We analyzed data on the FDA label, cancer type, therapeutic modality, inclusion/exclusion criteria, sponsor, and the protocol (version 1) publication date. Results: We identified 244 new therapy indications, based on supporting data from 259 pivotal clinical trials. 27% of trials permitted inclusion of PLWH. Pivotal trials for hematological cancers, compared to solid cancers, were significantly more likely to exclude PLWH [unadjusted Odds Ratio (OR) 3.15, 95% confidence interval (CI): 1.51-6.56; p=0.0012]. Pivotal trials of immunomodulatory agents were significantly more likely (OR 3.87, 95% CI: 1.91–7.83; p<0.0001) to exclude PLWH compared to other cancer therapies. The inclusion rate was 10.3% for AIDS-defining cancers and 29.8% for non-AIDS-defining cancers. Trials funded only by industry were significantly more likely (OR 2.80, 95% CI: 1.36-5.77; p=0.0078) to exclude PLWH, compared to non-industry funded trials. Inclusion rate of PLWH was higher in protocols published after 2020 (39.1%) compared to those before (26.3%). Conclusions: Our analysis indicates an improvement in the inclusion of PLWH in oncology pivotal trials following ASCO and FDA guidance. However, nearly three out of four pivotal cancer trials continue to exclude PLWH. This highlights an unmet need, resulting in uncertainty for healthcare professionals regarding the safety and clinical utility of new cancer treatments in PLWH. Additional strategies must be considered to address this disparity. Research Sponsor: None.

Rates of PLWH inclusion in oncology pivotal trials.	
	Include PLWH (%)
Total (n=259)	27.4
Solid Cancers (185)	33
Haematological malignancies (74)	13.5
Immunomodulatory agents (89)	12.4
Other agents*(170)	35.3
Industry-funded (223)	24.2
Non-industry funded (36)	47.2
AIDS-Defining Cancers (30)	10
Non-AIDS Defining Cancers (45)	29.8

*Chemotherapy, targeted therapy, drug-antibody conjugates, hormone therapy, radionuclide therapy.

Economic modelling to inform pricing for LMICs of immune checkpoint inhibitors in advanced PD-L1-high non-small cell lung cancer.

Giulia Segafredo, Dario Trapani, Manju Sengar, Paul Ruff, Esteban Burrone, Hannah Schirrmacher, Konstantina Politopoulou, Chrissy Bishop, Federico Cairoli; Medicines Patent Pool, Genève, Switzerland; European Institute of Oncology IRCCS, Milan, Milan, Italy; Tata Memorial Centre, Mumbai, India; University Witwatersrand Faculty Health Sciences, Johannesburg, South Africa; Medicines Patent Pool, Geneva, Switzerland; Triangulate Health Ltd, Doncaster, United Kingdom

Background: Lung cancer is the most common cancer and cause of cancer death, encompassing for 16.8% of all cancer-related deaths worldwide. Anti-PD(L)1 Immune Checkpoint Inhibitors (ICIs) as monotherapy currently represent the standard of care (SoC) for advanced Non-Small Cell Lung Cancer with high (≥50%) PD-L1 expression in high-income countries. Despite their efficacy, ICIs remain largely inaccessible in low- and middle-income countries (LMICs), with affordability being a significant barrier. Providing evidence on cost-effective (CE) price ranges for ICIs in LMICs is critical for global health policymakers to devise strategies to enhance access. Methods: A partitioned-survival model was used to estimate CE price targets for three ICIs (atezolizumab, cemiplimab, and pembrolizumab) as single agents compared to platinumbased combination chemotherapy (current SoC in several LMICs). Treatment duration was assumed of up to 35 cycles or until disease progression. Cost-effectiveness thresholds were set at 1, 2, and 3 times the gross domestic product (GDP) per capita per quality-adjusted life year (QALY) gained. Case studies were modelled in two LMICs (India and South Africa - not all ICIs were registered in both countries) to determine the maximum price at which ICIs would be CE from the perspective of publicly-funded health systems. Primary efficacy data were sourced from phase III clinical trials (KEYNOTE-024, IMpower110, and EMPOWER-Lung 1), and country-specific data were collected through interviews with key technical stakeholders. Values were reported in USD for 2023. Results: The analysis determined that the maximum acquisition costs for ICIs to be cost-effective at 1-, 2-, and 3-times GDP per capita in India and South Africa, range from \$14.20 to \$648.00 per cycle per patient. Current reference prices would require discounts of up to 93.3% to meet the 3 GDP threshold. Dose-optimization strategies such as low-dose and vial sharing were identified as feasible and evidence-based approaches to achieve partial price reduction (sensitivity analysis will be provided). Conclusions: To make ICIs cost-effective in LMICs, significant discounts from current reference prices are needed. Similar price reductions (up 93%) have been achieved for other monoclonal antibodies, such as trastuzumab, in India and South Africa, also driven by the availability and uptake of quality-assured biosimilars. A comprehensive approach, combining accelerated biosimilar availability, also leveraging voluntary licensing and technology transfer, with dose and treatment-duration optimization strategies could help achieve target price levels and improve accessibility. Research Sponsor: Medicines Patent Pool.

Country	WTP threshold (xGDP)	Pembrolizumab	Atezolizumab	Cemiplimab
India	1	\$72.6	\$74.2	\$66.5
	2	\$199.7	\$166.9	\$181.5
	3	\$308.6	\$259.6	\$300.0
South Africa	1	\$51.5	\$53.1	\$14.2
	2	\$349.9	\$289.0	\$314.7
	3	\$648.2	\$525.0	\$615.2

Association of court-documented major adverse financial events before cancer diagnosis and mortality risk in the US.

Robin Yabroff, Anne-Michelle Noone, Angela Mariotto, Veena Shankaran, Kevin C. Ward, Stephen M. Schwartz, Xiao-Cheng Wu, Joan L Warren; Surveillance and Health Equity Science, American Cancer Society, Atlanta, GA; National Cancer Institute, Rockville, MD; Fred Hutchinson Cancer Research Center, University of Washington, Seattle, WA; Emory University, Rollins School of Public Health, Atlanta, GA; Fred Hutchinson Cancer Center, Seattle, WA; Louisiana State University, New Orleans, LA; American Cancer Society, Silver Spring, MD

Background: Cancer diagnosis is associated with increased risk of financial hardship in the US. This study examined the associations of court-documented major adverse financial events (AFEs) of bankruptcies, liens, and evictions prior to cancer diagnosis and risks of all-cause and cancer-specific mortality. Methods: Individuals aged 21 to 69 years diagnosed with common cancer types, including bladder, female breast, colorectal, kidney, lung and bronchus, oral cavity/pharynx, or prostate cancers or melanoma during 2014-2015 were identified from the SEER population-based registries for Seattle, Louisiana, and Georgia. Registry data were linked with LexisNexis consumer data to identify history of court-documented AFEs of bankruptcies, liens, and evictions. Vital status and cause of death were examined through December 31, 2021. The association of pre-diagnosis AFEs and risk all-cause and cancer-specific mortality was assessed with separate multivariable Cox proportional hazards models for each survival outcome, stratified by cancer site. Models were adjusted for stage, age, race and ethnicity, marital status, registry, registry-specific income categories, and the interaction between income and registry. Results: Of 58,796 individuals diagnosed with one of the 8 selected cancers, 21,694 (36.9%) had a pre-diagnosis AFE and there were 16,714 deaths (28.4%) during the study period between 2014 and 2021. Pre-diagnosis AFEs were associated with higher risk of all-cause mortality for individuals diagnosed with female breast (hazard ratio (HR): 1.18; 95% confidence interval (CI): 1.09-1.28), colorectal (HR: 1.14; 95% CI: 1.06-1.23), oral cavity/pharynx (HR: 1.14; 95% CI: 1.06-1.23) and prostate (HR: 1.33; 95%CI: 1.20-1.47) cancer and early- and late-stage melanoma (HR: 2.23; 95% CI: 1.89-2.99 and HR:1.34; 95% CI:1.01-1.80, respectively), in adjusted models. Pre-diagnosis AFEs were also associated with significantly higher risk of cancer-specific mortality for these five cancers. **Conclusions:** Court-documented AFEs of prediagnosis bankruptcy, lien, or eviction was associated with increased risk of all-cause and cancer-specific mortality for multiple cancer types in this study using a novel SEER cancer registry-LexisNexis consumer data linkage. The association of pre-diagnosis AFEs and mortality risk underscores lasting adverse consequences of patient financial vulnerability prior to incurring high out-of-pocket costs of cancer treatment. Our findings are especially timely, with growing efforts by health care providers to screen and address patient health-related social needs as part of comprehensive oncology care. Research Sponsor: None.

Effect of broad-based genomic sequencing on survival outcomes in advanced nonsmall cell lung cancer: A national cohort study, 2011-2023.

Patricia Mae Garcia Santos, Lillian A Boe, Daniel Richard Gomez, Ravi Bharat Parikh; Division of Health Services, Outcomes, and Policy, Department of Radiation Oncology, Winship Cancer Institute, Emory University, Atlanta, GA; Department of Epidemiology and Biostatistics, Memorial Sloan Kettering Cancer Center, New York, NY; Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, NY; Winship Cancer Institute, Emory University, Atlanta, GA

Background: Use of broad-based genomic sequencing (BGS) for advanced non-small cell lung cancer (aNSCLC) is rising. While older studies have found no survival benefit with BGS, its impact on survival outcomes in the era of modern targeted therapy is unknown. Methods: In this retrospective cohort study, the 2011-2023 Flatiron Health Database—a nationally representative database of electronic health records from > 280 US cancer clinics—was queried for patients with Stage IIIB-IV NSCLC who received at least one line of systemic therapy with ≥12 months follow-up. Primary exposure was receipt of BGS vs. "Focused" biomarker testing (i.e., ALK FISH, EGFR PCR) within 90 days of first- and second-line therapy start. To address baseline confounding, we used 1:1 nearest-neighbor propensity score matching based on age at initial diagnosis, sex, self-reported race/ethnicity, histology (squamous vs. nonsquamous), insurance status, smoking status, ECOG performance status, practice type (academic vs. community), stage at diagnosis, advanced diagnosis year, and practice rate of BGS. Adjusted Cox proportional hazards models compared median progression-free survival (mPFS) and median overall survival (mOS) between groups. Sensitivity analyses adjusted for biomarker status and used an instrumental variable approach. Results: Our initial unmatched cohort consisted of 35,060 patients (BGS, *n* = 14,192; Focused, *n* = 20,868; 52% female, 3.5% Asian, 9.3% Black, 3.8% Hispanic, 79% community practice). In the propensity-matched first-line therapy cohort (BGS vs. Focused, n = 10,008 in each group; all standardized mean differences <0.1), BGS was associated with greater mPFS (6.4 vs. 6.0 months; adjusted HR [95%CI], 0.96 [0.92-1.0], p = 0.046) and mOS (16 vs. 14 months; 0.91 [0.86-0.95], p < 0.001). Sensitivity analyses were consistent with primary results. Patients receiving BGS had higher rates of ALK/ EGFR positivity (18% vs. 13%) and receipt of targeted therapy (20% vs. 17%). Upon adjustment for biomarker status, however, BGS remained associated with improved OS (1.01 [0.88-0.98], p = 0.004) but not PFS (0.98 [0.94-1.03], p = 0.4). In the propensity-matched second-line therapy cohort, no associations between BGS and survival outcomes were observed. Conclusions: This is the first national analysis of survival outcomes in aNSCLC to demonstrate a survival benefit with BGS. These findings support guideline endorsement and payer coverage of BGS prior to 1st line therapy. Research Sponsor: None.

		Median (95%CI)	Univariate HR (95%CI)	Adjusted HR (95%CI)
PFS, months	Focused	6.0 (5.8-6.1)	_	-
	BGS	6.4 (6.2-6.5)	0.95 (0.91-0.99)	0.96 (0.92-1.00)
OS	Focused	14 (14-15)	· –	` —
	BGS	16 (16-17)	0.90 (0.86-0.95)	0.91 (0.86-0.95)
PFS	Focused	3.8 (3.5-4.1)	· –	` —
	BGS	4.2 (4.0-4.5)	0.91 (0.82-1.01)	0.92 (0.83-1.02)
OS	Focused	13 (12-14)	· _ · ·	· –
	BGS	12 (12-14)	1.02 (0.91-1.15)	1.01 (0.89-1.14)
	PFS, months OS PFS OS	PFS, months Focused BGS OS Focused BGS PFS Focused BGS OS Focused BGS	Median (95%Cl) PFS, months Focused 6.0 (5.8-6.1) BGS 6.4 (6.2-6.5) 0S OS Focused 14 (14-15) BGS 16 (16-17) 16 (16-17) PFS Focused 3.8 (3.5-4.1) BGS 4.2 (4.0-4.5) 0S OS Focused 13 (12-14) BGS 12 (12-14) 12	Median (95%CI) Univariate HR (95%CI) PFS, months Focused 6.0 (5.8-6.1) - BGS 6.4 (6.2-6.5) 0.95 (0.91-0.99) OS Focused 14 (14-15) - BGS 16 (16-17) 0.90 (0.86-0.95) PFS Focused 3.8 (3.5-4.1) - BGS 4.2 (4.0-4.5) 0.91 (0.82-1.01) OS Focused 13 (12-14) - BGS 12 (12-14) 1.02 (0.91-1.15)

Financial toxicity and drivers of delayed care among cancer survivors across the lifespan.

Justine Po, Arthur Bookstein, ARCH Collaborative (Action for Resilience, Climate and Health Collaborative); Keck School of Medicine of University of Southern California, Los Angeles, CA

Background: Financial toxicity has been increasingly recognized as a cause of poor outcomes among cancer survivors. Cancer survivors have been shown to face greater healthcare access and affordability issues than the general population, and available evidence suggests that adolescent/young adult (AYA) cancer survivors may face especially high financial toxicity. However, existing research is limited by small sample sizes and methodological constraints. Understanding age-specific healthcare barriers could inform targeted interventions to improve outcomes for cancer survivors across the lifespan. Methods: Participants aged 18 and older were enrolled with informed consent in the All of Us Research Program, an NIH database integrating multiple health information sources. Included participants were cancer survivors who had available data for age, sex and other demographics. Cancer diagnoses were identified using ICD and SNOMED codes. Survey data were used to assess outcomes of financial toxicity and drivers of delayed care, as well as covariates of race, ethnicity, income, education, marital and insurance status. As all participants were insured, insurance status was dropped from the final models. Age groups were coded as 18-39, 40-49, 50-64, 65-74 and 75+. Statistical analysis was conducted using logistic regression by age group, adjusted for covariates. Results: 15,637 cancer survivors were included for analysis, including 1,090 participants aged 18-39 and 2,104 participants over age 75. Compared to 18-39 year olds, odds of being unable to afford specialist care decreased with age: [40-49] OR = 0.57 (p = 0.01), [50-64] OR = 0.18 (p < 0.0001), [65-74] OR = 0.07 (p < 0.0001), [75+] OR = 0.006 (p < 0.0001). Results were similar for primary care, with more extreme effect sizes. Causes of delayed care differed by age group. 18-39 year olds were more likely to report elderly caregiving responsibilities and inability to get time off work as drivers of delayed care, while 40–49 year olds were more likely to report difficulties accessing child care as a driver (OR = 5.25, p < 0.0001). Older cancer patients were also more likely than AYAs to report lack of transportation access as a cause of delayed care ([65-74] OR = 2.33, p < 0.0001). Conclusions: To date, this study represents the largest and most comprehensive analysis of healthcare barriers among cancer survivors across the lifespan. Targeted interventions based on the most significant barriers by age group may more effectively improve healthcare access and outcomes for all ages. Our results support that AYA cancer survivors may benefit most from financial support, elderly care resources and medical notes to facilitate time off work. By comparison, expanding childcare support may be most important for increasing access among those aged 40-49. Among older cancer survivors, ensuring reliable transportation presents the greatest opportunity for improving healthcare access. Research Sponsor: National Institutes of Health, Office of the Director.

Spillover effects of Medicaid expansion on insurance coverage, diagnosis, and survival among low-income elderly patients with cancer.

Kewei Sylvia Shi, Xu Ji, Robin Yabroff, Xuesong Han; American Cancer Society, Atlanta, GA; Emory University School of Medicine, Atlanta, GA; Surveillance and Health Equity Science, American Cancer Society, Atlanta, GA

Background: Medicaid expansion under the Affordable Care Act is associated with increased health insurance coverage and improved outcomes among patients with cancer < 65 years. Although not the target population, individuals ≥ 65 years may also benefit from Medicaid expansion through "welcome mat" effects, referring to the indirect increase in Medicaid enrollment from increased public awareness and streamlined enrollment procedures. This study examines the associations of Medicaid expansion with Medicaid coverage, stage at diagnosis, and survival among cancer patients ≥65 years. Methods: Using the National Cancer Database, we identified patients \geq 65 years newly diagnosed with cancer between 2010-2022 residing in areas with median household income below 200% of the federal poverty level. We applied a quasi-experimental difference-in-differences design, with multivariable linear probability models to compare the changes in the percentage of dual-eligible or Medicaidonly coverage, stage at diagnosis, and two-year survival post (vs. pre) Medicaid expansion in expansion states compared with non-expansion states. Results: A total of 1,468,116 patients with cancer were identified, with 885,671 patients from expansion states and 582,445 patients from non-expansion states. After adjusting for sociodemographic characteristics, the percentage of patients with dual or Medicaid-only coverage increased from 10.27% to 11.33% in expansion states and decreased from 9.4% to 8.11% in non-expansion states, resulting in a net increase of 1.34 percentage points (ppt, 95% confidence interval [CI]: 1.12, 1.56) associated with Medicaid expansion. Differences were more pronounced among patients with stage III-IV cancers, females, non-Hispanic Black, metropolitan residents, and those with ≥ 2 comorbidities. The percentage of early-stage (I/II) cancer diagnoses decreased more in non-expansion states (49.82% to 47.19%) than in expansion states (47.63% to 46.06%), resulting in a net increase of 0.96 ppt (95% CI: 0.58, 1.34). The protective effects of Medicaid expansion were stronger for late-stage (III/IV) non-small cell lung and uterine cancers, as well as early-stage thyroid and bladder cancers. Two-year overall survival rates increased from 58.86% to 62.39% in expansion states and from 59.18% to 62.55% in non-expansion states, leading to a net increase of 0.95 ppt (95% CI: 0.61, 1.29). Improvements were most notable for prostate, lung, kidney, and bladder cancers. Conclusions: Medicaid expansion was associated with an increase in Medicaid coverage, early-stage cancer diagnoses, and improved two-year survival among patients diagnosed with cancer ≥ 65 years. Findings underscore the spillover benefits of Medicaid expansion in supporting low-income elderly populations and the importance of indirect benefits when evaluating Medicaid expansion's broader impact. Research Sponsor: None.

Bolstering access to clinical trials: Sociodemographic characteristics of patients enrolled in interventional clinical trials within a large, NCORP-designated community oncology practice setting.

Meera Vimala Ragavan, Shiyun Zhu, Sabrina Kailu Zhong, Jingrong Yang, Desiree Goldstein, Raymond Liu, Samantha A. Seaward, Jennifer Marie Suga, Lawrence H. Kushi; Kaiser Permanente San Francisco Medical Center, San Francisco, CA; Kaiser Permanente Division of Research, Oakland, CA; Kaiser Permanente, Pleasanton, CA; Kaiser Permanente Division of Research, Pleasanton, CA; Kaiser Permanente Medical Center, Vallejo, CA; Department of Hematology Oncology, Kaiser Permanente, San Francisco, CA; Kaiser Permanente, Oakland, CA; Kaiser Permanente, Vallejo, CA; Kaiser Permanente Northern California, Pleasanton, CA

Background: Access to clinical trials is an important aspect of cancer care given rapidly changing treatment paradigms. Most patients with cancer including those belonging to racial/ethnic minoritized groups are treated in community oncology settings, but only a minority (< 5%) of these patients are enrolled on clinical trials. Barriers to trial enrollment in community oncology settings have been well described at the patient, provider, and system levels. The National Cancer Institute Community Oncology Program (NCORP) aims to address these barriers - and improve equity in trial enrollment - by providing support and infrastructure for community oncology practices to conduct clinical trials. Kaiser Permanente Northern California (KPNC) is a large integrated health system comprising thirty cancer trial sites and is part of the Kaiser Permanente NCORP, one of the largest NCORP-designated sites. In this study, we compared sociodemographic characteristics of patients enrolled in interventional trials with the overall cancer population within KPNC. Methods: We evaluated all patients enrolled on interventional cancer clinical trials within KPNC between 1/1/2015-12/31/2022. We abstracted demographic and clinical characteristics from the KPNC cancer registry. We compared characteristics to the incident cancer population diagnosed over the study period across KPNC. We used Pearson chi squared tests (categorical), binomial tests (binary) and one-sample t tests (continuous) to compare sociodemographic characteristics. Results: We identified 1,341 patients who were enrolled onto interventional clinical trials and compared them to 97,764 patients diagnosed with cancer over the study period. Patients enrolled on interventional trials were younger (mean age 60.2 vs 62.9 years, p < 0.001), more likely to have Stage IV disease (22.7% vs 11.2%, p < 0.001), more likely to reside in high-socioeconomic status neighborhoods (27.7 vs 23.8%, p < 0.001), and less likely to speak a language other than English (4.7 vs 7.1%, p < 0.001). There were no differences in race, ethnicity or sex distributions between the trial population and overall population. Conclusions: Across a large NCORP-designated community oncology trials program, the racial and ethnic makeup of patients enrolled on trials was similar to the broader cancer population within KPNC. These findings suggest that the trial infrastructure provided by NCORP may surmount the structural barriers that drive low access to trials among racial/ethnic minorities. Small differences in enrollment based on age, language and socioeconomic factors persisted. Efforts to bolster clinical trial portfolios in community oncology settings may address existing barriers to enrollment. Research Sponsor: KPNC Community Benefit Program- Cancer Section Pilot Funding.

Integrating collaborative care in oncology: Improving quality of life and mental health for patients with cancer.

Kyle N. Lavin, Nina Balanchivadze, Jacqlyn L. Yourell, Ayham Deeb, Alyssa Tilly, Graham Thomas Watson, Michael A. Danso; University of North Carolina at Chapel Hill, Chapel Hill, NC; Virginia Oncology Associates, Norfolk, VA; Fit Minded Inc., Chapel Hill, NC; Virginia Oncology Associates - Harbour View, Suffolk, VA; UNC School of Medicine, Chapel Hill, NC; Virginia Oncology Associates, The US Oncology Network, Norfolk, VA; Brock Cancer Center, Virginia Oncology Associates and Sarah Cannon Research Institute, Norfolk, VA

Background: In the U.S., 22 million patients with cancer face unmet behavioral health needs, contributing to up to \$245B in preventable healthcare costs. These unique challenges stem from physical, emotional, practical, and relational stressors associated with their cancer journey. Collaborative care, an evidenced based model that integrates behavioral health into medical settings, has been shown to improve access, outcomes, and reduce overall healthcare costs in primary care. Cerula Care offers a virtual collaborative care model that seamlessly integrates with oncology practices to improve quality of life and behavioral health outcomes. The team includes a Consulting Psychiatrist, Behavioral Health Care Manager, and Behavioral Health Coach working in coordination with oncology teams. Methods: This study analyzed data from 127 patients with cancer enrolled in Cerula Care's 12-week virtual care program between 1/31/24 and 8/31/24. Behavioral health outcomes, including anxiety (GAD-7), depressive symptoms (PHQ-9), and quality of life (FACT), were assessed monthly. Analyses focused on baseline to two-month outcomes due to limited sample sizes beyond two months (many patients were still in earlier stages of the program). Correlations and paired t-tests were conducted to evaluate changes in outcomes. Results: Of the 127 patients enrolled, mean age was 57.1 years (range: 28-78), 83.5% were female, 52.8% identified as White, 33.9% Black or African American, 0.8% Asian, and 3.1% other races. Breast cancer was the most common diagnosis (52.8%), followed by lung, colorectal, pancreatic, and ovarian cancers. Behavioral health outcomes from baseline to month 2 are shown in the table. Conclusions: Within just two months of care, Cerula Care significantly improved depressive symptoms and anxiety, as well as quality of life for cancer patients. Notably, improvements in quality of life were correlated with minority status, highlighting the program's potential to reduce disparities in cancer care. By integrating behavioral health into oncology treatment, this model demonstrates a scalable, impactful solution to enhance patient outcomes. Future research should focus on long-term sustainability, cost-effectiveness, and broader implementation across diverse oncology settings. Research Sponsor: None.

ehavioral health outcomes from baseline to month 2.								
Outcome	Measure	Sample Size (n)	Change	Statistical Significance (p-value)				
Depressive Symptoms Anxiety Levels Quality of Life	PHQ-9 Score GAD-7 Score FACT Score	50 52 N/A	↓ 4.47 points ↓ 2.06 points Improved, especially in racial minority patients	p < .001 p = .007 r = .439, p = .017				

From food deserts to clinical trial deserts: Challenges in access to breast cancer trials.

Rachel Ann Sachs, Larissa Pamen, Shruthi Reddy Perati, Xiang Gao, Ernie Shippey, Sana M. Mohayya, Coral Omene, Shicha Kumar, Henry A. Pitt, Mariam F. Eskander; Robert Wood Johnson Medical School, New Brunswick, NJ; Rutgers Robert Wood Johnson Medical School, New Brunswick, NJ; Vizient Clinical Database Inc, Irving, TX; Rutgers Cancer Institute, New Brunswick, NJ; Rutgers Cancer Institue, New Brunswick, NJ

Background: Patients who live in food deserts have high mortality rates from breast cancer and stand to benefit from participating in research studies, yet they may face complex barriers to doing so. This study explores the relationship between living in a food desert and breast cancer clinical trial enrollment and assesses the contribution of transportation barriers and distance. Methods: The national Vizient Clinical Database (which includes 98% of academic and 1,000 community hospitals) was queried for women treated for breast cancer between January 2022 and June 2024. Patients who traveled > 4 hours to get to treatment were excluded ("destination care"). The outcome of interest was participation in a clinical trial. A "clinical trial desert" was defined as > 2 hour driving time to the nearest hospital enrolling patients in clinical trials. Multivariable analysis evaluated the association between living in a level 1 (most severe) USDA food desert census tract, a clinical trial desert, a census tract with high transportation vulnerability (households with limited access to a car or public transit), and breast cancer clinical trial participation. Interaction analysis was performed between food desert and clinical trial desert status. Results: Of 1,317,269 patients, 103,790 (7.9%) lived in a food desert, and 22,779 (1.7%) participated in a clinical trial. Patients living in a food desert comprised 6.2% of patients enrolled in a trial vs 7.9% of patients not enrolled, p < .0001. 41.0% of patients living in a food desert also resided in a clinical trial desert. On multivariable analysis, living in a food desert was associated with decreased odds of trial participation (aOR 0.87, 95% CI 0.82-0.92, p < .0001), as was living in a clinical trial desert (aOR 0.89, 95% CI 0.84-0.94, p < .0001), and living in the most vulnerable quartile for neighborhood transportation (aOR 0.89, 95% CI 0.85-0.93, p < .0001; ref: least vulnerable). Medicaid insurance also decreased the odds of enrollment (aOR 0.84, 95% CI 0.80-0.89, p < .0001; ref: private). Conversely, receiving care at an academic hospital increased the odds of enrollment (aOR 2.98, 95% CI 2.62-3.15, p < .0001; ref community hospital). Living in both a food desert and a clinical trial desert decreased the odds of clinical trial participation by 27% (aOR 0.73, 95% CI 0.70-0.76, p < .0001) compared to 19% if living in a food desert alone (aOR 0.81, 95% CI 0.78-0.84, p < .0001); p < .0001 for interaction. **Conclusions:** Neighborhood transportation barriers, clinical trial deserts, and food deserts all independently confer a similar lower likelihood of participation in a clinical trial. Living in a clinical trial desert compounds the negative impact of living in a food desert alone, further taxing already disadvantaged populations. Interventions such as patient navigation, food banks, and opening clinical trials near communities experiencing food insecurity may mitigate these challenges. Research Sponsor: None.

Low-dose anti-PD-(L)1 inhibitor strategies: A systematic review.

Pablo Jiménez Labaig, Failah Mohamed Lamin, Nur Jihan Irwan Tan, Ilves Sanna, Khalid El Bairi, Shah Zeb Khan, Dario Trapani, Teresa Amaral, Amol Balvant Akhade, Amol Patel, Kevin Joseph Harrington; Head and Neck Unit, The Royal Marsden NHS Foundation Trust, London, United Kingdom; Department of Medical Oncology, Cruces University Hospital, Barakaldo, Spain; Faculty of Medical Sciences, University Mohammed VI Polytechnic, Ben Guerir, Morocco; Department of Clinical Oncology, BINOR Cancer Hospital, Bannu, Pakistan; European Institute of Oncology, IRCCS, Milan, Italy; Skin Cancer Center, Eberhard Karls University of Tübingen, Tübingen, Germany; Department of Medical Oncology, Nair Hospital and Topiwala National Medical College, Mumbai, India; Department of Medicine, Oncology Centre, Indian Naval Hospital Ship, Mumbai, India; The Institute of Cancer Research/The Royal Marsden NHS Foundation Trust, London, United Kingdom

Background: Immune checkpoint inhibitors (ICIs) targeting the PD-(L)1 pathway have revolutionized cancer therapy, but their high costs significantly limit accessibility, particularly in low- and middle-income countries (LMICs). Low-dose regimens may offer a viable solution to this challenge. This systematic review analysed study designs, dosing strategies, clinical outcomes, and potential cost savings of low-dose ICIs. Methods: A PRISMA/EQUATOR compliant systematic search of WebOfScience, Cochrane Central Register of Clinical Trials, ASCO and ESMO conference databases was conducted until October 10th, 2024. Studies investigating reduced-dose anti-PD(L)1 from those FDA/EMA-approved regimens were included. Data were categorized by dose and country income level. Results: From 1,751 records, 25 studies (4 clinical trials, 21 observational studies) involving 1,793 participants met inclusion criteria, with 1,202 receiving low-dose ICIs. Two studies used non-inferiority designs, and 21 evaluated participants across multiple treatment lines. The population had a median age of 53.1 years (range 19-84), 26% female, 88% with advanced disease, and 9% ECOG \geq 2. Most studies were conducted in Asia (81.4%, n = 1,459), with head and neck (22.8%, n = 409) and non-small cell lung cancers (17.3%, n = 311) being most studied. 48% studies were from LMICs, 44% from high-income countries (HIC), and 8% from upper middle-income countries (UMIC). India contributed the most (studies, k = 12, 839 participants). Nivo (k = 21), pembro (k = 6) and atezo (k=1) were assessed. The most common regimens were Nivo40mg Q2W (k=7), Nivo20mg Q3W (k= 6) and Nivo20mg Q2W (k= 5) [Table 1]. A radiological response rate between 5-75% was noted when low-dose ICI was used as monotherapy (k= 10). High variability in participant selection and interventions restricts further conclusions about efficacy and safety. The median projected savings were 83.3% (25–99.40%), with \geq 70% savings in half of the studies. **Conclusions:** This review described the use of low-dose anti-PD(L)1 drugs, especially in healthcare settings with limited resources, highlighting radiological responses observed with monotherapy. Non-inferiority or near-equivalence randomized clinical trials will be helpful in establishing their clinical validity. Research Sponsor: None.

Tumor type (origin from partici- pants assessed)	HNSCC n=409	NSCLC n=311	HCC n=93	RCC n=73	HL n=70	Multiple n=57	Melanoma n=56	Gastric/ GEJ n=42	Gyne n=35	CCR n=30	Cervical n=20	Thymic n=6
LMIC	409			57		57		42		30	20	
UMIC					23							6
HIC		311	93	16	47		56		35			
Number of studies (k)	k: 6	k: 4	k: 2	k: 2	k: 3	k: 2	k: 1	k: 1	n: 1	n: 1	n: 1	n: 1
assessing each dose												
per tumor											,	
Nivo U.3 mg/Kg Q2W							2			1	I	
Nivo 10 mg Q2W							2					
Nivo 20 mg O2W	1		2	1			1	1				
Nivo 20 mg O3W	3	1	2	i								
Nivo 40 mg 02W	ĩ			•	3	2						1
Nivo 40 mg Q3W	3				0	ĩ		1		1		•
Nivo 40 mg Q4W				1								
Nivo 80 mg Q4W						1						
Nivo 100 mg Q2W			1	1	1							
Nivo 100 mg Q3W		1										
Nivo 100 mg Q4W	1											
Nivo 140 mg Q2W				1	1							
Pembro 1 mg/Kg Q3W		1										
Pembro 1 mg/Kg Q6W						I			1			
Penibro 50 Mg Q3W		2			1				1			
Pembro 300 mg 06W		3							1			
Atezo 1 mg/Kg Q3W		1				1						

Characterizing transportation need and missed visits among patients receiving radiotherapy.

Kathleen Cui, William S. Chen, Katie Lichter, Alon Witztum, Julie Frank, Nicolas Prionas, Steve E. Braunstein, Jie Jane Chen; University of California, San Francisco, San Francisco, CA; Department of Radiation Oncology, University of California, San Francisco, San Francisco, CA

Background: Patients with cancer receiving radiotherapy (RT) are vulnerable to treatment interruptions, which affect oncologic outcomes. To prioritize program development for improved RT access, we aimed to characterize transportation need via standardized department screening and its association with missed RT visits. Methods: We prospectively identified a cohort of 552 consecutive patients with cancer who received RT at a single academic institution between September 2023 and March 2024, during which a quality improvement program for standardized transportation needs screening was implemented. Missed RT visits were determined computationally and counted if a patient did not arrive for a scheduled RT visit; these missed visits may have been due to pre-planned reasons, unplanned hospital admissions, or other logistical causes. Clinical data were extracted from the electronic medical record system. Univariable and multivariable logistic regression analyses were used to determine associations between demographic variables and transportation need. Fisher's exact test was used to compare missed RT visits between patients with varying social needs. Results: Median age was 66 years (IQR: 53.75-74). Most patients were English-speaking (85.1%), male (54%), and white (51.8%). Common planned transportation modes were driving (76.2%) and public transit (8%), as well as Veterans Affairs transportation, rideshare, and taxi. Of all patients, 26.4% missed \geq 1 RT visit and 19.9% reported transportation need. Overall, 39.1% versus 23.3% of patients with versus without transportation need missed ≥ 1 RT visit (p = 0.001). Other social needs were found among 17.6% of patients, the most common being housing (80.3%). Of those with transportation need, 45.5% had additional social needs. Frequency of missed RT visits were similar between patients with sole transportation need (41.7%) and those with additional social needs (39.1%) (p = 0.563). On univariable analysis, there was increased transportation need among patients identifying as Asian (OR = 1.87, 95% CI 1.05-3.27, p = 0.030), Latinx (OR = 3.14, 95% CI 1.74-5.63, p < 0.001), unknown/declined race/ethnicity (OR = 2.84, 95% CI 1.29-5.99, p = 0.007), non-English speaking (OR = 3.01, 95% CI 1.80-4.98, p < 0.001), with Medicaid insurance (OR = 3.61, 95% CI 1.94-6.71, p < 0.001), and with Medicare insurance (OR = 1.81, 95% CI 1.11-2.97, p = 0.019). On multivariable analysis, Latinx (OR = 2.18, 95% CI 1.02-4.52, p = 0.040) and Medicaid versus private insurance (OR = 2.28, 95% CI 1.12-4.61, p = 0.022) were independent predictors of transportation need. Conclusions: Our findings support the utility of transportation screening as a tool for anticipating and providing resources to minimize missed RT treatments. Future initiatives toward improving RT access may benefit from proactive assessment and support of social needs, including but not limited to transportation. Research Sponsor: None.

Disparities in breast cancer screening for the Brazilian Unified Health System (SUS): A warning of the need to change public policies.

Ruffo Freitas-Junior, Aline Ferreira Bandeira de Melo Rocha, Leonardo Ribeiro Soares, Nilceana Maya Aires Freitas; CORA – Advanced Center for Diagnosis of Breast Diseases Federal University of Goias, Goiania, Goias, Brazil; Federal University of Goias, Goiania, Goias, Brazil; CORA - Advanced Center for Diagnosis of Breast Cancer, Federal University of Goias, Goiania, Goias, Brazil

Background: Breast cancer is the most prevalent form of cancer in Brazilian women, contributing significantly to cancer-related mortality, particularly when diagnosed at advanced stages. Public policies of the Ministry of Health have been not changed for the last 2 decades. Methods: This ecological, temporal series study evaluated breast cancer screening coverage, clinical staging, and the time from diagnosis to treatment initiation in women of 40-49, 50-69 and 70 years of age in Brazil as a whole, its geographical regions, and states between 2013 and 2022. The data were extracted from databases of the Unified Health System (DATASUS). **Results:** There was a decreasing trend in screening coverage for the 40-49-year age group between 2013 and 2020 (APC = -10.79; p < 0.001), followed by stability in 2020-2022. Rates for the 50-69-year group remained stable, while coverage fell for women 70 years of age (APC = -6.27; p < 0.001) between 2013 and 2022. Cases of advanced stages at diagnosis tended to increase in all age groups: 40-49 (APC = 1.71; p < 0.001), 50-69 (APC = 1.43; p < 0.001) and 70 years (APC = 1.82; p = 0.001). Breast cancer screening coverage was low for all the age groups and all geographical regions, with lower rates found for the 40-49 and 70-year age groups. The poorest coverage was in the north, northeast and Midwestof the country, revealing regional disparities. The proportion of cases diagnosed at advanced stages (III/IV) increased, particularly in younger women (40-49 years) and the elderly (70 years). Time from diagnosis to treatment initiation exceeded 60 days in > 50% of cases in all age groups, with an increasing trend in women of 50-69 (APC = 1.27; p < 0.001) and 70 years of age (APC = 1.83; p < 0.001). Conclusions: This study highlightsthe urgent need for public policies to increase breast cancer screening coverage beyond the 50-69-year age group, and to guarantee equitable access to early diagnosis and timely treatment, particularly in less affluent areas. Dealing with these disparities is crucial to improving breast cancer outcomes in Brazil. Research Sponsor: None.

Differences in insurance status among Asian Americans with cancer: A disaggregated analysis by ethnic subgroup.

Lilac Nguyen, Isabella Nguyen, Emily Feng, Eric Li-Len Feng, Erin Feliciano, Edward Christopher Dee; Memorial Sloan Kettering Cancer Center, New York, NY; Memorial Sloan Kettering Cancer Center, New York, MA; Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco, San Francisco, CA; NYC Health + Hospitals/Elmhurst, New York, NY; Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, NY

Background: Asian Americans, the fastest-growing racial/ethnic group in the U.S., experience significant variation in barriers to cancer care access, yet most research treats them as a monolithic group. Insurance is crucial for accessing cancer care, but limited data exist on noninsurance rates among Asian Americans. This study investigates the heterogeneity in insurance status across Asian American subgroups in the context of common cancers. Methods: We analyzed data from the National Cancer Database (NCDB), and focused on breast, prostate, and non-small-cell lung cancers among patients under 65. Insurance status was dichotomized as non-insured/Medicaid versus private/government/Medicare/other, and binary logistic regression was used to calculate odds ratios (ORs) for insurance status by Asian American subgroups. Results: There were 2,161,947 patients with breast cancer, 603,172 with lung cancer, and 964,423 with prostate cancer. We found significant heterogeneity in insurance status among Asian American subgroups; such heterogeneity was mirrored across the three most common cancer types. Consistently, Japanese Americans were less likely to be uninsured or have Medicaid than White Americans (4.5%, 2.5%, and 12.2%, for patients with breast, prostate, and lung cancer, respectively, among Japanese-Americans vs. 10.2%, 5.5%, and 20.7% among White Americans, (odds ratio 0.54(95% CI: 0.47-0.61) for breast, 0.55(0.37-0.83) for prostate, 0.72(0.56-0.91) for lung), while every other Asian subgroup was significantly more likely to be uninsured or have Medicaid than White Americans (OR range 1.24 to 7.23 for breast, 1.25 to 10.42 for prostate, 1.12 to 6.39 for lung, all p-values < 0.05 except for Laotians, Hmongs, and Thai with prostate cancer). Pakistani Americans were the group most likely to be uninsured or on Medicaid among patients with breast cancer (OR 7.22 (6.17-8.46) and prostate cancer (OR 10.41 (7.08-15.33) and were the second-most likely subgroup among patients with lung cancer (OR 4.82 (3.21-7.23). Hmong and Kampuchean were among the top three groups with breast or lung cancer who were uninsured or on Medicaid. Conclusions: Significant heterogeneity exists in insurance coverage among Asian American subgroups, which highlights the diversity of disparities Asian American patients face; these findings call into question the model minority myth, as every other Asian American subgroup besides Japanese-American was significantly less likely to be insured than White Americans. Asian American patients have broad differences in histories, social determinants of health, and barriers to accessing care, which may merit differentially targeted health interventions among certain subgroups. Research Sponsor: None.

Breast cancer screening mammography among transgender and gender diverse (TGD) individuals: A nationwide study of >10,000 TGD individuals.

Elizabeth Jane Cathcart-Rake, Viengneesee Thao, Jennifer Le-Rademacher, David A. Helfinstine Jr., Kathryn Jean Ruddy, Celine Vachon, Caroline Davidge-Pitts, Evelyn Carroll, Jennifer Ridgeway, Chrisandra Shufelt, Amye Juliet Tevaarwerk, Aminah Jatoi; Mayo Clinic, Rochester, MN; Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Mayo Clinic & OptumLabs, Rochester, MN; Mayo Clinic, Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Rochester, MN; Division of Endocrinology, Diabetes and Metabolism, Mayo Clinic, Rochester, MN; Department of Radiology, Mayo Clinic, Rochester, MN; Department of Health Care Delivery Research, Mayo Clinic, Rochester, MN; General Internal Medicine, Mayo Clinic, Jacksonville, FL

Background: Regular breast cancer screening reduces mortality. The American College of Radiology (ACR) recommends annual screening mammography for asymptomatic, average risk 1) transgender and gender diverse (TGD) men (individuals assigned female sex at birth but identify as men) age 40+ and with residual breast tissue and 2) TGD women (individuals assigned male sex at birth but identify as women) age 40+ and on gender-affirming hormone therapy for 5+ years. This nationwide study investigated screening mammography in TGD individuals. Methods: Four cohorts were identified with complex algorithms of medical and pharmacy data in the OptumLabs Data Warehouse, a longitudinal, administrative insurance claims database that includes patients with commercial insurance and Medicare Advantage: 1) TGD men, 2) TGD women, 3) individuals with gender dysphoria not meeting other TGD criteria (NMOT), and 4) cisgender women – all of whom met ACR screening criteria. The primary endpoint was the percentage of individuals with high adherence, defined as completing >75%of recommended screenings; comparisons were made across the cohorts (Chi-square test). Multivariable logistic regression was used to compare adherence between TGD men and cisgender women with adjustment for demographics and with 1:4 matching (on race/ ethnicity, age group, year of healthcare plan enrollment, and duration of follow-up). Results: 10,478 TGD individuals (3,778 TGD men; 1,294 TGD women; and 5,406 with gender dysphoria NMOT) and 6,218,369 cisgender women were identified. For TGD men, TGD women, individuals with gender dysphoria NMOT, and cisgender women, high adherence was observed in 41.1% (95% confidence interval (CI): 39.5, 42.6%); 7.4% (95% CI: 6.0, 8.8%); 11.9% (95% CI: 11.0, 12.7%); and 38.3% (95% CI: 38.3, 38.4%), respectively, p < 0.0001. No screening ever in these same populations was observed in 23.6% (95% CI: 22.2, 24.9%); 81.3% (95% CI: 79.2, 83.4%), 72.8% (95% CI: 71.6, 74%), and 35.9% (95% CI: 35.8, 35.9%), respectively, p < 0.0001. When TGD men were matched and compared to 15,112 cisgender women, a differential association was observed between gender and high adherence by age group (p < 0.0001); compared to cisgender women, the likelihood of high adherence in TGD men ages 40-49 (n = 2,472), 50-59 (n = 852), 60-69 (n = 320), and 70+ (n = 134) were as follows: odds ratios (OR's): 1.38 (95% CI: 1.28, 1.50), p < 0.0001; 1.57 (95% CI: 1.35, 1.81), p < 0.0001; 0.812 (95% CI: 0.619, 1.065), p = 0.1316; and 1.277 (95% CI 0.835, 1.951), p = 0.2595, respectively. Conclusions: This study found that TGD men manifest relatively high adherence to screening mammography, whereas TGD women and individuals with gender dysphoria NMOT manifest low adherence. Future research should focus on improving breast cancer screening in these underserved populations. Research Sponsor: National Institutes of Health, National Institute of Aging; K23 MD019644; National Institutes of Health, NCI; K07 AG076401.

Implementation of an academic precision oncology service in a community setting.

Junione Moy, Jaime Richardson, Shetal Arvind Patel, Amber Cipriani; Eshelman School of Pharmacy, The University of North Carolina at Chapel Hill, Chapel Hill, NC; University of North Carolina at Chapel Hill, NC; The University of North Carolina at Chapel Hill, NC; The University of North Carolina Medical Center, Chapel Hill, NC

Background: Implementation of precision oncology (PO) in community practice remains challenging due to insufficient resources to order and interpret genomic test results. In 2023, our PO program (located at an academic hub) partnered with a community site to optimize clinical workflows around molecular testing and to provide documented expert review of testing results. To date, the service has reviewed over 150 cases. We undertook a retrospective review to determine the impact of our intervention on the rates of next generation sequencing (NGS) ordered at this site. Methods: Patients with visits to the community cancer center between 1/2022 and 7/2024 were screened for inclusion (n = 900). Eligible patients had an advanced/metastatic solid tumor and were managed at the community site. Patients were placed in the historical or interventional cohort based on the date that their cancer became advanced/metastatic relative to the service implementation (1/1/2023). Due to a historical lack of genomic data integration within the EHR, evaluation of NGS results and subsequent treatment required manual chart review. The study was approved by the IRB of the University of North Carolina. Results: We identified 109 historical patients and 76 interventional patients who met eligibility. NSCLC patients comprised the majority of the population (27%), followed by prostate (12%), breast (10%), and colon (7%) cancers. We observed a significantly increased rate of NGS testing in solid tumors after implementation of the service (40.4% versus 57.9% before and after, p = 0.0192). The rate of NGS testing within 30 days of diagnosis of advanced/ metastatic disease also improved in the interventional cohort (21.1% versus 36.8%, p = 0.0187). The median time from first clinic visit to results was 20.5 days in those who were testing in the historical cohort versus 10.5 days in the interventional cohort. RNA transcriptome sequencing was used more frequently in the interventional cohort (40.9% versus 6.8%, p = 0.0003). **Conclusions:** Utilization of a PO program at an academic hub to support NGS testing at a community site resulted in increased testing rates and more timely access to results in advanced cancer patients. Although limited by sample size, the data emphasizes a continued need for infrastructure to support the application of PO in community settings. Research Sponsor: None.

	Historical (Prior to 1/1/2023)	Interventional (After 1/1/2023)	P-value
Rate of NGS testing in all patients	44/109 (40.4%)	44/76 (57.9%)	0.0192
Rate of NGS testing within 30 days of diagnosis	23/109 (21.1%)	28/76 (36.8%)	0.0187
Rate of NGS testing in NSCLC	15/24 (62.5%)	22/26 (84.6%)	0.109
Rate of blood-only NGS testing in those with results	27/44 (61.4%)	19/44 (43.2%)	0.0896
Rate of genome-informed therapy (all patients)	5/109 (4.6%)	8/76 (10.5%)	0.121
Rate of genome-informed therapy (NSCLC)	1/24 (4 .2%)	4/26 (15.4%)	0.3508
Median time from clinic visit to NGS testing results	20.5 days	10.5 days	

Development and fairness assessment of machine learning models for predicting 30-day readmission after lung cancer surgery.

Atulya Aman Khosla, Mohammad Arfat Ganiyani, Manas Pustake, Yagnapriya Ammakola, Nitya Batra, Akshit Chitkara, Rohit Singh, Yanjia Zhang, Gilbert Revoredo, Sonal Yadav, Vedant Tripathi, Anshul Saxena, Karan Jatwani, Ishmael A. Jaiyesimi; Department of Internal Medicine, William Beaumont University Hospital, Royal Oak, MI; Miami Cancer Institute, Baptist Health South Florida, Miami, FL; Texas Tech University Health Sciences Center, El Paso, TX; Corewell Health, Royal Oak, MI; Corewell Health William Beaumont University Hospital, Royal Oak, MI; Sidney Kimmel Comprehensive Cancer Institute, Thomas Jefferson University, Philadelphia, PA; University of Vermont Medical Center, Burlington, VT; Baptist Health South Florida, Miami, FL; The George Washington University Hospital, Washington, DC

Background: Predicting post-surgical readmissions is essential for improving patient outcomes and reducing healthcare costs. While machine learning (ML) models offer high predictive accuracy, they may perpetuate healthcare disparities if not rigorously evaluated for algorithmic bias. In this study, we examine the limitations of ML-based readmission prediction models, highlighting how bias can persist despite strong performance metrics. We also explore the impact of integrating fairness constraints to mitigate these disparities, ensuring equitable clinical decision-making across racial and ethnic groups. Methods: We analyzed National Surgical Quality Improvement Program (NSQIP) data (2016–2020) for 23,843 lung cancer surgery patients. Multiple ML models were developed using demographic, clinical, and laboratory variables. Model performance was assessed using standard accuracy metrics alongside fairness evaluations, including Demographic Parity and Equalized Odds, to measure disparities across racial groups. Results: The cohort had 56.5% females; 66.4% of cases belonged to the White race, 6.3% were Black, and 2.9% belonged to the Hispanic ethnicity. The median [Q1, Q3] was 69.0 [62.0, 74.0] years, and the overall readmission rate was 7.5%. The median operation time was higher among readmitted cases (171 minutes vs. 157.0; p < 0.001). However, there was no clinically significant difference between median [Q1, Q3] LOS between the two groups (4.0 [2.0, 6.0] vs. 4.0 [3.0, 7.0]; p < 0.001). The best-performing model (CatBoost) achieved high accuracy but showed disparities in prediction rates across racial groups (Demographic Parity Difference: 0.030, Equalized Odds Difference: 0.333) since the model disproportionately flagged Hispanic patients for readmission risk while potentially under-identifying risk in other groups. Significant predictors included operative time, preoperative sodium (139 vs. 140 mmol/L, p <0.001), and COPD status (33.8% vs. 25.3%, p < 0.001). After implementing fairness constraints, the model maintained strong predictive performance while reducing demographic disparities, with selection rates balancing across racial groups (range: 0.51%-3.50%). Conclusions: Despite their high accuracy, ML models for predicting post-surgical readmissions can reinforce existing healthcare disparities. Our findings underscore the importance of fairness-aware modeling to mitigate bias, ensuring equitable clinical decision support. While fairness constraints improved demographic balance, residual disparities persisted, highlighting the need for ongoing scrutiny when deploying AI in clinical settings. This study emphasizes the critical need for continuous fairness evaluation in medical AI applications to prevent unintentional harm to vulnerable patient populations. Research Sponsor: None.

Fall risk assessment by QTUG device in geriatric cancer patients on chemotherapy at a tertiary care hospital.

Poster Session

Tilak Tvsvgk, Simran Kaur Bhatia, Vivek Aggarwal; Command Hospital (AF), Bengaluru, India; Armed Forces Medical College, Pune, India

Background: Age-related changes, such as declines in muscle strength, balance, and coordination, are exacerbated by cancer and its treatments elevating the risk of falls. Cancer chemotherapy often lead to adverse effects which can increase fall risk. The consequences of falls in older cancer patients can be severe impacting the recovery process. The aim of the study was to estimate the baseline fall risk and frailty in geriatric patients and comparing the same after 03 cycles of chemotherapy and correlate the factors contributing to the increased risk. Methods: A prospective observational study enrolling elderly cancer patients, who are not bed-bound or using a limb prosthesis were enrolled. Patients with brain/spinal cord tumours were excluded. Fall risk assessment was done using the Kinesis Q-TUG device. Based on the scores the patients were classified into low-risk, moderate-risk and high-risk of falls. The fall risk assessment was repeated after three cycles of chemotherapy. Results: A total of 94 males and 122 females (n = 216) patients, 25% of whom were more than 70 yrs of age were enrolled. Overall the females were associated with higher fall risk and frailty compared to males. The combined fall risk estimates at baseline and post 3 cycles did not reveal a significant fall risk increase, however the timed-up-and-go (TUG) times were significantly lower post 3 cycles [Table-1]. The average stride length, stride velocity did not show any significant difference but the number of steps to turn increased post 3 cycles. Though the frailty did not show a significant difference, the correlation between fall risk and frailty showed a significant positive correlation (r = -0.91). Conclusions: While there was a slight increase in fall risk and frailty among geriatric cancer patients undergoing chemotherapy, these changes were not statistically significant. However, the decline in mobility underscores the adverse effects of chemotherapy on functional performance. The strong correlation between fall risk and frailty emphasizes the need for assessments and targeted interventions to mitigate fall risks. With increasing number of older adults with cancer, the findings advocate for enhanced monitoring and early management strategies to improve safety and outcomes for elderly cancer patients. Research Sponsor: None.

Characteristics of QTUG device in elderly cancer patients.										
Parameter	Category	Median	IQR	Min	Max	P value				
Combined Fall Risk (%)	Pre	49.18	73.44 - 31.53	11.78	79.46	0.098				
Combined Frailty Risk (%)	Post	63.48	74.98 - 47.27	12.33	93.15	0.743				
TUG (s)	Post Pre	60.25 12	75.29 - 39.98 17 - 9.69	6.5	94.41 28.29	0.002				
Average Stride Velocity (cm/s)	Post Pre	13.44 93.73	15.8 – 11.19 105.67 – 73.37	7.19 48.31	274.29 135.67	0.062				
Time taken to turn (s)	Post Pre	95.73 2.78	115.23 - 77.29 3.4-2.24	54.22 1.10	132.66 36.32	<0.001				
Number of stens to turn	Post Pre	6.18	7.2-5.3	3.66	56.48 9	~0 001				
	Post	3.5	4-3	2	10	NO.001				

APP-first as a strategy to increase new patient access and treatment of patients with gastrointestinal malignancies within a cancer center.

Amalia Stefanou, Leah Hendrick, Kristin Allen, Jason Denbo, Pamela Joy Hodul, Jason B. Fleming, Sarah E. Hoffe, Daniel A. Anaya; H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL; Moffitt Cancer Center, Tampa, FL; Department of Surgical Oncology, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL; UT Southwestern Medical Center, Dallas, TX; Department of Radiation Oncology, H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL

Background: Quality cancer care depends on timely and efficient evaluation of patients to determine next steps in treatment. To support this goal, we implemented a care delivery model where advanced practice providers (APP) were tasked with seeing new patients as an entry into the system, with a goal of completing testing and referrals prior to a subsequent visit with a surgical oncologist. Methods: A retrospective review was performed focusing on four hepatobiliary and pancreatic surgeons and their corresponding APP teams. The APP-First program was deployed in 2021. The purpose was to increase capacity and best prepare the patient's workup prior to an appointment with the surgeon to facilitate treatment initiation. We compared NPs during two distinct time periods, before (7/2018-6/2020) and after (7/2022-6/2024) implementation of APP First. The primary outcome, impact on access, was determined by change in the number of NP seen by the group, and the secondary outcomes were number and proportion of patients receiving treatment at our institution. Patients were excluded if time to care was > 180 days or they received non-GI related care. Changes in outcomes of interest before and after implementation of the program were compared by Chi-square with significance set at p = 0.05. Results: A total of 2585 NPs were seen during the study period with 1797 beginning treatment at our facility (69.5%). During the pre-intervention period 1091 NPs were seen by the group, including 277 (25.5%) initially evaluated by an APP. Following the model implementation, 1494 NPs were seen, 915 (61.2%) by an APP and 579 (38.8%) by an MD (p < 0.001). There was no change in percent of NPs choosing to pursue care at our institution (68.7% vs 68.7%, p = 0.970), however after implementation, patients were more likely to be scheduled for operations after their initial visit (11.4% vs 14.3%, p = 0.031). Conclusions: Implementation APP-first led to increased NPs capacity translating into a 36.9% higher volume of NPs seen, without change in patient satisfaction as demonstrated by an unchanged percentage of patients choosing treatment at our institution. The established workflow within this model facilitated expedited care, resulting in higher proportion of patients treated and an increase in the number and proportion of patients receiving surgery. These data support the implementation of delivery of care models leveraging the role of APPs in a well-integrated system, with overall improved capacity, access, and treatment for patients with cancer. Research Sponsor: None.

Outcomes of APP-First program.			
	FY 19-20 (n,%)	FY 23-24 (n,%)	<i>p</i> value
Total # NP	1,091	1,494	-
NP Distribution			
APP	277 (25.4)	915 (61.2)	<0.001
MD	814 (74.6)	579 (38.8)	
Treated	((
Yes	750 (68.7)	1026 (68.7)	0.970
No	341 (31.3)	468 (31.3)	
Surgery	124 (Ì11.4)	213 (14.3)	0.031
Chemotherapy	143 (13.1)	194 (13.0)	0.928
Endoscopy	376 (34.5)	466 (31.2)	0.080
Radiation	112 (10.3)	154 (10.3)	0.972

Gender, place of death, and racial disparities in the reporting odds ratio of cardiovascular disease burden in leukemia across age groups (15–85) in the U.S.: A CDC WONDER disproportionality analysis.

Tehmasp Mirza, Faizan Ahmed, Aman Ullah, Izzah Nayyab, Najam Gohar, Abdullah Zia, Yasir Rashid, Omar Kamel, Kainat Aman, Yusra Junaid, Mohamed Bakr, Sherif Eltawansy, Mohammad Hossain, Areehah Zafar Masood, Hira Zahid, Husnain Ahmad, Brijesh Patel; Shalamar Medical and Dental College, Lahore, Pakistan; Duke University Hospital, Division of Cardiology, Durham, NC; SSM Health Saint Louis University Hospital, Saint Louis, MO; Allama Iqbal Medical College, Lahore, Pakistan; Ameer-ud-din Medical College, Lahore, Pakistan; Rai Medical College, Sargodha, Punjab, Pakistan; South Valley, Cairo, Egypt; Batterjaee Medical College, Jeddah, Saudi Arabia; Dow Medical College, Karachi, Pakistan; Jersey Shore, New Jersey, NJ; Jersey Shore University, New Jersey, NJ; Jersey Shore University, Neptune City, NJ; Ziauddin Medical University, Karachi, Pakistan; Shalamar Medical & Dental College, Lahore, Punjab, Pakistan; Indiana University, Indianapolis, IN

Background: Leukemia, a hematologic malignancy, often coexists with cardiovascular disease (CVD), worsening outcomes due to shared risk factors like diabetes, hypertension, and smoking. Despite CVD's known impact on leukemia mortality, research on demographic and geographic disparities remains limited. This study examines disparities in the Reporting Odds Ratio (ROR) of CVD burden among leukemia deaths across age, gender, place of death, and race/ ethnicity using CDC WONDER data (1999–2020). Methods: A disproportionality analysis of CDC WONDER death certificate data for U.S. adults (15–85) was conducted. Records were grouped into four variables: leukemia deaths with CVD (A), leukemia deaths (B), CVD deaths (C), and all deaths (D). RORs were calculated as (A/B) / (C/D) and stratified by gender, race/ethnicity, urbanization, and place of death. Age groups were categorized into 15–24, 25–64, and 65+ years. Joinpoint regression was used to compute annual percentage change (APC) and average annual percentage change (AAPC) to identify trends. Results: Analysis of 22 years of data revealed disparities in RORs across demographics. The 15-24 age group had the highest ROR for males (2.51) and females (1.59), indicating a greater CVD burden in leukemia deaths than allcause mortality. Middle-aged (25-64) and older adults (65+) had lower RORs (<1), suggesting a reduced CVD-leukemia burden in these groups. Trends: The young female cohort showed a sharp ROR decline (2018–2020, APC: -22.02%; 95% CI -36.00 to -1.23; p=0.039), while the elderly male cohort (85+) had a steady rise (APC: 6.93%; 95% CI 1.74–9.24; p<0.0001). Place of Death: Medical facilities had the highest CVD burden in leukemia deaths, especially in younger cohorts (15-24; ROR: 1.47). Hospice facilities had the lowest RORs across age groups. The "Other/Unknown" category had an outlier ROR of 4.81 in the youngest cohort, suggesting data limitations. Race/Ethnicity: Hispanics had the highest ROR (2.64) in the 15–24 age group, followed by Asians (2.21). In middle and older age groups, RORs declined for all races. Hispanics (65-74) showed an increasing ROR trend (AAPC: 0.92%; 95% CI 0.45-1.36; p=0.002). Conclusions: Significant disparities exist in CVD burden among leukemia deaths, with younger cohorts, males, Hispanics, and patients in medical facilities showing the highest RORs. These findings highlight the need for targeted cardio-oncology strategies to address CVD risk in leukemia patients. Further research on chemotherapy-related cardiotoxicity and healthcare disparities is crucial to reducing inequities and improving outcomes. Research Sponsor: None.

Oncofertility practice patterns in NCCN cancer centers after the overturn of *Roe v. Wade*.

Nikita V. Baclig, Jordyn Silverstein, Vrushangi Shah, Beth Y. Karlan, Sidharth Anand, John A. Glaspy; University of California Los Angeles, Los Angeles, Los Angeles, CA; University of California Los Angeles, David Geffen School of Medicine, Los Angeles, CA; University of California, Los Angeles, Los Angeles, CA; UCLA Department of Hematology & Oncology, Los Angeles, CA

Background: The Supreme Court decision of Dobbs v. Jackson to overturn Roe v. Wade gave states authority to regulate reproductive health. This has led to concerns about access to assisted reproductive technologies used in oncofertility. The impact of this legal climate on oncofertility practices remains unknown. This study aims to understand how academic cancer centers across the United States have experienced changes in oncofertility care in a post-Roe world. Methods: In collaboration with the National Comprehensive Cancer Network (NCCN) Best Practices Committee, a survey was developed to evaluate changes in oncofertility access and utilization in the 2 years since the Dobbs decision. In July 2024, the survey was sent to NCCN Member Institutions, which represent 23 states with varied post-Roe protections for reproductive care. The survey responses were de-identified for analysis. Questions were both multiple choice and free response. Results: The survey was sent to 33 NCCN Member Institutions and yielded 24 responses (72.7%). A majority (83.3%) indicated that reproductive care was a moderate-high priority for their cancer center. Most (62.5%) reported an increase in the number of cancer patients receiving fertility preservation. According to the Center for Reproductive Rights, 13 institutions are in states that have restricted reproductive rights since the Dobbs decision. However, only 4 (16.7%) survey respondents reported that reproductive health laws had become more restrictive. The remaining reported that laws had not changed, were less restrictive, or abstained (83.3%). All 4 respondents who indicated more restrictive laws reported moderate-high priority placed on reproductive care and half reported an increase in cancer patients receiving fertility care. In the states that reported no or neutral change (n=14, 58.3%) or less restrictive laws (n=5, 20.8%), most (68.4%) reported an increase in patients receiving fertility care. One respondent who indicated more restrictive laws reported a decrease in resources for fertility care. Many centers have prioritized oncofertility by developing oncofertility programs, assigning fertility navigators, and creating electronic health record-assisted referral alerts and clinical pathways. **Conclusions:** Large academic NCCN Member Institutions, most in states with no change or less restrictive reproductive laws since the Dobbs decision, reported an increase in number of patients who accessed fertility care. Additional studies will clarify whether this reflects underlying trends or increased fertility care due to a fear of limited future access. Only a minority of the institutions in restrictive states responded to the survey and most who did reported similar or improved access to oncofertility care. The lack of response from restrictive states needs to be examined further as it may reflect concerns about oncofertility care in the new political landscape. Research Sponsor: None.
Trade-off preferences in older adults with newly diagnosed acute myeloid leukemia.

Kah Poh Loh; University of Rochester Medical Center, Rochester, NY

Background: Treatment decisions for older adults with acute myeloid leukemia (AML) are highly preference-sensitive, requiring a balance between survival and other important outcomes such as toxicities and quality of life (QoL). Understanding patients' trade-off preferences is critical for guiding personalized treatment planning. We examined the trade-off preferences of older adults newly diagnosed with AML and factors influencing these preferences. Methods: We collected data from two clinical trials evaluating an AML communication tool. Older adults completed questionnaires at diagnosis assessing trade-offs between survival and two key outcomes: a) maintaining QoL and b) treatment-related toxicities (nausea/vomiting, bedbound status, assistance with daily activities, worsening memory, and confusion). The survival-QoL trade-off was categorized as agree vs. disagree. Trade-offs for treatment-related toxicities were scored from 0 to 5, with higher scores indicating a greater willingness to endure toxicities for survival. We used binary logistic regression to identify factors associated with survival-QoL trade-off, while ordinal logistic regression was used for survival-toxicity trade-off. Results: We included 95 older patients with newly diagnosed AML; mean age was 73.7 (SD 7.6), 38% female, and 94% White. Approximately 37% received intensive and 54% received lower-intensity treatment. Only 15% prioritized survival over maintaining QoL, 39% neutral, and 46% prioritize maintaining QoL over survival (Table). Over 60% would decline treatments leading to confusion, and 45% would avoid treatments causing bedbound status. On multivariable analyses, patients enrolled with a caregiver had a significantly higher odds of prioritizing survival over QoL [Odds Ratio (OR): 5.92, p=0.04]. Employed patients were more likely to endure treatment-related toxicities for survival compared to those who were unemployed, retired or homemaker (OR: 7.76, p<0.01). Conclusions: Trade-off preferences among older adults with AML vary widely and are influenced by caregiving support and employment status. Actively eliciting these preferences is essential to align treatment decisions with individual patient values. Research Sponsor: Conquer Cancer Foundation Walther Cancer Foundation; American Cancer Society.

Preferences of older adults with AML.			
I would like to try treatments for my cancer if they could help me live longer, even if it is very likely they would	Agree/ Strongly agree	Neutral	Disagree/ Strongly disagree
Have high level of side effects (e.g., nausea/vomiting)	60%	24%	16%
Make me require more assistance from family and friends with completing daily activities (e.g., shopping, managing money)	53%	22%	25%
Make me bedbound and unable to use the bathroom without assistance	35%	20%	45%
Make my memory worse	29%	29%	40%
Cause me to become confused often so that I am not aware of my surroundings	15%	23%	61%
Living longer is more important to me than maintaining my quality of life	15%	39%	46%

OP-35: Does a tool designed to measure potentially preventable chemotherapy toxicities do so effectively?

Ryan W. Huey, Aneeqa Zafar, Phat Le, Natalie E. Sanchez, Krista Patlovich, Nicholas D. Olivieri, Eric Kumar Singhi, Jose A. Rivera, Ryan Roux, Kerin B. Adelson; The University of Texas MD Anderson Cancer Center, Houston, TX; Department of General Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX

Background: OP-35 is a measure developed by the National Quality Foundation that the Center for Medicare and Medicaid Services (CMS) uses to evaluate the quality of care for patients undergoing outpatient chemotherapy treatment. Launched in 2021, it was intended to measure rates of potentially preventable complications of chemotherapy treatment. The tool assesses the rate of emergency department visits and admissions (EDV/A) visits for patients receiving outpatient intravenous (IV) systemic anti-cancer therapy (SACT) and defines potentially preventable by the presence of \geq 1 of 10 diagnoses: anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis. However, it is unknown if these diagnoses track truly preventable visits and therefore if it is a valid measure of quality. Methods: We conducted a retrospective review of patients who received outpatient IV SACT (the denominator for OP-35) at the University of Texas MD Anderson Cancer Center between January 2023 and December 2023. All patients who had an EDV/A were assessed to understand the primary and secondary diagnoses associated with their encounters. Results: The total number of patients included in the population who received outpatient IV SACT was 10,353. Of these, 2,401 (23.2%) had an EDV/A within 30 days of receiving outpatient IV SACT. Of patients with an EDV/A, 67% of patients had one EDV/A, 21% had 2, and 12% had \geq 3. The most common diagnosis groups were pain (83%), anemia (69%), nausea (44%), and fever (35%). 82% of patients had more than one qualifying diagnosis. For 68%, the qualifying diagnosis was a secondary diagnosis. Of patients with a qualifying EDV/A, only 15% did not have a qualifying OP-35 diagnosis. Conclusions: While OP-35 was designed to measure potentially preventable chemotherapy-related complications, the exclusion of relatively few patients among those with an EDV/A suggests that a significant proportion of qualifying events may not truly be preventable. The qualifying diagnosis list may need to be tailored to exclude non-preventable admissions. This would improve the metric's specificity and validity as measure of care-quality. Future work should clarify which diagnoses lead to misclassification of non-preventable EDV/As. Research Sponsor: None.

Patients with qualifying EDV/A		N = 2,401
Type of Cancer	Solid Malignancy	2,020 (84%)*
	Heme Malignancy	383 (Ì6%)*
Qualifying OP-35 Diagnosis	Pain	1,998 (83%)
	Anemia	1,652 (69%)
	Nausea	1,065(44%)
	Fever	833 (35%)
	Dehydration	679 (28%)
	Pneumonia	552 (23%)
	Neutropenia	509 (21%)
	Diarrhea	534 (22%)
	Sepsis	364 (15%)
	Emesis	148 (6%)
Number of EDV/A Per Patient	1	1,614 (67%)
	2	502 (21%)
	≥3	285 (12%)

*Two patients categorized with both solid and heme malignancies.

Poster Session

Qualitative findings from providers and patients for planning implementation of screening clinical breast examination in Soweto, South Africa.

Daniel O'Neil, Gugulethu Tshabalala, Janan Dietrich, Meisie Lerutla, J. Lucian Davis, Lydia E. Pace, Eric P. Winer, Maureen Joffe; Yale Cancer Center, Yale University, New Haven, CT; University of Witwatersrand Faculty of Health Sciences, Johannesburg, South Africa; Perinatal HIV Research Unit, University of Witwatersrand, Johannesburg, South Africa; University of Witwatersrand, Johannesburg, South Africa; Yale School of Public Health, Yale University, New Haven, CT; Harvard Medical School, Harvard University, Boston, MA; Yale Cancer Center, New Haven, CT

Background: Over 50% of South African women with breast cancer (BC) are diagnosed at stages III & IV. To inform an Implementation Mapping process to design strategies for implementing screening clinical breast exam (CBE) in primary care facilities in Soweto, South Africa, we gathered qualitative data from local primary care providers and patients on barriers to CBE and possible implementation approaches. Methods: We conducted semi-structured interviews with administrators, nurses, doctors, and community health workers (CHWs) and focus groups with women potentially eligible for screening CBE at four Soweto primary care facilities that do not offer BC screening. Our discussion guide explored BC screening perceptions among both groups. We also asked providers for recommendations about how to best implement a future CBE screening program, and we asked patients about factors that would motivate them to participate in such a program. We analyzed transcripts deductively in parallel with data collection. We organized themes using the Consolidated Framework for Implementation Research (CFIR). To support Implementation Mapping's emphasis on addressing the needs of individual stakeholders, our analysis focused on the CFIR Individuals domain and Characteristics subdomain taken from the COM-B system. Results: We analyzed 27 interviews with 8 administrators, 1 medical officer, 14 nurses, 3 CHWs, and 1 clerk, and 4 focus groups with 23 total women. Providers (*i.e.*, deliverers) and patients (*i.e.*, recipients) alike expressed enthusiasm for CBE's potential to decrease BC mortality and morbidity. Both groups also cited CBE's potential to overcome and counteract patients' limited knowledge of breast health and BC symptoms. The primary barrier to CBE, according to both groups, is the high patient volume at public facilities. Providers described staff shortages limiting opportunity to perform CBE and patients cited long wait times as a barrier to pursuing "extra" services. Providers often recommended hiring new personnel designated for CBE screening. Patients suggested various approaches to expanding access, such as screening in both the clinic and community, opportunistic screening while patients wait for other clinic services, and walk-in access for "screening only" visits. Patients also emphasized the need to improve trust in the clinics and their staff. Regarding educational outreach, providers focused on expert-delivered teaching in both the clinic and community. Patients valued experts but also recommended engaging BC survivors and other community members to promote screening through word-of-mouth. **Conclusions:** Soweto's primary-care clinicians and patients expressed enthusiasm for the health benefits of BC screening, but successful implementation must address barriers faced by both groups, including long clinic wait times and personnel shortages. Research Sponsor: National Cancer Institute.

Development of an early sepsis treatment-decision algorithm in children and adolescents with cancer in a middle-income country: Results from a multinational modified Delphi consensus.

Paula Aristizabal, Eileen Viviana Fonseca, Carlos Portilla, German Camacho, Javier Aguilar, Santiago Bolivar, Michele McDaniel, Juan Jaramillo, Yvette Wang, Helen Harvey, Margaret Nguyen, Edmund Milder, Paul Ishimine, Bianca Quinones-Perez, Monica Quijano, Oscar Ramirez, Leidy Tovar Padua, Eliana Lopez, on behalf of MAMMUTS (MAnejo Multidisciplinario para el Manejo de la NeUTropenia febril y Sepsis) Taskforce; Division of Hematology/Oncology, Department of Pediatrics, University of California San Diego and Rady Children's Hospital-San Diego and University of California San Diego Moores Cancer Center, San Diego, CA; Fundacion Hospital de la Misericordia-HOMI/Universidad Nacional De Colombia, Bogota, Colombia; Department of Pediatrics, Universidad del Valle and Clinica Imbanaco, Cali, Colombia; Fundacion Hospital de la Misericordia-HOMI/Universidad Nacional de Colombia, Bogota, Colombia; School of Medicine, Pontificia Universidad Javeriana, Bogota, Colombia; Division of Emergency Medicine, Department of Pediatrics, University of California San Diego and Rady Children's Hospital-San Diego, CA; Department of Pediatrics and Critical Care, Hospital Pablo Tobón Uribe/Universidad de Antioquia, Medellin, Colombia; Division of Critical Care, Department of Pediatrics, University of California San Diego and Rady Children's Hospital-San Diego, San Diego, CA; Division of Infectious Diseases, Department of Pediatrics, University of California San Diego and Rady Children's Hospital-San Diego, San Diego, CA; Division of General Pediatrics, Department of Pediatrics, Boston Children's Hospital and Harvard Medical School, Boston, MA; Pediatric Hematology/Oncology, Clinica Imbanaco and Cali's Population-Based Cancer Registry, Universidad del Valle, Cali, Colombia; School of Public Health and Information Sciences, University of Louisville and Department of Pediatrics Universidad de Antioquia, Louisville, KY

Background: Despite global efforts, striking childhood cancer survival gaps between low- and middle-income countries (LMIC) and high-income countries persist. Based on data from the Colombian childhood cancer clinical outcomes surveillance system, VIGICANCER, sepsis accounts for approximately 90% of all preventable deaths. In response, we developed a consensus-based Treatment-Decision Algorithm (TDA) for early sepsis detection and treatment, adapted to the local context and balancing optimal clinical management and resource utilization. Methods: We used RAND/UCLA Delphi method (preparatory phase, literature review, rating) to consult experts on the appropriateness of the proposed risk/alert definitions, critical steps, evidence-based interventions, and decision-making trees in the adapted TDA. Consensus involved: a) Pilot anonymous voting on a 22-statement online survey (5-point Likert scale, open-ended questions); b) Reading/rating in a hybrid meeting (in-person/ virtual); and c) Voting on statements where consensus was not reached. Consensus was defined as: \geq 70%, strong; 51%–69%, moderate; \leq 50%, no consensus. **Results:** Preparatory phase and literature review: A multinational (Colombia, Mexico, US), interprofessional panel of 19 members, including from pediatric cancer centers and academic societies (oncology, emergency medicine, hospital medicine, critical care, infectious diseases, nursing) ensured geographic and resource representation. A Colombian internal expert taskforce (n = 6) completed a comprehensive literature review, met biweekly, and developed the Colombian Protocol for Early Sepsis Detection in Children with Cancer and accompanying TDA with 3 domains: sepsis screening, sepsis huddle, and early treatment. Consensus results: a)Pilot(n = 19 members), strong agreement was obtained for 81% of statements in one round; b) Reading/rating (n = 8 members), strong agreement was reached in 90% of statements after two rounds; and c) Voting on statements without consensus (n = 11 members, online), moderate agreement was reached in 100% of statements (2) in one round. **Conclusions:** Through collaborative consensus, we successfully developed an evidence-based, user-friendly TDA for early sepsis detection and treatment, tailored to resource-constrained settings. The diverse, interprofessional panel facilitated contextual adaptations of the TDA. The proposed TDA provides clinicians serving children with cancer in Colombia with an easy-to-follow TDA that is clear, exhaustive, and suitable for adaptation to individual local settings. Next steps involve applying improvement science methodology to implement the TDA in Colombia and Mexico and evaluating its predictive value for prompt sepsis detection in children with cancer, contributing to reduction of survival gaps in LMIC. Research Sponsor: None.

Impact of the eSyM symptom monitoring program on nurse telephone encounters across six cancer centers.

Michael J. Hassett, Hajime Uno, Angela C. Tramontano, Christine M. Cronin, Jessica J. Bian, Don Steven Dizon, Hannah W. Hazard-Jenkins, Gabriel A. Brooks, Raymond U. Osarogiagbon, Sandra L. Wong, Deb Schrag; Dana-Farber Cancer Institute, Boston, MA; MaineHealth Cancer Care, South Portland, ME; Legorreta Cancer Center at Brown University, Providence, RI; WVU Cancer Institute, West Virginia University, Morgantown, WV; Dartmouth Cancer Center, Lebanon, NH; Baptist Cancer Center, Multidisciplinary Thoracic Oncology Program, Memphis, TN; Emory University, Atlanta, GA; Memorial Sloan Kettering Cancer Center, New York, NY

Background: After developing an ePRO-based, EHR-integrated symptom monitoring program (eSyM) and implementing it across 6 health systems, we found lower odds of acute care utilization among those who used eSyM to report symptoms. Facilitating communication between patients and clinicians is a potentially important mechanism by which symptom monitoring programs may improve outcomes. We measured the association between eSyM deployment, symptom reporting and severe symptom reporting on the frequency and number of nurse telephone encounters (TELs). Methods: eSyM was deployed in a stepped wedge RCT from 2018-2023 for adults who started chemotherapy (CHEM) or were discharged following surgery (SURG) for a suspected or confirmed GI, GYN or thoracic cancer. We analyzed three cohorts: 1) for all patients, we compared those treated before vs. after eSyM deployment; 2) for post-deployment patients (eSyM eligible), we compared those who did vs. did not report symptoms within 30 days of first eSyM prompt; and 3) for symptom reporters (eSyM users), we compared those who did vs. did not report severe symptoms. Outcomes of interest were the proportion of patients with at least one TEL and total number of TELs within 30 days of first eSyM prompt. Poisson regression was used to estimate the number of TELs within 30 days accounting for cancer and treatment type, as well as age, gender, and other factors. Results: In total, 18,830 patients were and 21,112 were not exposed to eSyM (median age 64, 66% female). Among eligible patients, 8,298 (44%) reported symptoms within 30 days. Among eSvM users, 3,666 (44%) reported one or more severe symptoms within 30 days. The proportion of patients with TELs and the number of TELs per patient are below (Table). In regression analyses, there were more TELs within 30 days after eSyM deployment (SURG 0.09 [95%CI 0.07-0.11; P <.0001], CHEM 0.26 [95% CI 0.23-0.28; P < .0001]) and among severe symptom reporters (SURG 0.42 [95%CI 0.38-0.45; P < .0001], CHEM 0.43 [95% CI 0.38-0.48; P < .0001]). Conclusions: eSyM exposure and reporting severe symptoms were associated with a greater likelihood and larger number of TELs, supporting nurse intervention as a mediator of the association between ePRO monitoring and clinical outcomes. Future studies should explore the impacts of ePRO systems on nursing workload and health system costs. Clinical trial information: NCT03850912. Research Sponsor: National Cancer Institute; 1UM1CA233080-01.

Cohort	Treatment	% patients reporting within 30 days, P value			Mean number with at least o	of TELs among ne TEL (SD), P	those value
All patients		Control	Intervention		Control	Intervention	
•	Surg Chemo	63% 60%	69% 79%	<.0001 <.0001	2.6 (2.5) 3.9 (3.6)	2.9 (2.5) 4.0 (3.5)	<.0001 0.08
eSyM eligible		Non-reporter	Reporter		Non-Reporter	Reporter	
2	Surg Chemo	66% 77%	71% 81%	<.0001 <.0001	3.0 (2.6) 4.1 (3.6)	2.9 (2.4) 3.9 (3.4)	0.23 0.04
eSyM users		No severe symptoms	Severe symptoms		No severe symptoms	Severe symptoms	
	Surg Chemo	67% 76%	77% 89%	<.0001 <.0001	2.6 (2.1) 3.4 (3.0)	3.3 (2.7) 4.5 (3.5)	<.0001 <.0001

Cost and resource utilisation for liquid biopsy vs tissue biopsy genotyping in advanced NSCLC: A micro-costing model.

David O'Reilly, Carolyn Moloney, Anthony O'Grady, David Synnott, Daniel Ryan, Michael Emmet O'Brien, Ross E. Morgan, Ian Counihan, Sinead Cuffe, Grzegorz Korpanty, Lisa Mary Prior, Stephen Finn, Robert Cummins, Sinead Toomey, Bryan T. Hennessy, Jan Sorensen, Kathleen Bennett, Parthiban Nadarajan, Brendan Doyle, Jarushka Naidoo; Beaumont RCSI Cancer Centre, Dublin, Ireland; Department of Histopathology, Beaumont Hospital, Dublin, Ireland; Trinity St James's Cancer Institute, Dublin, Ireland; University Hospital Limerick, Kingston, ON, Canada; Beacon Hospital, Dublin, Ireland; Trinity St. James's Cancer Institute, Dublin, Ireland; Department of Histopathology, Dublin, Ireland; Royal College of Surgeons in Ireland, Dublin, Ireland; Healthcare Outcomes Research Centre, School of Population Health, RCSI University of Health Sciences, Dublin, Ireland; Department of Data Science, Royal College of Surgeons of Ireland, Dublin, Ireland; Trinity St. James's Cancer Institute, Dublin, Ireland

Background: For patients with advanced non-small cell lung cancer, tumour genotyping identifies actionable variants that inform targeted therapeutic choices, that improve outcomes. Liquid biopsy genotyping (LBG) is a non-invasive approach to tissue biopsy genotyping (TBG) that reduces turnaround, avoids repeat tissue biopsy, and can identify additional actionable variants. However, despite these benefits, patient access to LBG is not universal in a range of healthcare systems. While others have developed models evaluating the cost-effectiveness of LBG, these have are limited by assumptions regarding frequency of oncogenic variants and treatment utilisation. We utilised a micro-costing model (MCM) to quantify the cost/resources of LBG and TBG in a prospective trial (PLAN; ClinicalTrials.gov Identifier: NCT05542485) aimed at investigating the feasibility of LBG in a tertiary cancer centre. Methods: A deterministic MCM was developed to enumerate the cost to generate a genomics report for both LBG and TBG in NSCLC. Capital costs were calculated based on up-front investment and annual depreciation/ maintenance. Costs of consumables and staff time associated with each procedure was sourced from relevant hospital departments (e.g. Medical Physics) and evaluated for accuracy by a health economist and medical oncologist. We calculated the cost of sample acquisition (endobronchial ultrasound-guided biopsy or phlebotomy), processing, and genotyping for both LBG and TBG, from patients enrolled on the PLAN study (n = 100) between 08/2023-07/2024. Finally, we performed an exploratory analysis investigating potential reduction in staff time associated with automated library preparation, using currently available technology. Results: We identified that TBG requires more staff time (\in 534 vs \in 330), capital investment (\in 326 vs \in 16), and consumables (\in 1544 vs \in 788), resulting in an overall increased cost, compared with LBG (\in 2404 vs \in 1135). Automation of library preparation would reduce staff time required for LBG (Reduced to \in 191; 33% reduction) with less of an impact on TBG (Reduced to \in 485; 10% reduction). This difference was due to the increased wet-lab time with LBG and greater staff time for sample acquisition in TBG vs LBG (\in 298 vs \in 8). Finally, in the PLAN study, LBG resulted in cancellation of 12 repeat tissue biopsies, resulting in further savings. **Conclusions:** LBG is a cheaper alternative to TBG. Our data indicates LBG saves cost in the areas of healthcare staffing and capital infrastructure with further savings made through avoidance of repeat tissue biopsies. Thus, the resources required for LBG and TBG are different and should be considered in service planning for tumour types such as NSCLC in which genotyping is standard-of-care. Clinical trial information: NCT05542485. Research Sponsor: AstraZeneca; Amgen; Novartis; Irish Cancer Society; Charitable Infirmary Charitable Trust.

Impact of a collaborative care-based symptom intervention model on chemotherapy adherence in patients with breast cancer.

Michael H. Storandt, Kathryn Jean Ruddy, Veronica Grzegorczyk, Kurt Kroenke, Michael J. Hassett, Jacob Greenmyer, Sandra A. Mitchell, Ashley Wilder Smith, Deirdre R. Pachman, Andrea L. Cheville; Mayo Clinic, Rochester, MN; Indiana University School of Medicine and Regenstrief Institute, Indianapolis, IN; Dana-Farber Cancer Institute, Boston, MA; National Cancer Institute, Bethesda, MD

Background: Treatment toxicity may limit the ability of cancer patients to receive all recommended cycles of therapy. Four to six cycles of docetaxel plus cyclophosphamide (TC) is a common adjuvant chemotherapy regimen for early-stage breast cancer. We assessed the impact of routine collection of patient-reported outcomes (PROs), coupled with a collaborative care model-based symptom management intervention, on the number of cycles of TC received by patients with breast cancer. Methods: The Enhanced, EHR-facilitated Cancer Symptom Control (E2C2) trial was a cluster-randomized, pragmatic clinical trial, conducted between March 2019 and January 2023 at Mayo Clinic Rochester and within the Mayo Clinic Health System in Minnesota and Wisconsin. Patients regularly reported the severity of 6 SPPADE symptoms (Sleep deficit, Pain, Physical function impairment, Anxiety, Depression, and Energy deficit/fatigue) on 11-point numerical rating scales. Each symptom score was interpreted as none to mild (0-3), moderate (4-6), or severe (7-10). The E2C2 intervention included symptom management education modules, clinician decision support aids, and the option to discuss severe symptoms with a nurse, physical therapist, or social worker. Patients with breast cancer who received at least one cycle of TC were included in this analysis. We compared the number of cycles of docetaxel and cyclophosphamide completed by patients in the control condition versus those in the intervention condition. Results: We identified 198 patients with breast cancer who received TC during the control condition and 128 who received TC during the intervention condition. Median age was 61.3 years in the control group and 60.3 years in the intervention group, and 94% and 95% were white, respectively. Those receiving treatment during the control condition, on average, completed 3.53 cycles of docetaxel, while those receiving TC during the intervention condition completed 3.77 cycles (p = 0.014). Seventyeight percent in the control group completed at least 4 cycles of docetaxel, compared to 84% in the intervention group. Those receiving TC during the control condition completed an average of 3.71 cycles of cyclophosphamide, compared to 3.78 cycles in the intervention condition (p = 0.231). Eighty-four percent of patients in the control group and 86% in the intervention group completed at least 4 cycles of cyclophosphamide. Conclusions: Routine PRO surveillance, coupled with guideline-based collaborative care interventions, was associated with completion of a greater number of cycles of docetaxel. These findings suggest that routine symptom surveillance and management may enhance the docetaxel tolerance profile and improve treatment adherence in patients with early-stage breast cancer, allowing for delivery of an optimized treatment course. Research Sponsor: NCI of the National Institutes of Health; UM1CA233033 (PI Cheville, Mayo Clinic, Rochester, MN).

Successful accrual of a cluster randomized controlled trial (RCT) comparing an educationally enhanced genomic tumor board (EGTB) intervention to usual practice (S2108CD, NCT# 05455606).

Meghna S. Trivedi, Jens Rueter, Joseph M. Unger, Kathryn B. Arnold, Sarah Colby, Kate Reed, Johannes Fischer, Lindsey Kelley, Pankaj Kumar, Bryan Faller, Kendrith M. Rowland, Daniel A. Nikcevich, Banu Symington, Veena Shankaran, Scott David Ramsey, Dawn L. Hershman; Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center, New York, NY; The Jackson Laboratory, Brewer, ME; SWOG Statistics and Data Management Center, Fred Hutchinson Cancer Center, Seattle, WA; SWOG Statistics and Data Management Center, Seattle, WA; Fred Hutchinson Cancer Research Center and SWOG Statistics and Data Management Center, Seattle, WA; JAX, Bar Harbor, ME; Jackson Laboratory, Bar Harbor, ME; Illinois CancerCare, P.C., Peoria, IL; BJC Healthcare, St. Louis, MO; Carle Clinic, Champaign, IL; Essentia Health Duluth, Duluth, MN; Sweetwater Regional Cancer Center, an Affiliate of Huntsman Cancer Institute, Rock Springs, WY; University of Washington, Seattle, WA; Public Health Sciences Division, Fred Hutchinson Cancer Center, Seattle, WA; Herbert Irving Comprehensive Cancer Center, Columbia University Irving Medical Center, New York, NY

Background: Observational studies show genomic tumor boards (GTBs) can enhance clinician knowledge and application of genomic tumor test (GTT) results. An RCT is needed to evaluate the impact of GTBs on treatment and outcomes. Conducting such a trial requires physician engagement and recruitment of an unbiased study population over a short period of time due to rapid changes in cancer genomics. S2108CD prospectively evaluates the impact of an educationally enhanced GTB (EGTB) intervention through a cluster RCT design across rural and community oncology practices in the United States. Methods: Recruitment Centers (RCs) were selected from the NCI Community Oncology Research Program (NCORP) with a focus on rural and minority/underserved (RMU) sites and cluster randomized 1:1 to EGTB intervention (virtual GTB and physician educational materials) versus usual practice (UP). Oncologists and their patients with advanced solid tumors who had GTT ordered were enrolled. The primary aim is to compare the proportion of patients receiving evidence-based genome informed therapy by arm. Here, we describe accrual and baseline characteristics of the RCs and the enrolled physicians and patients. Results: Between 8/2022 and 11/2024, 18 RCs were randomized to UP versus EGTB intervention. A median of 5 clinics (range, 1-13) comprised each RC. Six RCs were classified as RMU in each arm (n = 12). Overall, 121 physicians registered to the study and they registered 1284 patients (median 47.5 patients/month), of which 983 (77%) were registered at RMU RCs. In the UP arm, 614 patients and 61 physicians registered, and in the EGTB arm, 670 patients and 60 physicians registered (demographics of registered patients in table; unknown race/ethnicity [3%] not shown), meeting accrual goal within target timeframe. The 3 most common patient neoplasms were lung, mediastinal and pleural (n = 352, 27.4%), gastrointestinal (n = 344, 26.8%), and breast (n = 152, 11.8%). Conclusions: Timely accrual to S2108CD demonstrates the feasibility of conducting a cluster RCT to evaluate an EGTB intervention. There was high participation of RMU sites with a study population reflecting cancer types relevant for GTT; however, there were fewer than anticipated non-White and Hispanic patients registered. Study endpoint data are currently maturing. The final analysis of S2108CD will be conducted and reported in 2026. Clinical trial information: NCT05455606. Research Sponsor: NIH/NCI/NCORP; UG1CA189974; The Hope Foundation for Cancer Research.

Patient characteristic		Overall (N=1284, %)	UP (N=614, %)	EGTB (N=670, %)
Age, median (range)		67.7 (20.3, 96.7)	67.6 (20.3, 96.7)	67.7 (22.4, 94.2)
Sex	Female	646 (50)	325 (53)	321 (48)
Race	American Indian or Alaska Native	10 (1)	4 (1)	6 (1)
	Asian	56 (4)	51 (8)	5 (1)
	Black or African American	88 (7)	26 (4)	62 (9)
	Native Hawaiian or other Pacific Islander	23 (2)	23 (4)	0(0)
	White	1047 (82)	490 (80)	557 (83)
	Multiracial	25 (Ì)	8 (Ì) ´	17 (̀3) ́
Ethnicity	Hispanic	106 (8)	25 (4)	81 (ÌŹ)

Electronic patient-reported outcomes with vital sign monitoring versus usual care during trastuzumab deruxtecan treatment for metastatic breast cancer: Updated results from the PRO-DUCE study.

Yuichiro Kikawa, Yukari Uemura, Tetsuhiko Taira, Chiyoe Kitagawa, Hideki Maeda, Hiroaki Kato, Naoki Hashimoto, Mitsuchika Hosoda, Yohei Hamanaka, Yuko Tanabe, Tatsuya Yoshida, Kaori Tane, Daisuke Takabatake, Takashi Ishikawa, Takayuki Iwamoto, Takeshi Yamaguchi, Daisuke Takiguchi, Hirofumi Mukai, Naruto Taira, Takafumi Sangai; Department of Breast Surgery, Kansai Medical University Hospital, Hirakata, Japan; Center for Clinical Science, National Center for Global Health and Medicine, Tokyo, Japan; Department of Medical Oncology, Sagara Hospital, Kagoshima, Japan; Department of Medical Oncology, NHO Nagoya Medical Center, Nagoya, Japan; Department of Breast and Endocrine Surgery, Higashi Sapporo Hospital, Sapporo, Japan; Department of Chest Surgery, Teine Keijinkai Hospital, Sapporo, Japan; Department of Breast Surgery, Aomori Prefectural Central Hospital, Aomori, Japan; Department of Breast Surgery, Hospital, Sapporo, Japan; Department of Breast and Endocrine Surgical Oncology, Graduate School of Medicine, Tohku University, Sendai, Japan; Department of Medical Oncology, Toranomon Hospital, Tokyo, Japan; Department of Breast Surgery, National Hospital Organization Shikoku Cancer Center, Matsuyama, Japan; Breast Surgical Oncology, Tokyo Medical University, Tokyo, Japan; Breast and Thyroid Surgery, Kawasaki Medical School Hospital, Kurashiki, Japan; Daiichi Sankyo Co., Ltd., Tokyo, Japan; Division Of Medical Oncology, National Cancer Centre Hospital East, Kashiwa, Japan; Department of Breast and Thyroid Surgery, Kawasaki Medical School Hospital, Kurashiki, Japan; Daiichi Sankyo Co., Ltd., Tokyo, Japan; Division Of Medical Oncology, National Cancer Centre Hospital East, Kashiwa, Japan; Department of Breast and Thyroid Surgery, Japan; Department of Breast School of Medical Oncology, National Cancer Centre Hospital East, Kashiwa, Japan; Department of Breast and Thyroid Surgery, Japan; Department of Breast Surgery, Division Of Medical Oncology, National Cancer Centre Hospital East, Kashiwa, Japan; Department of Breast

Background: The PRO-DUCE study (jRCTs031200387), a multicenter, randomized controlled study, evaluated the impact of ePRO plus body temperature (BT)/SpO₂ monitoring (ePROm) vs.usual care (UC) on the quality of life (QoL) for patients (pts) with HER2-positive metastatic breast cancer (MBC) treated with T-DXd. The primary results presented at ASCO 2024 showed that at week 24, ePROm demonstrated better results for global health status (GHS) vs. UC. Based on recent studies showing that symptom monitoring and alert notifications via ePROs could improve pt QoL and overall survival (OS), we consider the effects of long-term QoL scores and OS. Methods: The pts population was observed from March 1, 2021, to February 29, 2024 (data cutoff date: May 20, 2024). We randomized pts with HER2-positive MBC eligible for T-DXd to the ePROm or UC group. ePROm involved weekly reporting of symptoms based on PRO-CTCAE and daily monitoring of BT and SpO_2 reports via a smartphone at home. If any reported symptoms exceeded the predetermined thresholds, an email alert was sent to the medical staff: the ePRO data were then reviewed, and, if necessary, a phone consultation was provided. Endpoints in this updated analysis included QoL scores and cancer-related fatigue beyond week 24 using the EORTC QLQ-C30 (C30) and EORTC QLQ-FA12 (FA12), OS, and safety. Results: Between March 2021 and January 2023, 111 pts were enrolled (ePROm: 56; UC: 55). Throughout the observation period, 1045 alert notifications were generated, of which 279 were considered necessary to contact pts and 231 telephone counseling was conducted by healthcare providers (response rate: 82.8%). Throughout 48 weeks, the PRO-CTCAE response rate was > 89% in the ePROm group. The number of evaluable pts at 48 weeks was 37 in the ePROm and 41 in the UC group. At week 48, changes in GHS from baseline in the ePROm and UC groups were -3.7 ± 18.6 and -12.7±23.8, and those in FA12 total score were -4.9±14.3 and 8.1±16.4, respectively. The median OS was 24.5 months (95% CI: 21.8, not reached) in the ePROm group with a median follow-up duration of 18.3 months, whereas in the UC group, the median OS was not reached (95% CI: 20.7, not reached) with a median follow-up duration of 18.1 months [HR = 1.39; 95% CI: 0.75, 2.59]. The majority of any-grade treatment-emergent adverse event using CTCAE were reported in a higher proportion of pts in the ePROm group than in the UC group during the observation period. Interstitial lung disease incidence was similar in both groups (7.4% in ePROm group vs. 9.3% in UC group), with all cases being grade 1. Conclusions: Long-term findings from the PRO-DUCE study demonstrated that QoL observed at week 24 in the ePROm group was maintained over time. While there was no difference in OS, these findings might support the integration of ePROm in clinical practice to optimize QoL for pts receiving T-DXd. Clinical trial information: jRCTs031200387. Research Sponsor: Daiichi Sankyo.

Advancing equity and collaboration in a dedicated young onset cancer clinic: A prospective study.

Ilit Turgeman, Inna Tsvitman, Suha Egbaria, Dikla Lazarovich, Shir Daniel, Ofir Michaelis, Galit Tamir, Shahar Turgeman, Meirav Hermesh, Narmin Khouri, Tal Minkowich, Maria Kaminski, Michal Weizman, Michal Reinhorn, Michal Arbel, Gil Bar-Sela; Lin Medical Center, Haifa, Israel; Oncology, Emek Medical Center, Afula, Israel; Emek Medical Center, Afula, Israel; Medica Elisha Medical Center, Haifa, Israel; Psychology, Emek Medical Center, Afula, Israel; Occupational Therapy, Emek Medical Center, Afula, Israel; Physiotherapy, Emek Medical Center, Afula, Israel; Nutrition, Emek Medical Center, Afula, Israel; Haemek Medical Center, Afula, Israel; Oncology & Hematology Division, Afula, Israel

Background: Coordinated young onset cancer (YOC) clinics improve patient experience and access to supportive services. However, geographic and ethnic disparities hinder equitable representation and outcomes. This study describes the design and impact of a YOC clinic serving a socioeconomically diverse population. Methods: A YOC clinic was established at a peripheral cancer center for patients aged 18-49, staffed with an oncologist, nurse, and social worker. Tailored referrals were facilitated to designated psychosocial and integrative services. Monthly team meetings and biweekly patient support activities were implemented. Data on demographics, cancer characteristics, coping styles (BASIC-Ph model), anxiety and depression (HADS-A/D), referral patterns and satisfaction were prospectively collected and analyzed across ethnic and clinical subgroups. Results: From 6/2022 - 4/2023, 104 patients enrolled (mean age 38; 76% female; 62.4% Jewish, 34.7% Arab). Most were married (63.5%), had children (81.4%), unemployed (72.3%), with up to high school education (50.7%). Most (76%) were on active treatment and 38% had metastatic disease. Breast cancer was most common (46.2%), followed by gastrointestinal and thoracic malignancies. Family cancer history (61.5%) actionable somatic (25%) and germline (6.7%) alterations were noted. Referrals were most frequent for integrative medicine (50%), genetics (41.3%), psychology, occupational therapy, with adherence rates of 88%. Ethnic and cancer-type variations in referral patterns were observed, but high uptake was consistent. HADS-A correlated with lack of exercise and HADS-D with unemployment and non-metastatic disease (p < 0.05). Females tended more to beliefbased coping, males favored imagination, academics employed cognitive strategies, alcohol use to affect and cannabis to imagination (p < 0.05), while those with advanced cancer preferred physical coping (p = 0.82). HADS-A correlated with psychology referrals (M = 9.78 vs. 6.86, p =0.013), belief-based coping to spirituality, social coping to physiotherapy and nutrition (p < 0.013) 0.05). Social coping and sexuality services were less utilized in ethnic minorities and those on active treatment. Nearly all (94.2%) had no prior support group yet satisfaction was high (mean 5/5) with patients citing community, supportive services and side effect management as key benefits. Conclusions: A structured, multidisciplinary YOC clinic leverages existing services to enhance collaboration, equity, and access to tailored resources, meeting the unique needs of diverse young cancer patients. Beyond addressing disparities, this model fosters a sense of community among patients, promoting engagement with supportive services that may enhance treatment outcomes. Sharing this approach globally may inspire broader adoption of YOC clinics to benefit underserved populations and advance cancer care equity. Research Sponsor: None.

Automated conversational artificial intelligence (AI) for outpatient malignant bowel obstruction (MBO) symptom monitoring.

Ainhoa Madariaga, Isabel Tuñon, Sara Sánchez-Castro, Marta Ruiz, Ainhoa Herrero, Carla María Nuñez, María Maiz, Reyes Oliver, Begoña Azcoitia, Rodrigo Sanchez-Bayona, Cristina González Deza, Luis Manso, María Dolores Pérez, Pablo Tolosa Ortega, Manuel Alva Bianchi, Laura Lema, Eva Maria Ciruelos, Santiago Ponce Aix, Luis G. Paz-Ares, Andrea Modrego; Hospital Universitario 12 de Octubre, Madrid, Spain; 12 de Octubre University Hospital, Madrid, Spain; Hospital 12 de Octubre, Madrid, Spain; Oncology Department, Hospital Universitario 12 de Octubre, Madrid, Spain; Hospital Universitario 12 de Octubre and Oncosur Foundation, Madrid, Spain; Hospital Universitario 12 De Octubre, Madrid, Spain

Background: MBO is a severe complication of advanced cancer. A Canadian ambulatory MBO program with nurse-led proactive call management demonstrated reduced hospitalization rates and improved survival. To overcome resource limitations, a smartphone app was developed, achieving 65% adherence. Building on this foundation, automated phone calls offer a promising approach to enhance adherence and improve symptom monitoring. Methods: We conducted a prospective pilot study at a tertiary Spanish hospital to remotely monitor MBO signs and symptoms using a conversational AI-based platform (Lola-Tucuvi). Patients (pts) with cancer with an active MBO or at risk of developing it (per PMMBO criteria) were enrolled. Automated, interactive phone calls were performed by the platform (Lola) weekly or biweekly. Lola performed structured MBO symptom assessments utilizing advanced natural language processing and AI algorithms, to analyze responses in real time. Alerts were generated for moderate or severe symptoms, which were flagged on a dashboard. Nurses contacted pts based on alerts. The primary objective was feasibility measured by adherence (% of answered calls), with a hypothesized adherence of \geq 65% considered optimal. **Results:** From January 2024 to January 2025, 54 pts were enrolled, with 25 still active at the time of analysis. Median age was 60 years (range 29-86), and 96% of pts are female. Type of tumors included gynecologic (87%) and gastrointestinal (13%). All pts were on systemic therapy: chemotherapy (50%), immunotherapy (24%), ADC (15%), targeted (11%). Median prior lines of therapy were 2 (1-6), and 41% (22/54) of pts had an active MBO prior to enrollment. Lola performed 716 phone calls and 645 were answered, with an adherence of 90%. This resulted in an estimated 183.2 hours of nursing call time saved. Median time on the program was 117 days (7-356), and pts received a median of 14 calls. Of answered calls, the 36% (234/645) generated alerts, with 44% classified as severe. Most frequent severe and moderate alerts were constipation and abdominal pain, respectively. Nurses acted on 73% (171/234) of the alerts, providing interventions such as dietary modifications, medication adjustments, clinical or emergency assessments. During follow-up in the program 31.5% (17/54) of pts had \geq 1 active MBO and 18.5% (10/54) required admissions for MBO. Feedback was received from 26 pts, indicating a high satisfaction (4.6/5), and 96% would recommend the use of Lola. Conclusions: This conversational AI platform demonstrated excellent feasibility with 90% adherence, higher than prior app-based solutions. It effectively monitored MBO symptoms, enabling timely clinical interventions and enhancing patient engagement. These results highlight the potential of AI-driven remote monitoring system to improve outcomes in cancer care. Further validation through randomized studies is warranted. Research Sponsor: Spanish Society of Medical Oncology (SEOM).

Oncologists' perspectives on challenges using chemotherapy, immune checkpoint inhibitors, and targeted kinase inhibitors for metastatic cancer.

Christine M. Veenstra, Nathaniel R. Wilson, Paul Abrahamse, Allison W. Kurian, Sarah T. Hawley, Ann S. Hamilton, Kevin C. Ward, Steven J. Katz; University of Michigan, Ann Arbor, MI; Division of Hematology and Oncology, University of Michigan Ann Arbor, Ann Arbor, MI; Stanford University School of Medicine, Department of Medicine, Stanford, CA; Michigan Medicine, Ann Arbor, MI; University of Southern California, Los Angeles, CA; Emory University, Rollins School of Public Health, Atlanta, GA; University of Michigan Medical School, Ann Arbor, MI

Background: Compared to cytotoxic chemotherapies, the standard of care for metastatic cancers for decades, use of immune checkpoint inhibitors (ICI) and targeted kinase inhibitors (TKI) has rapidly expanded with evolving indications for patients with advanced disease. We evaluated oncologists' report of challenges to using each type of therapy and associations between challenges and oncology practice resources. Methods: From 2023-24 we surveyed 824 medical oncologists, identified using SEER registry data, in Georgia and Los Angeles. We asked oncologists about challenges to using chemotherapy, ICIs and TKIs for the treatment of metastatic cancer. We also asked about resources available at their practice, including administrative and clinical support staff, financial counselors, dedicated pharmacists, social workers, genetic counselors, and interpreters. We generated descriptive statistics of challenges and assessed bivariate associations between challenges and practice resources. Results: We present results for a preliminary sample (N = 370). The Table shows the proportion of oncologists who endorsed each challenge. Compared to cytotoxic chemotherapy, oncologists were more likely to endorse moderate to big challenges using ICIs and TKIs related to insurance approval/prior authorization, co-pay assistance and out-of-pocket costs, as well as keeping up with clinical guidelines and familiarity with dosing and side effects; symptom management was more likely to be a moderate to big problem for chemotherapy and TKIs than for ICIs (all p < 0.01). Challenges with insurance approval/prior authorization, co-pay assistance, and out-of-pocket costs were associated with the availability of administrative and clinical support staff, dedicated pharmacists, and social workers (all p < 0.05). Challenges with symptom management were associated with the availability of clinical support staff and dedicated pharmacists (all p < 0.05). Conclusions: Oncologists endorsed more challenges using ICIs and TKIs compared to cytotoxic chemotherapy in the treatment of metastatic cancer. TKIs were associated with the most challenges, including problems keeping up with clinical guidelines and familiarity with dosing and side effects for nearly 20% of respondents. It is reassuring that many practice resources exist to help address these challenges. Oncologists may benefit from more educational resources—particularly related to TKIs—in their practices. Research Sponsor: National Cancer Institute; CA251464.

Oncologist-reported challenges.						
	% reporting moderate to big challenge					
	Cytotoxic chemotherapy	ICI	ткі	Р		
Obtaining insurance approval/prior authorization	13	26	35	<0.01		
Obtaining co-pay assistance for patients	19	27	43	< 0.01		
Out-of-pocket costs to patients	25	42	66	< 0.01		
Symptom management	50	17	43	<0.01		
Keeping up with clinical guidelines	7	14	19	< 0.01		
Familiarity with dosing and side effects	6	7	17	<0.01		

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Improving access to cancer screening through national telehealth-based lung and colorectal cancer screening programs.

Deanna Brockman, Cynthia Neben, Deanna Erwin, Keegan Duchicela, Jennifer Fung, William L. Dahut, Rebecca A. Miksad; Color Health, Burlingame, CA; American Cancer Society, Bethesda, MD

Background: Access to routine cancer screening remains a significant barrier to early detection, especially among historically underserved populations. However, little is known about how virtual care can improve access to cancer services. Color and the American Cancer Society (ACS) collaborated to develop two community-based, telemedicine programs for national colorectal and lung cancer screening. Here we evaluate the impact of these programs in expanding access. Methods: The Colorectal Cancer (CRC) Screening Program (launched in June 2025) provides athome fecal immunochemical tests (FIT) to eligible individuals aged 45-75 years. Kits are distributed through federally qualified health centers and other community locations. The Lung Cancer Screening Program (launched in November 2023) offers eligible individuals access to scheduling support for low-dose screening CTs based on ACS guidelines. Both programs leverage a virtual-first approach: patients provide health history information for a cancer risk assessment through an online platform where they can also access educational resources and schedule appointments with physicians to discuss cancer risk (note: screening eligibility is determined based on self-report). Care advocates provide personalized support, including step-by-step guidance on completing tests, navigating screening guidelines, and coordinating follow-up care. Results: Across both cancer screening programs (n = 548), participants were predominantly female (CRC: 62.0%; lung: 62.9%) and had similar average ages (CRC: 50.3 years, range 18-90; lung: 53.9 years, range 18-81). In the CRC screening program, 397 participants picked up or requested kits, with the highest demand in California (10.1%), Texas (9.1%), and Florida (7.1%). In total, 126 participants were eligible and activated a kit; participant ineligibility was largely due to already being up-to-date with screening (29.1%) or age (28.5%). Of the 94 completed tests, 4 (4.3%) were abnormal results. In the lung cancer screening program, 71 participants (47%) across 28 states met ACS eligibility criteria; the remaining participants were ineligible due to age (21.1%), less than 20-pack year smoking history (25.4%), no smoking history (25.4%), or a combination of age and smoking history (28.2%). A total of 17 participants (23.9%) subsequently completed a lung CT. Average time to appointment was 29 days (range 9-93), and all appointments were located within 11 miles of the participant's preferred location. Clinically significant findings included Lung-RADS 3 or 4 nodules (29.4%, n = 5) and other incidental findings requiring follow-up care. **Conclusions:** These results illustrate how targeted, community-based approaches can bridge critical gaps in cancer screening by simplifying logistics, reducing costs, and providing tailored support through virtual and community-based solutions. Research Sponsor: None.

Current treatment patterns for early breast cancer among healthcare professionals and concordance with expert recommendations: Analysis of an online interactive decision support tool.

Timothy Quill, Kristen M. Rosenthal, Megan Cartwright; Clinical Care Options, Reston, VA; Clinical Care Options, LLC, Reston, VA

Background: The treatment paradigm for HER2-negative early breast cancer (EBC) now includes pembrolizumab and targeted therapies such as olaparib, abemaciclib, and most recently, ribociclib in the adjuvant setting for eligible patients. Here, we assess current intended treatment patterns among healthcare professionals (HCPs) for EBC and compare them with those of experts using an online Interactive Decision Support Tool (IDST). Methods: We developed an online IDST in July 2024 with input from 5 breast cancer experts providing therapy recommendations for 12 unique patient case scenarios based on presentation characteristics including disease subtype, disease burden, treatment history, BRCA mutation status, and risk of recurrence. HCPs entered specific patient characteristics to define a case along with their intended management for that case. The IDST then showed each expert's recommendation for that case scenario and asked the HCPs if the recommendations affected their intended approach. Here, we report a comparison of the expert recommendations and HCPselected therapy for different EBC case scenarios. Results: Between August 2024 and January 2025, 140 HCPs entered 182 cases. Among the 138 HCPs who indicated their treatment plan, plans were concordant with experts for 59% of the cases. Of note, the 5 experts showed complete concordance in their treatment recommendations for all 12 unique case scenarios. Concordance with the experts was higher among HCP treatment plans for cases of hormone receptor-positive (HR+)/HER2-negative (HER2-) cases compared with triple-negative cases (65% vs 49%). High concordance was seen for HR+/HER2- cases receiving adjuvant AI with BRCA WT and high risk of recurrence per the monarchE trial criteria (86%; n = 37) with lower concordance for this setting without a high risk of recurrence (65%, n = 26) with HCPs often choosing endocrine therapy plus a CDK4/6 inhibitor. In the setting of TNBC, HCPs entered cases predominantly related to adjuvant therapy after neoadjuvant chemotherapy plus pembrolizumab (n = 44). Among cases without a pathologic CR in this setting (n = 29), concordance was 50% with or 54% without a pathologic germline BRCA variant, respectively. Among TNBC cases with a pathologic CR in this setting (n = 15), concordance was 40% with overtreatment by HCPs evident in 33% of cases. HCPs indicated that expert recommendations changed their intended treatment in 28 of 84 (33%) cases and confirmed their choice in 45 of 84 cases (53%). Conclusions: These data suggest ongoing challenges with incorporating pembrolizumab and the newest targeted therapies into adjuvant treatment plans for high-risk EBC, particularly TNBC. Continued education and development of resources for HCPs, including online IDSTs, may be increasingly important as the treatment of high-risk EBC continues to evolve. Research Sponsor: None.

LBA1551

Cancer Care Beyond Walls (CCBW): A randomized pragmatic trial of home-based versus in-clinic cancer therapy administration.

Roxana Stefania Dronca, Jeremy Clifton Jones, Hemant S. Murthy, Pooja Prem Advani, Ricardo Daniel Parrondo, Sikander Ailawadhi, Gina L. Mazza, Sunnie Confiado, Amber Baskin, Grzegorz S. Nowakowski, Tufia C. Haddad, Winston Tan, Adam McLain Kase, Cheryl Willman; Mayo Clinic, Rochester, MN; Mayo Clinic Florida, Jacksonville, FL; Division of Hematology/Oncology, Mayo Clinic, Jacksonville, FL; Mayo Clinic, Jacksonville, FL; Mayo Clinic Comprehensive Cancer Center, Rochester, MN

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, 2025, issue of the *Journal of Clinical Oncology*.

Evaluation of longitudinal image-derived AI prognostication as a predictor of overall survival (OS) in a phase 3 advanced non-small cell lung cancer (aNSCLC) trial.

Javier Montalt-Tordera, Omar Farooq Khan, John Riskas, Shahid Abbas Haider, Vignesh Sivan, Oleksandra Samorodova, Thomas Jay Hennessy, Sadegh Mohammadi, Emmanuelle DiTomaso, Topia Banerji, Felix Baldauf-Lenschen, Charles Glaus; Bayer, Sant Joan Despi, Spain; Breast Cancer Canada; POET Oncology, Cumming School of Medicine, University of Calgary, Calgary, AB, Canada; Altis Labs, Toronto, ON, Canada; Bayer, Leverkusen, Germany; Bayer Pharmaceuticals US, Cambridge, MA; Bayer, Whippany, NJ; Bayer, Cambridge, MA

Background: Confidently anticipating an overall survival (OS) benefit in cancer care and therapeutic research is a defining challenge. AI tools may offer longitudinal measurements that predict OS differences objectively from existing data. Longitudinal imaging-based prognostication (IPRO- Δ), a fully automated deep learning system, was independently trained on real-world imaging data to predict survival from pairs of longitudinal computed tomography (CT) scans. Methods: We retrospectively assessed and compared how IPRO- Δ and percent change in RECIST sum of longest diameters (Δ SLD) predicted OS from 165 pairs of baseline and week 13 CT scans acquired in NExUS (NCT00449033), a phase 3 randomized controlled trial evaluating chemotherapy in combination with either sorafenib or placebo for first-line treatment of subjects with aNSCLC. The two study arms did not show a difference in OS and were combined for this analysis. To examine the association of IPRO- Δ and Δ SLD with OS, we measured the concordance index (c-index) and the standardized hazard ratios (HRs, change in risk for a one-standard-deviation increase in the marker). We also report median OS (mOS) for patients with partial response (PR, n = 60), stable disease (SD, n = 83) and progressive disease (PD, n = 22) at week 13, as defined by RECIST 1.1 guidelines (zero patients had a complete response). To explore the stratification potential of IPRO- Δ , we also define equivalent strata by ordering patients by their IPRO- Δ score and maintaining the same proportions (e.g., the top 60 patients by IPRO- Δ would be IPRO-PR, while the bottom 22 patients would be IPRO-PD), and report the mOS for these strata. Results: For the combined trial arms, median OS was 10.9 months (95% CI: 8.6 - 13.6), 108 (65.4%) were male, and 145 (87.9%) were diagnosed as stage IV. Table 1 reports the c-index, HR and stratified mOS values for both survival markers. **Conclusions:** At week 13 in NExUS, IPRO- Δ predicted OS differences significantly better than Δ SLD. Future work will explore how IPRO- Δ could serve as the basis for a surrogate endpoint in aNSCLC trials. Research Sponsor: None.

Summary of association of IPRO- Δ and Δ SLD with OS.					
	IPRO-∆ @ Week 13 (95% CI)	ΔSLD @ Week 13 (95% Cl)	<i>p</i> -value		
C-Index HR (1SD) OS (months, PR / SD / PD or IPBO equivalent)	0.654 (0.604 - 0.713) 1.72 (1.38 - 2.15) 16.5 / 10.9 / 5.7	0.543 (0.495 - 0.599) 1.14 (0.94 - 1.38) 12.5 / 12.3 / 4.6	<0.01 <0.01 -		

Real-world side effects of targeted therapies: High-throughput association studies leveraging the CancerLing Discovery lung cancer database.

Joseph Vento, Lisa Bastarache, Qingxia M. Chen, Travis Osterman; Department of Internal Medicine, Division of Hematology and Oncology, UT Southwestern, Dallas, TX; Vanderbilt University Medical Center, Nashville, TN

Background: Targeted therapies have unique side effect profiles distinct from other cancer drugs. Challenges of collecting generalizable toxicity data on these medications include the self-reporting infrastructure of existing post-market surveillance databases, as well as the infrequent use of many of these drugs by single cancer centers. The CancerLinQ Discovery (CLQD) database synthesizes deidentified electronic health record (EHR) data from millions of U.S. cancer patients. Diagnosis codes in this database can be used to study treatment side effects. Methods: We developed high-precision phenotyping algorithms to identify non-small cell lung cancer (NSCLC) patients receiving targeted therapies in the CLQD database. We then performed phenome-wide association studies (PheWAS) comparing new diagnosis codes in patients receiving each targeted therapy to new codes in patients receiving chemotherapy or immunotherapy. Codes with significant associations were compared to toxicity data reported in clinical trials and the FDA Adverse Event Reporting System (FAERS) database. Results: We identified 5,278 NSCLC patients who received targeted therapies with the latest CLQD data pull in 2022. For each of the 18 targeted therapies with five or more patients in the database, descriptive statistics and two PheWAS analyses are reported: one for diagnosis codes relative to chemotherapy, and one relative to immunotherapy. These analyses identified significant associations corresponding to known toxicity profiles as well as potentially underreported side effects. Conclusions: This high-throughput framework augments the characterization of side effect profiles for existing targeted therapies and can proactively monitor for toxicity signals as novel therapies and treatment indications emerge. The importance of collecting realworld data across institutions is highlighted in the ability to find clinically relevant associations even in targeted therapies directed against rare mutations. Research Sponsor: National Library of Medicine.

PheWAS analysis sample for side effects of osimertinib and capmatinib.						
Drug	Control	Side Effect Code	p-value	OR		
Osimertinib	10	Abnormal EKG	3.68E-14*	2.91		
		Dermatitis	1.91E-09*	1.98		
		Disorders of muscle	8.18E-06*	2.13		
		Other CNS disorders	2.41E-05*	2.17		
		Thrombosis	2.90E-05*	1.49		
	Chemo	Dermatitis	1.42E-62*	7.90		
		Skin symptoms	5.00E-45*	3.70		
		Abnormal EKG	3.95E-33*	4.93		
		Other musculoskeletal symptoms	5.61E-27*	6.14		
		Joint pains	1.09E-22*	2.43		
Capmatinib	10	Edema	2.34E-08*	4.19		
-		Other soft tissue disorders	9.93E-05*	3.81		
		Hypocalcemia	1.06E-02	3.82		
		Pleural effusion	1.96E-02	2.22		
		Abnormal LFT results	4.97E-02	3.24		
	Chemo	Edema	2.05E-14*	7.03		
		Other soft tissue disorders	1.75E-11*	10.10		
		Respiratory failure	4.20E-08*	7.12		
		Abnormal LFT results	3.12E-04*	8.70		
		Stroke	1.48E-03	6.68		

IO-immunotherapy, OR- odds ratio.

*Statistically significant after Bonferroni correction.

Transforming oncology clinical trial matching through multi-agent AI and an oncology-specific knowledge graph: A prospective evaluation in 3,800 patients.

Arturo Loaiza-Bonilla, Selin Kurnaz, Ertugrul Tuysuz, Oz Huner, Dersu Giritlioglu, Juan Pablo Noel Meza; St. Luke's University Health Network, Easton, PA; Massive Bio, New York, NY; Massive Bio Inc., New York, NY

Background: Clinical trial enrollment in oncology is often hampered by the manual, timeintensive process of matching patients to trials with highly specific eligibility criteria. Advances in artificial intelligence (AI)—particularly multi-agent large language models (LLMs) and oncology-specific knowledge networks-hold promise for streamlining this workflow and minimizing human labor. This abstract presents a prospective evaluation of an AI platform that automates medical data extraction, leverages an oncology-specific knowledge graph, and provides real-time trial recommendations, demonstrating a significant reduction in staff effort while maintaining high clinical accuracy. Methods: Multi-Agent AI & Oncology Knowledge Graph 1. OncoAgents: Specialized LLMs (data extraction, eligibility, trial matching), collaborating to outperform generic or zero-shot AI. 2. OncoGraph: Domain-specific knowledge graph uniting patient data, molecular profiles, and clinical guidelines for context-aware matching. 3. OncoRecommend: Real-time engine processing new data, trials, and guidelines, delivering rapid, relevant suggestions. 4. OncoSet: Expert-curated dataset (>2,000 patient records, 14,000+ trials, 50+ tumor subtypes) ensuring robust AI performance. Prospective Analysis (Jan-Dec 2024): Cohort: 3,804 patients (ECOG 0-2) with metastatic/progressing malignancies seeking trial options. Data Extraction: 157,367 pages (~86.5M tokens) processed for tumor type, stage, treatment lines, and biomarkers. Trial Matching: Automated application of inclusion/ exclusion criteria; oncologists validated AI-generated matches. Efficiency: Manual matching for large cohorts can require thousands of hours; this AI approach condensed it to ~1 hour of expert review. Results: 1. Screening & Identification: 3,804 patients screened; 23,912 trials identified; 17,912 confirmed after expert review. 2. Time-to-Recommendation: Under one week from screening to final recommendations via real-time AI prioritization. 3. Performance Metrics: Sensitivity (Recall): 0.8375, Specificity: 0.8359, Precision: 0.8121, F1 Score: 0.8246. Demonstrates advantages over zero-shot or frontier GPT-based models. 4. GPT Comparison: Extraction Accuracy: 80.29% vs up to 63.15% (GPT-40); Trial Matching Accuracy: 82.06% vs 47.00% (GPT-40). Conclusions: This multi-agent AI platform, underpinned by an oncologyspecific knowledge graph, significantly boosts efficiency and accuracy in oncological trial matching. By cutting manual workloads from thousands of hours to near-automated speeds, recommendations allow for just-in-time, decentralized and patient-centric trial activation. Ongoing enhancements—such as deeper biomarker integration, expanded knowledge graph coverage, and seamless EHR interoperability - promise further gains in personalized oncology care. Research Sponsor: None.

Breath-based VOC analysis leveraging canine olfaction for multi-cancer detection: Insights from a 1000-sample study.

Akash Kulgod, Sanjeev Kulgod, B.R. Patil, K. Shashidhar, Itamar Bitan, Minal Dakhave; Dognosis, Inc., Bangalore, India; RadOn Cancer Centre, Hubballi, India; Karnataka Cancer Therapy and Research Institute (KCTRI), Karnataka, India; Karnataka Institute of Medical Sciences, Hubballi, Karnataka, India; Dognosis, Bangalore, India

Background: Volatile organic compound (VOC) analysis is a validated approach for identifying disease-specific metabolic alterations through exhaled breath. The non-invasive and low-cost nature of breath sample collection makes it particularly suitable for large-scale cancer screening in resource-limited settings, such as those commonly found in the Global South. Canine olfaction has been demonstrated in prior controlled studies to detect VOCs with high accuracy across a range of pathologies, including malignancies. This study evaluates the performance of trained biomedical detection dogs in identifying multiple cancer types using VOC analysis and examines the integration of neurobehavioral data to support real-world diagnostic applications. Methods: A retrospective case-control study was conducted involving 1000 participants across three clinical sites in Hubli, India. Exhaled breath samples (n = 105 cancer-positive, n =895 healthy controls) were collected using standardized protocols designed to maintain VOC integrity. Trained biomedical detection dogs analyzed these samples, with their behavioral responses recorded via motion sensors, video data, and electroencephalography (EEG) systems. A consensus-based decision framework was implemented to account for variability among individual dogs. Preliminary machine learning models were trained using the recorded neurobehavioral data to evaluate their potential for augmenting detection accuracy; however, these models remain in the validation phase. Results: The detection system demonstrated a sensitivity of 96% and a specificity of 100% across multiple cancer types in the test set, including oral, breast, esophageal, and cervical cancers. Sensitivity for early-stage cancers was 85%. The consensus-based approach among dogs enhanced reliability and minimized individual variability. Preliminary analysis of neurobehavioral data indicates potential for machine learning applications to refine diagnostic interpretation. **Conclusions:** Breath-based VOC analysis combined with canine olfaction demonstrates high accuracy in multi-cancer detection, including early-stage cancers. Its suitability for non-invasive and low-cost implementation, particularly in resource-constrained settings like the Global South, highlights its potential for addressing disparities in cancer screening access. Future research will focus on validating machine learning models and comparing the system's performance with existing diagnostic standards to further support global scalability and clinical adoption. Research Sponsor: None.

PRESCIENTai, an AI-based digital histopathological image signature for risk of late distant recurrence and extended endocrine therapy (EET) benefit in hormone receptor-positive breast cancer.

Eleftherios P. Mamounas, Ming Chen, Tanner Freeman, Nicolas Stransky, Md Ashequr Rahman, Mark Robert Miglarese, Hanna Bandos, Yating Cheng, Tommy Boucher, Mukund Varma, Jennifer Ribeiro, Stewart J. Anderson, Casey L Bales, Matthew James Oberley, Charles E. Geyer Jr., Priya Rastogi, David Spetzler, George W. Sledge Jr., Norman Wolmark; NSABP and AdventHealth Cancer Institute, Orlando, FL; Caris Life Sciences, Irving, TX; NSABP Foundation, Inc.; University of Pittsburg School of Medicine, Pittsburgh, PA; Caris Life Sciences, Phoenix, AZ; NRG Oncology Statistical and Data Management Center; University of Pittsburgh, PA; NSABP Foundation, Inc.; NRG Oncology SDMC; Department of Biostatistics and Health Data Science, University of Pittsburgh, PA; NSABP Foundation, Inc.; UPMC Hillman Cancer Center; and University of Pittsburgh School of Medicine, Pittsburgh, PA; NSABP Foundation, Inc.; UPMC Hillman Cancer Center; University of Pittsburgh School of Medicine, Pittsburgh, PA; NSABP Foundation, Inc.; UPMC Hillman Cancer Center; University of Pittsburgh School of Medicine, Pittsburgh, PA; NSABP Foundation, Inc.; UPMC Hillman Cancer Center; University of Pittsburgh School of Medicine, Pittsburgh, PA; NSABP Foundation, Inc.; UPMC Hillman Cancer Center; University of Pittsburgh School of Medicine, Pittsburgh, PA; NSABP Foundation, Inc.; UPMC Hillman Cancer Center; University of Pittsburgh School of Medicine, Pittsburgh, PA; NSABP Foundation, Inc.; UPMC Hillman Cancer Center; University of Pittsburgh School of Medicine, Pittsburgh, PA

Background: A subset of patients (pts) with hormone receptor-positive (HR+) breast cancer (BC) experiences late distant recurrence (DR) and is more likely to benefit from EET. Clinical practice guidelines recommend use of genomic assays such as Breast Cancer Index (BCI) to identify these pts. We developed an updated AI-based digital histopathological risk score model to predict risk of late DR and extended letrozole therapy (ELT) benefit in this population. **Methods:** The AI model, PRESCIENTai, was trained on eligible samples (N = 2,271) from the National Surgical Adjuvant Breast and Bowel Project (NSABP) B-42 cohort, which randomized postmenopausal women with HR+ BC who were disease-free after 5 yrs of endocrine therapy (aromatase inhibitor (AI) or tamoxifen followed by AI) to either 5 yrs of letrozole or placebo. A transformer-based end-to-end deep learning model predicted risk score from H&E wholeslide images (WSI) in conjunction with clinical information (age at randomization, surgery type, node status, prior use of tamoxifen, race, lowest bone mineral density T-score, HER2 status). CTransPath was used for feature extraction from WSI tiles. 5-fold cross validation was performed with data split into training, validation, and test sets (60:20:20). The risk score threshold was defined by the 50% quantile of the training set for each fold. Cox regression and Kaplan-Meier analysis evaluated late DR and ELT benefit in high- and low-risk pts. Results: Hazard ratio (HR) was computed for DR in low- vs. high-risk pts [HR = 0.198 (95% CI: 0.124, 0.317); *p* < 0.001], with absolute difference of 7.61% in 10-yr DR (1.84% vs. 9.46%). High-risk pts experienced greater ELT benefit over placebo (HR = 0.622; 95% CI: 0.416-0.929; p = 0.02) than low-risk pts (HR = 0.727; 95% CI: 0.305–1.733; p = 0.471), with 10-yr absolute benefit of 3.74% vs. 0.66%. Even among node(+) pts, PRESCIENTai identified greater ELT benefit for high-risk pts (HR = 0.521; 95% CI: 0.329-0.827; p = 0.006) than low-risk pts (HR = 0.53; 95% CI: 0.048-5.905, p = 0.606), with 10-yr absolute benefit of 6.66% vs. 1.89%. ELT benefit was also observed for high-risk pts in other clinical subgroups such as age ≤ 60 years and prior tamoxifen. However, p-interaction for ELT benefit in high- vs. low-risk groups was not significant for all pts (p = 0.791) or node(+) pts (p = 0.889). Conclusions: This novel digital signature predicts risk of late DR in pts with HR+ BC. Although absolute ELT benefit was greater in high- vs. low-risk pts, the treatment by risk score interaction was not statistically significant. This is, to our knowledge, the first AI model to predict long-term outcomes in pts with HR+, early BC using a single slide image and clinical information. Successful validation in additional pt cohorts will confirm the clinical utility of PRESCIENTai for prediction of late DR risk and EET benefit. Research Sponsor: U.S. National Institutes of Health; U10CA180868; U.S. National Institutes of Health; UG1CA189867; U.S. National Institutes of Health; U24CA196067; U.S. National Institutes of Health; U10CA180822.

Computational pathology to predict docetaxel benefit for high-risk localized prostate cancer in NRG/RTOG 0521 (NCT00288080).

Sebastian R. Medina, Naoto Tokuyama, Kamal Hammouda, Tilak Pathak, Tuomas Mirtti, Pingfu Fu, Shilpa Gupta, Priti Lal, Howard M. Sandler,

Rohann Jonathan Mark Correa, Susan Chafe, Amit I. Shah, Jason A. Efstathiou, Karen E. Hoffman, Michael Wayne Straza, Mark A. Hallman, Richard C. Jordan, Stephanie L. Pugh, Felix Y. Feng, Anant Madabhushi; Wallace H. Coulter Department of Biomedical Engineering at Georgia Tech and Emory University, Atlanta, GA; Emory University, Atlanta, GA; Helsinki University Hospital, Helsinki, Finland; Department of Population and Quantitative Health Sciences, Case Western Reserve University, Cleveland, OH; Cleveland Clinic Taussig Cancer Institute, Cleveland, OH; University of Pennsylvania, Philadelphia, PA; Cedars-Sinai Medical Center, Los Angeles, CA; London Health Sciences Centre, London, ON, Canada; Cross Cancer Institute, Edmonton, AB, Canada; WellSpan Health, York, PA; Massachusetts General Hospital, Boston, MA; Department of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX; Medical College of Wisconsin, Milwaukee, WI; Fox Chase Cancer Center, Philadelphia, PA; NRG Oncology Biospecimen Bank, San Francisco, CA; NRG Oncology Statistics and Data Management Center, Philadelphia, PA; University of California, San Francisco, San Francisco, CA; Wallace H. Coulter Department of Biomedical Engineering at Georgia Tech and Emory University, Atlanta Veterans Administration Medical Center, Atlanta, GA

Background: The benefit of adding docetaxel (DTX) to standard of care (SOC) for high-risk localized prostate cancer remains debated. The NRG/RTOG 0521 randomized phase III trial demonstrated that docetaxel, when added to SOC-comprising radiotherapy (RT) and longterm androgen deprivation therapy (ADT)—improved overall survival (OS). However, while RTOG 0521 demonstrated improved OS with DTX, the observed improvement did not meet the predetermined threshold for clinical significance, leaving the role of DTX intensification uncertain. Enhanced stratification methods are needed to identify aggressive disease phenotypes and guide patient selection for adjuvant chemotherapy. This study aims to develop and validate a computational AI derived pathology image classifier (APIC) to quantify the tumor-immune microenvironment from diagnostic biopsy specimens and predict DTX benefit in patients from the NRG/RTOG 0521 trial. Methods: The study included patients with available high-quality biopsy images from the NRG/RTOG 0521 trial. Primary outcome was OS, median follow-up was 5.7 years. After segmenting nuclei and identifying lymphocytes, we derived features that captured immune-tumor spatial patterns and nuclear diversity in the tumor microenvironment to construct APIC. DTX benefit was evaluated using Cox proportional hazards models with interaction terms, log-rank tests and Kaplan-Meier analyses by comparing OS between treatment arms within APIC-stratified groups. Results: Among NRG/RTOG 0521 trial participants, 350 patients had evaluable quality biopsy slide images. Half of the SOC (RT+ADT) arm was used for training (84 patients), and 266 patients were used for validation (SOC: 85 patients, and SOC+DTX arm: 181 patients). DTX significantly improved OS in APICpositive (n = 119, 45%) patients (HR = 0.49, 95% CI: 0.26-0.92, p = 0.023) but not in APICnegative (n = 147, 55%) patients (HR = 1.17, 95% CI: 0.59-2.3, p = 0.66). APIC-positive patients derived 22% 10-year OS benefit (95% CI: 1.7%-41.6%) from DTX. The 10-year OS was 74% in the DTX arm compared to 52% with RT and ADT alone in the APIC-positive group. A significant interaction (p = 0.024) was observed between APIC status and treatment. Conclusions: We validated APIC as a predictive biomarker for DTX benefit in high-risk localized prostate cancer patients from NRG/RTOG 0521, identifying a subset who achieved significant survival improvement from treatment intensification - a benefit not reached in the unselected trial population. Further investigation is warranted to evaluate APIC's predictive potential of DTX intensification in metastatic disease settings. Research Sponsor: NCORP; UG1CA189867; NCI/NIH; R01CA202752-01A1; NCI/NIH; R01CA208236-01A1; NCI/NIH; R01CA216579-01A1; NCI/NIH; R01CA220581-01A1; NCI/NIH; R01CA257612-01A1; NCI/NIH; 1U01CA239055-01; NCI/NIH; 1U01CA248226-01; NCI/NIH; 1U54CA254566-01; National Heart, Lung and Blood Institute; 1R01HL15127701A1; National Heart, Lung and Blood Institute; R01HL15807101A1; NRG Oncology Operations; U10CA180868; National Institute of Biomedical Imaging and Bioengineering; 1R43EB028736-01; VA Merit Review Award; IBX004121A; Breast Cancer Research Program; W81XWH-19-1-0668; Prostate Cancer Research Program; W81XWH-20-1-0851; Lung Cancer Research Program; W81XWH-18-1-0440; Peer Reviewed Cancer Research Program; W81XWH-20-1-0595; Peer Reviewed Cancer Research Program; W81XWH-18-1-0404; Peer Reviewed Cancer Research Program; W81XWH-21-1-0345; Peer Reviewed Cancer Research Program; W81XWH-21-1-0160; NRG Oncology SDMC; U10CA180822; NRG Specimen Bank; U24CA196067; National Cancer Institute (NCI) and Sanofi; NCI/NIH; R01CA268287A1; NCI/NIH; U01CA269181; NCI/NIH; R01CA26820701A1; NCI/NIH; R01CA249992-01A1.

Use of a large language model (LLM) for pan-cancer automated detection of anticancer therapy toxicities and translational toxicity research.

Ziad Bakouny, Nishat Ahmed, Christopher Fong, Afsana Rahman, Tomin Perea-Chamblee, Karl Pichotta, Michele Waters, Chenlian Fu, Mark Yungjie Jeng, Mindy Lee, Chris Marotta, Neil J. Shah, Nikolaus Schultz, Adam Jacob Schoenfeld, Robert J. Motzer, Justin Jee, Craig B. Thompson, Jian Carrot-Zhang, Eduard Reznik, MSK Cancer Data Science Initiative (CDSI); Memorial Sloan Kettering Cancer Center, New York, NY; Thoracic Oncology Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY

Background: Understanding why patients develop adverse events to anti-cancer therapies and predicting the occurrence of these toxicities has lagged behind tumor response biomarker development. This critical gap is primarily due to limited availability of large-scale curated toxicity data. Here, we leverage advances in natural language processing (Jee J et al., Nature, 2024), pooled clinical trial data, and associated germline sequencing to detect adverse event data and determine clinical and genomic correlates. Methods: We utilized the Llama 3.1 LLM to automatically annotate patient adverse event data for 5 of the most common anti-cancer therapy related adverse events (adrenal insufficiency, hyperthyroidism, hypothyroidism, colitis, and pneumonitis). To validate LLM predictions at the patient-level, we used a pooled institutional dataset with gold standard prospectively collected adverse event data from 1,754 patients with solid tumors across 675 individual clinical trials. We further validated the LLM predictions at the clinical note-level using a subset of 100 manually curated notes. We evaluated note-level and patient-level predictions using sensitivity and specificity. Patient-level timeto-adverse event development predictions were evaluated using Pearson R² coefficients. Common Terminology Criteria for Adverse Events v 5.0 was used for toxicity definitions. Results: The patients' average age (standard deviation) was 61.6 (14.5) years and 836 (47.7%) were female. The most common cancers were non-small cell lung cancer (N= 194, 11.1%), soft tissue sarcoma (N=171, 9.7%), breast cancer (N=155, 8.8%), and melanoma (N=129, 7.4%). 44 (2.5%) patients had adrenal insufficiency, 88 colitis (5.0%), 253 hypothyroidism (14.4%), 66 hyperthyroidism (4.4%), and 146 pneumonitis (8.3%). Among 1258 patients with complete systemic therapy information available, 422 (33.5%) were treated with immunotherapy and 563 (44.8%) with chemotherapy. The performance metrics for LLM predictions at the note and patient levels are summarized in the table. Conclusions: We demonstrate the ability of an LLM to accurately annotate anti-cancer therapy toxicity data across a large number of patients. This approach is scalable to other toxicities and promises to spur adverse event research. Clinical and genomic correlates of anti-cancer therapy adverse events, using data from all patients with solid tumors with MSK-IMPACT data, will also be presented at the meeting. Research Sponsor: National Cancer Institute; T32CA009512-35; National Cancer Institute; P30-CA008748.

Toxicity	Note-level (N= 100 notes)		Patient-level (N= 1,754 patients)		
	Sensitivity	Specificity	Sensitivity	Specificity	R ²
Adrenal insufficiency	100.0%	97.8%	97.7%	94.7%	98.2%
Colitis	66.7%	99.0%	94.3%	80.4%	89.2%
Hyperthyroidism	57.1%	100.0%	74.0%	91.4%	98.7%
Hypothyroidism	100.0%	88.9%	88.1%	74.0%	96.1%
Pneumonitis	76.9%	97.7%	98.6%	70.1%	83.9%

Association of deep learning CT response assessment and interpretable components with overall survival in advanced NSCLC: Validation in a trial of sasanlimab and a real-world dataset.

Chiharu Sako, Taly Schmidt, Chong Duan, Kevin Maresca, Alan C. Gowan, Shraddha Vyas, George R. Simon, Ravi Bharat Parikh, Petr Jordan, Ronan Joseph Kelly; Onc.AI, San Carlos, CA; Pfizer Inc., Cambridge, MA; Baylor Scott & White Medical Center, Temple, TX; Charles A. Sammons Cancer Center at Baylor University Medical Center, Dallas, TX; OhioHealth, Columbus, OH; Emory University, Atlanta, GA

Background: Identifying advanced non-small cell lung cancer (aNSCLC) patients who derive long-term benefit from immune checkpoint inhibitors (ICIs) remains a significant challenge. Radiomic analyses, particularly leveraging deep learning, hold promise for improving prognostic accuracy beyond tumor size metrics. We developed serial CTRS, a novel biomarker using deep learning to quantify thoracic CT changes from baseline to 3 months post-treatment, predicting overall survival (OS) in patients receiving PD-(L)1 inhibitors. Methods: SerialCTRS was previously trained and validated on a multi-institutional Real-World Dataset (RWD) (training: 1,171 aNSCLC patients, 14,424 CT scans; validation: 612 patients; Sako et al. SITC, 2024). For this study, we retrospectively validated serialCTRS in two distinct cohorts of aNSCLC patients: (1) a clinical trial (N = 52) treated with the PD-1 inhibitor sasanlimab in the second or later line and (2) a fully blinded RWD from Baylor Scott & White Health system (N = 147), an institution not used for training. The pipeline—spanning image quality control, preprocessing, feature extraction, and survival modeling—operated without manual annotations. To enhance interpretability, we developed 3D submodels for prognostic signals related to (i) tumor burden, (ii) body composition, and (iii) lung vasculature. Predictive performance was compared to RECIST 1.1 using concordance index (c-index) and ROC-AUC for 24-month OS (OS24 AUC). Results: SerialCTRS outperformed RECIST in OS prediction and remained a significant predictor after multivariate adjustments with other known predictors including age, sex, PD-L1 TPS, and NLR across both validation cohorts. In the sasanlimab cohort, serialCTRS achieved a c-index of 0.77, surpassing RECIST (0.72), with an OS24 AUC of 0.86 (95% CI: 0.74-0.98). In the Baylor cohort, serialCTRS demonstrated a c-index of 0.68 vs. RECIST (0.62) and an OS24 AUC of 0.76 (0.67–0.86). Submodels targeting individual components achieved c-indices of 0.65 (tumor burden), 0.61 (body composition), and 0.61 (vasculature) in the sasanlimab cohort, and 0.63, 0.61, and 0.59, respectively, in the Baylor cohort. Combining the submodels improved c-indices to 0.69 (sasanlimab) and 0.66 (Baylor), demonstrating complementary signal among radiographic features. Conclusions: SerialCTRS outperformed RECIST 1.1 in predicting OS in independent clinical trial and RWD datasets. Interpretable submodels highlighted the prognostic value of tumor burden, body composition, and vasculature changes. SerialCTRS offers a promising tool for personalizing therapy and accelerating drug development in aNSCLC, with a fully automated pipeline for robust and scalable clinical use. Future work will focus on larger, more diverse cohorts to validate utility in guiding precision oncology. Research Sponsor: None.

Computational pathology to predict docetaxel benefit in patients with metastatic hormone-sensitive prostate cancer from the CHAARTED trial (ECOG-ACRIN E3805).

Sebastian R. Medina, Naoto Tokuyama, Kamal Hammouda, Tilak Pathak, Tuomas Mirtti, Pingfu Fu, Shilpa Gupta, Priti Lal, Christopher Sweeney, Anant Madabhushi; Wallace H. Coulter Department of Biomedical Engineering at Georgia Tech and Emory University, Atlanta, GA; Emory University, Atlanta, GA; Helsinki University Hospital, Helsinki, Finland; Department of Population and Quantitative Health Sciences, Case Western Reserve University, Cleveland, OH; Cleveland Clinic Taussig Cancer Institute, Cleveland, OH; University of Pennsylvania, Philadelphia, PA; South Australian Immunogenomics Cancer Institute, University of Adelaide, Adelaide, SA, Australia; Wallace H. Coulter Department of Biomedical Engineering at Georgia Tech and Emory University, Atlanta Veterans Administration Medical Center, Atlanta, GA

Background: The CHAARTED trial demonstrated the efficacy of early docetaxel (DTX) in combination with androgen deprivation therapy (ADT) for metastatic hormone-sensitive prostate cancer (mHSPC), particularly in patients (pts) with high volume (HV) disease. Volume of metastases has been shown to assist pts selection, however more precise biomarkers are needed to select pts that might benefit from early DTX, especially in low volume (LV) metastasis. We aim to validate a computational AI pathology image classifier (APIC), that quantifies the tumor-immune microenvironment from biopsy images to predict DTX benefit in pts from the CHAARTED trial. Methods: The study included a subset of pts from CHAARTED for whom high-quality biopsy images were available. Outcomes were defined as overall survival (OS) and time to castration resistance (CRPC). After segmenting nuclei and identifying lymphocytes, we derived features that captured immune-tumor spatial patterns and nuclear diversity to construct APIC and stratify patients into positive or negative groups. DTX benefit was evaluated using Cox proportional hazards with interaction terms, log-rank tests and Kaplan-Meier analyses by comparing endpoint estimates between treatment arms within APIC-stratified groups. Results: Among CHAARTED trial pts, we analyzed H&E images that met quality control and excluded prostatectomies (N = 286/790, 36.2%). Half of the ADT arm was used for training (78 pts), and 208 pts were used for validation (ADT = 77, DTX = 131). Among these, 118 pts (56%) were classified as APIC-positive and 90 pts (44%) as APIC-negative. In APIC-positive, DTX significantly improved OS (HR = 0.52 [95% CI: 0.31–0.85], p = 0.0075, interaction p < 0.05) and delayed time to CRPC (HR = 0.48 [95% CI: 0.33-0.71], p = 0.00019, interaction p < 0.05). APICpositive pts who received DTX derived a 24.3% higher 5-year OS and remained castrationsensitive 21.8% longer than those who received ADT alone. In APIC-negative pts, no prolongation effects of OS or time to CRPC were observed from the addition of DTX. APIC was able to identify pts benefiting from DTX in the HV group for OS (HR = 0.43 [95%CI: 0.24-0.77], p = 0.0035), and in both HV (HR = 0.50 [95%CI: 0.31-0.79], p = 0.0027) and LV (HR = 0.42 [95%CI: 0.20-0.91], p = 0.023) groups for time to CRPC. While CHAARTED showed modest CRPC delay in LV pts and no clear OS benefit, APIC identified a subset of LV pts who derived substantial CRPC delay from DTX. Conclusions: We validated APIC as a predictive biomarker for DTX benefit in mHSPC pts from CHAARTED. Notably, in unselected pts with LV disease where the benefit of DTX is less, APIC identified an LV subset who derived significant delayed progression to CRPC from adding DTX to ADT. This work, validated in the context of ADT alone, warrants investigation alongside androgen receptor axis-targeted agents. Research Sponsor: NCI/NIH; R01CA268287A1, U01CA269181, R01CA26820701A1, R01CA249992-01A1,R01CA202752-01A1,R01CA208236-01A1,R01CA216579-01A1,R01CA220581-01A1,R01CA257612-01A1, 1U01CA239055-01, 1U01CA248226-01, 1U54CA254566-01; National Heart, Lung and Blood Institute; 1R01HL15127701A1, R01HL15807101A1; National Institute of Biomedical Imaging and Bioengineering; 1R43EB028736-01; United States Department of Veterans Affairs; IBX004121A; Biomedical Laboratory Research and Development Service the Office of the Assistant Secretary of Defense for Health Affairs, through the Breast Cancer Research Program; W81XWH-19-1-0668; Biomedical Laboratory Research and Development Service the Office of the Assistant Secretary of Defense for Health Affairs, through the Prostate Cancer Research Program; W81XWH-20-1-0851; Lung Cancer Research Program; W81XWH-18-1-0440, W81XWH-20-1-0595; Peer Reviewed Cancer Research Program; W81XWH-18-1-0404,W81XWH-21-1-0345, W81XWH-21-1-0160; Kidney Precision Medicine Project; Sanofi.

Frailty in motion: How Fitbit data reflects patients with cancers' functional status in the All-of-Us database.

Kenan Najjar, Maaz S. Imam, Nabiel Ali Mir; Carle Illinois College of Medicine, Champaign, IL; Carle Illinois College of Medicine, Urbana, IL; The University of Chicago Comprehensive Cancer Center, Chicago, IL

Background: Frailty is a vital determinant of outcomes in adults with cancer, leading to heightened toxicity, morbidity, and reduced survival. Despite its significance, comprehensive frailty assessment remains constrained by time, resources, and knowledge. Deficit-based frailty indices (FIs) require extensive surveys, limiting real-world use. Wearable devices (e.g., Fitbit) that track daily steps offer a straightforward measure of physical function, yet their associations with FIs are uncertain in oncology. Leveraging the All of Us Research Program (Controlled Tier Dataset Version 7), one of the most diverse NIH resources, we examined the association between steps and the validated All of Us Frailty Index (AoU-FI) [Wong et al. J Gerontol A Biol Sci Med Sci. 2023]. We hypothesized that higher step counts would correspond to lower (fitter) AoU-FI scores. Methods: We identified adults \geq 50 years old with cancer and 3–7 days of Fitbit data between 2017–2025. The AoU-FI comprises 33 deficits encompassing lifestyle, comorbidities, overall health, and healthcare access. Frailty was categorized as Fit (<0.15), Pre-Frail (0.15–0.25), or Frail (> 0.25). Scores were matched with wearable data \pm 30 days; outliers (< 300 or > 20,000 steps/day) and records missing \ge 20% of FI items were excluded. Demographics (age, sex, race/ethnicity) and cancer diagnoses were documented. Mean step counts were compared via t-tests. A linear regression assessed the step-frailty link, and a multivariable logistic model for discerning Fit vs Pre-Frail or Frail (age \geq 65, male, > one cancer) employed normalized step counts (per 1,000). Results: Among 361 participants (mean age 65.7±7.8; 66.8% female; 92.5% White; 97.5% non-Hispanic/Latino), 86.2% had one cancer (skin 55.7%, breast 24.8%, prostate 9.9%). Frailty categories were 44.0% Fit, 40.4% Pre-Frail, and 15.5% Frail. Mean steps declined with increasing frailty (Fit vs. Pre-Frail 8,136±3,251 vs. 7,067 \pm 3,598; p = 0.007; vs. Frail 5,486 \pm 3,623; p < 0.0001). A linear regression confirmed an inverse link between frailty and steps. (slope = -7.38×10^{-6} ; p < 0.0001). Adjusted analysis showed steps remained highly significant (OR = 1.14, 95% CI: 1.07-1.21, p < 0.0001), whereas gender, > one cancer, and age \geq 65 were not. **Conclusions:** All-of-Us is designed to represent many populations, and our sample showed older adults adopting wearable technologies, highlighting their potential for clinical use. However, the sample was primarily White individuals with skin cancer, reflecting coverage gaps in wearable data across the cancer population. Step counts strongly correlated with fitness, supporting wearable-based functional assessment in oncology. Chronological age did not correlate with frailty, aligning with guidelines prioritizing holistic assessments. Future efforts should integrate broader populations, minute-level metrics, and cancer and treatment information to refine frailty classification as recruitment grows. Research Sponsor: "The All of Us Research Program is supported by the National Institutes of Health, Office of the Director. The program would not be possible without the partnership of its participants."

DeepSeal: Empowering clinical researchers to analyze clinicogenomic data with an intuitive chat-based interface.

Gaurav Sharma, Shawn Baker, Guillaume Marcais, Eric Schultz, Roby Antony Thomas, Thom Gulish, Rob Patro, Carl Kingsford; Ocean Genomics, Pittsburgh, PA; University of Pittsburgh Medical Center, Hillman Cancer Center, Pittsburgh, PA

Background: Traditional clinicogenomic analysis workflows in oncology require substantial bioinformatics expertise and custom coding, creating a bottleneck where clinical researchers must rely on analysts for data interpretation. This dependency hinders hypothesis development, exploration and discovery, as researchers cannot directly interact with their data in realtime. DeepSeal addresses these challenges by providing a user-friendly, chat-based interface that enables immediate analysis of clinicogenomic data and seamless generation of results, empowering clinical researchers to independently explore and validate hypotheses. Methods: DeepSeal, an integration of a large language model with clinical and molecular databases and bioinformatics tools, was evaluated by replicating the findings of Riaz et al. (Cell, 2017), in advanced melanoma patients treated with nivolumab. Through natural language prompts, DeepSeal performed multiple analyses including differential gene expression analysis and Gene Set Enrichment Analysis (GSEA) to generate comprehensive molecular profiles of responders versus non-responders and to identify molecular signatures associated with treatment response. Results: DeepSeal successfully replicated the key findings of Riaz et al., identifying significant differential expression of immune-related genes in treatment responders. GSEA executed through DeepSeal's chat interface further revealed enrichment of immune-related pathways critical for response, including B cell activation (GO:0042113), T cell activation (GO: 0042110), and regulation of adaptive immune response (GO:0002819). The chat interface enabled rapid hypothesis testing and visualization generation, with analyses completed in minutes without the need for programming expertise. Conclusions: DeepSeal demonstrates the feasibility of enabling clinical researchers to independently analyze complex clinicogenomic data through natural language interaction. By successfully replicating and validating findings from Riaz et al., it generates reliable insights without programming expertise, offering a transformative approach to accelerate translational research. This removal of technical barriers between researchers and their data has the potential to substantially speed hypothesis testing and discovery in oncology, ultimately enhancing the pathway from molecular insights to improved patient care. Research Sponsor: None.

Virtual oncology collaborative tumor board using multiple artificial intelligence agents.

Jiasheng Wang, Sayan Mullick Chowdhury, Aziz Nazha; Comprehensive Cancer Center & James Solove Research Inst., The Ohio State University Medical Center, Columbus, OH; The Ohio State Comprehensive Cancer Center, Columbus, OH; Thomas Jefferson University, Philadelphia, PA

Background: Clinical guidelines are complex documents with tables and figures. Finding specific answers to questions within these guidelines can be challenging and timeconsuming. Current AI tools often struggle to extract information from these PDF guidelines. To address this, we developed a novel system that uses a group of artificial intelligence (AI) agents, where each agent is designed to perform a distinct job, like finding information, reading documents, or summarizing findings. These agents communicate with each other to analyze complex clinical guidelines, working as a team to answer physician questions like trained oncologists discussing cases in a tumor board environment. Methods: Publicly available PDF guidelines published by the ASCO from Jan 2021 to Dec 2024 were acquired. A three-agent framework was constructed using the AutoGen platform, comprising a Coordinator Agent, a PDF Viewer Agent, and a Reviewer Agent. The Coordinator Agent selects the appropriate guideline based on a user's question; the PDF Viewer Agent extracts information from the selected guideline file, and the Reviewer Agent generates a summary of the findings answering the original question. The agents were powered by Anthropic's Claude 3.5 Sonnet. The primary objective of the study was to evaluate the platform's accuracy in selecting the relevant guideline based on user questions and in subsequently answering those questions accurately. Results: A total of 34 ASCO guidelines were obtained, covering a range of cancer types: breast (15), GI (4), head and neck (4), thoracic (4), neuro-oncology (3), GU (2), melanoma (1), and gynecologic (1). One hundred question-answer pairs were created by board-certified oncologists based on these guidelines to evaluate the system's performance. It's important to note that these answers were based directly on the information in the guidelines and may not always reflect the most current clinical knowledge, thus serving as a rigorous test of the framework's ability to adhere to the provided documents. Our multi-agent framework achieved a 93% accuracy rate in matching user questions with the correct guideline and answered 88% of the questions accurately. Comparatively, when the same questions were evaluated using OpenAI's GPT-40 (ChatGPT) and Claude 3.5 Sonnet without the multi-agent framework, the accuracy was significantly lower at 48% and 49%, respectively. The total computational cost of processing all questions using the multi-agent framework was 13.44 USD. The complete code, dataset, and detailed results are publicly accessible at https://github.com/jwang-580/ASCO_guideline_agents. Conclusions: This study demonstrates that a collaborative AI agent system can accurately provide answers from clinical guidelines that is more accurate than ChatGPT and similar software. Our results suggest a promising way to develop more effective AI tools for clinicians to use in their practice. Research Sponsor: None.

Comparison of artificial intelligence to expert physician assessments of real-world oncology cases.

Olivia Main, Matthew Struck, John L Vaughn, Jingmei Hsu, Shella Saint Fleur-Lominy, Mohammad Issam Abu Zaid, Marc Justin Braunstein; NYU Perlmutter Cancer Center, NYU Grossman Long Island School of Medicine, Mineola, NY; Primum, Inc., New York, NY; NYU Perlmutter Cancer Center, NYU Grossman School of Medicine, New York, NY; Community Physician Network, Kokomo, IN

Background: Artificial intelligence (AI) is increasingly being incorporated into the oncology field as a tool to support clinical decisions. AI tools such as ChatgGPT or OpenEvidence provide responses to user-generated queries, whereas some institutions or companies such as Primum, Inc, offer consultations with actual experts who provide personalized responses to cliniciansubmitted real-world cases. However, the value of AI tools to augment expert consultations continues to evolve. We report results of a study comparing AI versus expert oncologists' responses to 107 real-world hematology/oncology cases. Methods: Among 107 cases, inquiries included lymphomas (30), myeloma (24), leukemias (11), myeloid disorders (10), as well as classical hematology (32), assessed among 20 experts. Responses to de-identified cases submitted by practicing clinicians to Primum (www.primum.co) between June 2022-July 2023 were compared to GPT-4 responses (openai.com/chatgpt). The instructional prompt to GPT-4 was, "You are an expert oncologist conversing with another oncologist as a peer. You prefer to rely on guidelines and data published in reputable medical journals when responding." Five expert faculty at our institution adjudicated the blinded comparative responses, including their preference, quality and practical value scores, and prediction of which response was AI generated. Comparison of scores was by t-test to generate P-values between expert and AI groups, and Pearson correlation was used for comparisons between adjudication scores. **Results:** Expert responses were preferred by > 50% of adjudicators in 75% of cases (deviation \pm 25%). Randomized AI responses were correctly identified 90% of the time. Mean expert vs AI scores (Likert scale 0-4) for quality (2.0 vs 2.1, P = 0.9) and practical value (2.1 vs 2.1, P = 0.9) were equivalent. Interestingly, AI responses were preferred in 46% (n = 15) of classical hematology and 31% (n = 9) of lymphoma cases, largely due to being more concise. However there was no concordance between high practical value scores and disease subtype for either group. Conclusions: : Expert physician responses were preferred over AI responses for most of the cases based on the level of detail presented, suggesting an implicit value of personalized responses compared to AI. Results showed no significant differences in quality or practical utility between AI generated responses and those from experts, reflecting a similarity in the information extracted from standardized guidelines, and potentially adding value of AI in supporting clinical decision making. Our findings are limited by the broad coverage of hematologic conditions for which experts and guidelines vary. Overall, these data suggest that while AI can supplement knowledge of management paradigms by providing basic management strategies, at present it cannot replace personalized expert consultation in clinical practice. Research Sponsor: None.

Evaluating fairness and mitigating bias in models predicting financial toxicity among patients with genitourinary cancers.

Atulya Aman Khosla, Mohammad Arfat Ganiyani, Manas Pustake, Yagnapriya Ammakola, Nitya Batra, Karan Jatwani, Anshul Saxena, Ishmael A. Jaiyesimi, Rohan Garje, Ishwaria M. Subbiah; Department of Internal Medicine, William Beaumont University Hospital, Royal Oak, MI; Miami Cancer Institute, Baptist Health South Florida, Miami, FL; Texas Tech University Health Sciences Center, El Paso, TX; Corewell Health William Beaumont University Hospital, Royal Oak, MI; The George Washington University Hospital, Washington, DC; Medical Oncology and Palliative Care, Nashville, TN

Background: Financial toxicity, the economic burden patients face from healthcare expenses, is a growing concern in cancer care. Recognizing the high costs of diagnosis and treatment of genitourinary (GU) cancers, this study aims to (1) comprehensively characterize the socioeconomic, demographic, and care-related factors associated with financial toxicity in patients with GU cancers, and (2) evaluate bias in the predictive model developed using these patient factors. Methods: The 2019–2022 Medical Expenditure Panel Survey (MEPS) data was used to identify patients with GU cancers. MEPS captures utilization, frequency, cost, and payment sources of U.S. health services alongside health insurance coverage characteristics and accessibility in the workforce. Financial toxicity was defined as patient-reported difficulties paying medical bills, high out-of-pocket expenses (> 10% of total income), and high self-pay ratios (> 20% of total healthcare expenditure). Predictive modeling was performed using logistic regression using age, sex, race/ethnicity, income, insurance status, and expenditure-related predictors. To address potential algorithmic bias, Fairlearn's ThresholdOptimizer, a postprocessing algorithm, was applied to this predictive model, adjusting predictions to ensure equalized odds across racial groups. Performance metrics, including accuracy, precision, and recall, were evaluated overall and by racial group. Results: Overall, we identified 1131 patients with GU cancers (weighted n = 11,723,024) in the MEPS data; median age 72 yrs; sex 93.4% male; 71.6% White, 18.3% Black, 6.5% Hispanic, and 3.5% Other. 22.2% of patients reported financial toxicity with a median [Q1, Q3] total healthcare expenditure of \$2,645.0 [\$898.5, \$5328.0] vs. \$503.5 [\$171.0, \$1286.8]. Logistic regression achieved an overall accuracy of 95%, with a precision of 97% and recall of 77% for financial toxicity cases. Fairness metrics of the unadjusted predictions revealed bias to specific communities with lower recall for Black (46.2%) and Other Races (33.3%) compared to Hispanic (75.0%) and White (90.4%) patients. After threshold optimization, recall improved to 61.5% for Black and 50% for Other Races, while Hispanic (84.6%) and White (100%) patients maintained high performance. However, disparities persisted, as evidenced by an equalized odds difference of 0.21. Conclusions: This study underscores the critical need for responsible development of predictive models impacting cancer care. Our findings show that a bias-correcting postprocessing algorithm can be an essential tool since it can be applied to existing models without requiring retraining; however, these algorithms do not represent a definitive solution since this model's underlying bias persists, highlighting the need to ensure models learn from fair data sets that are representative of the US population. Research Sponsor: None.

Machine learning model to forecast patient availability for oncology clinical trials.

Rajeev Kulkarni, Vivek Prabhakar Vaidya, Dhaval Parmar, Abhishek Tibrewal, Payal Keswarpu, Ravi Bharat Parikh; ConcertAl, Cambridge, MA; ConcertAl, Bengaluru, India; ConcertAl LLC, Bengaluru, India; Emory University, Atlanta, GA

Background: Automating eligibility criteria assessment for oncology clinical trials is an emerging application of machine learning (ML). However, machine learning applications to predict patient availability - the likelihood of a patient beginning a new treatment (time to next treatment) in a prespecified time window – are not well described. We used a large clinicogenomic database of patients diagnosed with solid cancer indications to train ML model to predict patient availability for clinical trials. Methods: This was a retrospective study based on data drawn from the ConcertAI Oncology Research database, enriched by key variables derived from unstructured data. Line of therapy was derived from expert rules applied to structured medications data. Our cohort consisted of patients with confirmed diagnosis of solid cancers without a second malignancy. Patient follow-up period started on the date of diagnosis of metastasis and ended on the earlier of last date of activity / date of death. Random observation date was set between start and end dates to label patients. Patients administered a new treatment after the random observation date were labelled evet, else censored (no new treatment began). Label date is start of new treatment and end dates for event & censored cases respectively. The time to event (TTE) was defined as the duration between the random observation and the label dates. In the event cases, this duration is the time to next treatment (TTNT). Over 2000 features based on variables broadly grouped as tumor-specific biomarkers (PTEN, KRAS, etc.), ECOG, staging, disease status, medications, and imaging (evidence of image, not report) were employed to build multiple ML models. Temporal validation of the models was performed by setting up a simulated index date and predicting the probability of patient beginning a new treatment within 60 days of the simulated index date. Patients receiving new treatment within the 60 days were true positives. Results: TTE models were trained on a cohort comprised of 90K patients across 12 cancer indications with 54% patients starting a new treatment. Median age and overall survival (OS) of the cohort was 73 years and 703 days respectively. Temporal validation was performed on 25K patients with similar demographics/OS and 58% patients starting new treatment. Multiple ML methods were used to train models, with boosted gradient model demonstrating highest c-index of 0.73 based on 87 features. Temporal validation demonstrated AUC and weighted F1 of 87% and 67% respectively. True positive cases were assigned high predicted probability in 75% of the cases. **Conclusions:** AI models supporting 12 solid cancer indications accurately predicted patient availability. These models can be integrated into real-time clinical workflows alongside patient eligibility models to provide clinicians and patients visibility in ascertaining a patient's likelihood of being eligible for a clinical trial. Research Sponsor: None.

Magnetic resonance imaging (MRI) radiomics as predictor of clinical outcomes to neoadjuvant immunotherapy in patients with muscle invasive bladder cancer undergoing radical cystectomy.

Andrea Necchi, Giorgio Brembilla, Yuki Arita, Oguz Akin, Aditya Apte, Michele Cosenza, Brigida Maiorano, Valentina Tateo, Antonio Cigliola, Chiara Mercinelli, Francesco De Cobelli, Karissa Whiting, Marinela Capanu, Amita Dave, Lawrence Howard Schwartz; IRCCS San Raffaele Hospital, Vita-Salute San Raffaele University, Milan, Italy; Department of Radiology, IRCCS San Raffaele Hospital, Milan, Italy; Memorial Sloan Kettering Cancer Center, New York, NY; Department of Radiology, IRCCS Ospedale San Raffaele, Milan, Italy; Oncologia Ospedale San Raffaele, Milano, Italy; IRCCS San Raffaele Hospital, Milan, Italy; Gastrointestinal Oncology Service, Memorial Sloan Kettering Cancer Center, New York, NY

Background: Muscle-invasive bladder carcinoma (MIBC) is a deadly disease, for which we pioneered the use of neoadjuvant immune-checkpoint inhibitors (ICI) in a clinical trial (PURE-01, NCT02736266) testing 3 cycles of neoadjuvant pembrolizumab before radical cystectomy (RC). The objective of this study is to assess the ability of radiomic features extracted from a robust MRI processing pipeline to predict the pathological response to neoadjuvant pembrolizumab. Methods: A total of 120 patients (pts) with MIBC (102M/18 F), with median age of 68 years, a clinical stage T2N0 (n = 53; 44%) or T3-4N0 (n = 67; 56%), who were enrolled in PURE-01 study were analyzed. Patients had matched pre- and post-ICI MRIs, and tumors were segmented on both T2w images by GU radiologists. The MRI signal intensities were standardized by N4-bias field correction and robust z-scores. IBSI-compatible pyCERR software was used to extract radiomics features. A total of 289 radiomic features, including shape, first-order statistics, and higher-order textures, were analyzed for associations with pathological complete response (pCR at RC). An additional association was also investigated for major response groups, i.e., CR and partial response (PR, i.e. downstaging to ypT≤1N0) versus no response (NR). We employed Elastic Net, a machine learning technique that blends the strengths of Lasso and Ridge regression and is particularly effective for datasets with many correlated features such as in our study. The endpoint was modeled by training Elastic Net logistic regression models separately for pre- and post-ICI MRI features, as well as clinical T-stage. Models were evaluated on a 30% held-out test set using ROC curves (AUC). Results: For pCR, the bestperforming model included four post-ICI MRI features: shape (flatness) and texture features from Gray Level Co-occurrence Matrix (GLCM: homogeneity, sum average, and sum entropy), and had a test AUC of 0.83 (95%CI: 0.66 - 0.99). Separate models fit on pre-ICI MRI features selected two important pre-ICI MRI features: shape (surface-to-volume ratio) and first order (robust mean absolute deviation), but the overall performance was lower than post-ICI models (test AUC 0.66; 95%CI: 0.42 - 0.89). For major response assessment, the best-performing model included two post-ICI MRI features: shape (flatness) and texture (GLCM sum average) and had a test AUC of 0.92 (95%CI: 0.8-1.0). Conclusions: This is one of the first machine learning models using MRI radiomics to predict neoadjuvant immunotherapy response in pts with MIBC. These results could be instrumental for improving the way we can predict the pathological response in these pts. Clinical trial information: NCT02736266. Research Sponsor: Associazione Italiana per la Ricerca sul Cancro (AIRC); IG 27746.

Acoustic biomarkers and AI: Transforming NSCLC detection and personalized care.

Chiara Giangregorio, Cristina Maria Licciardello, Anthea Iacobucci, Leonardo Provenzano, Vanja Miskovic, Paolo Ambrosini, Laura A. Ferrari, Andra Diana Dumitrascu, Laura Mazzeo, Marco Meazza Prina, Teresa Beninato, Marta Brambilla, Claudia Proto, Simona Ferrante, Giuseppe Lo Russo, Emilia Ambrosini, Alessandra Pedrocchi, Marina Chiara Garassino, Arsela Prelaj; Department of Electronics, Information and Bioengineering, Politecnico di Milano, Milan, Italy; Fondazione IRCCS Istituto Nazionale dei Tumori di Milano, Milan, Italy; University of Chicago, Department of Medicine, Chicago, IL

Background: Implementing a mass screening program for lung cancer using low-dose chest CT presents significant challenges, including financial constraints and concerns about radiation exposure. Nonetheless, recent evidence reveals that lung cancer is not limited to smokers, as it also affects non-smoker populations who are currently excluded from existing screening programs. As part of the I3LUNG study (NCT05537922), we investigated the use of AI-based forced cough analysis as a non-invasive approach to distinguish NSCLC patients undergoing immunotherapy (IO) from healthy individuals. Additionally, we examined whether cough features could differentiate patients based on their baseline clinical features. Methods: Machine Learning-based preprocessing isolated meaningful cough events and extracted 39 acoustic features from the time and frequency domains. To reduce redundancy and improve model performance, highly correlated features (> 85%) were eliminated. Support Vector Machines (SVM) and Deep Learning (DL) models were then employed to distinguish NSCLC patients from healthy controls. Additional statistical analyses of acoustic features were conducted on cough recordings from patients to evaluate differences based on smoking status (current, former, or never smokers) using the Kruskal-Wallis test with Benjamini-Hochberg post-hoc correction. Similarly, differences based on the presence or absence of lung metastases were assessed using the Mann-Whitney test. Results: A total of 200 individuals were enrolled in the study, including 91 stage IIIB-IV NSCLC patients undergoing IO and 109 healthy controls. Cough recordings were analyzed, with the SVM model achieving an accuracy of 82% and a specificity of 92% on the test set. The DL model demonstrated superior performance, with an accuracy of 95% and a specificity of 100%. Significant differences were observed in the peak-to-root-mean-square value ratio and cough duration among smokers (current, former, or never), with P-values of 0.026 and 0.042, respectively. Furthermore, spectral features - including centroid, rolloff, spread, kurtosis, bandwidth, and flatness - differed significantly between patients with and without lung metastases (P < 0.01). Conclusions: These findings highlight the potential of cough as a valuable digital biomarker for NSCLC diagnosis. The tool's high sensitivity facilitates the effective identification of individuals at risk for lung cancer, while its exceptional specificity makes it a promising initial screening method, efficiently triaging positive cases for follow-up chest CT scans. Future studies should validate these results on larger cohorts. Moreover, the correlation of specific cough features with smoking status and the presence of lung metastases suggests that this tool could extend beyond screening to monitoring disease progression over time. Research Sponsor: HorizonEurope; Grant agreement ID: 101057695.

Real-time AI-based computer-aided detection/diagnosis (AI-CAD) for breast ultrasound: A prospective, multicenter, multinational study.

Jeeyeon Elizabeth Lee, Won Hwa Kim, Ava Kwong, Jaeil Kim, Hye Jung Kim, John Baek, Ho Yong Park, Yee Soo Chae, Soo Jung Lee, In Hee Lee; Department of Surgery, Kyungpook National University Chilgok Hospital, School of Medicine, Kyungpook National University, Daegu, South Korea; Kyungpook National University Hospital, Daegu, Korea, Republic of; The University of Hong Kong, Hong Kong; Hong Kong; School of Computer Science and Engineering, Kyungpook National University, Daegu, South Korea; Kyungpook National University, Daegu, South Korea; BeamWorks Inc., Daegu, South Korea; Department of Oncology/Hematology, Kyungpook National University Chilgok Hospital, School of Medicine, Kyungpook National University, Daegu, South Korea

Background: To evaluate the effectiveness of a real-time AI-based computer-aided detection/ diagnosis (AI-CAD) system as a diagnostic decision support tool for breast ultrasound in a realworld clinical setting, conducted as a prospective, multicenter, and multinational study. Methods: From May to December 2024, a total of 75 patients undergoing breast ultrasound were enrolled in a prospective study conducted in Korea (n = 38) and Hong Kong (n = 37). In this study, six experts operated a real-time AI-CAD system (CadAI-B, BeamWorks Inc., Korea) on a tablet PC connected to a handheld ultrasound device during breast ultrasound examinations. Image and clinical data were collected from patients with established ground truth through follow-up, biopsy, or surgery. The AI-CAD system highlights suspicious areas during scanning to assist physicians in detecting breast cancer and supports big data-driven differential diagnosis by providing BI-RADS categories and malignancy scores (0-100%) when the user freezes the image. The diagnostic performance of experts and the real-time AI-CAD system was evaluated using the area under the receiver operating characteristic curve (AUC), along with sensitivity and specificity. Results: The analysis included 75 patients (mean age 55 years, IQR 46-66) with 24 malignancies (32.0%), 45 benign lesions (60.0%), and 6 normal cases (8.0%). The mean breast mass size was 1.2 cm (\pm 1.0 cm): benign 0.8 cm (\pm 0.7 cm), malignant 1.8 cm (±1.3 cm). The BI-RADS category distribution was as follows: for experts—category 1 (4.0%), 2 (21.3%), 3 (24.0%), 4a (16.0%), 4b (18.7%), 4c (4.0%), 5 (12.0%); and for AI-CAD-category 1 (32.0%), 2 (5.3%), 3 (9.3%), 4a (17.3%), 4b (21.3%), 4c (13.3%), 5 (1.3%). The overall diagnostic performance of experts and AI-CAD, as AUCs calculated by BI-RADS, were 0.801 and 0.751, respectively (P = .679). The sensitivity and specificity were 91.7% (22/24) and 68.6% (35/51) in experts and 87.5% (21/24) and 57.8% (32/51) in AI-CAD, respectively (P = .481). Conclusions: In this real-world clinical study conducted across multiple centers and countries, CadAI-B demonstrated performance comparable to that of experts and showed its potential as a valuable diagnostic tool. Clinical trial information: NCT06622967. Research Sponsor: None.

Cancer patients' messages about radiology/pathology reports: Insights for AI.

Susan Chimonas, Allison Lipitz-Snyderman, Gilad Kuperman; Memorial Sloan Kettering Cancer Center, New York, NY

Background: Cancer patients often use portals to view results prior to discussing with physicians, leading to messages with questions or concerns.¹ These messages vary widely in content and urgency, creating challenges for healthcare providers to respond effectively.² Categorizing and triaging these messages through AI-enhanced tools could streamline communication and improve patient care and satisfaction. Methods: This study assessed common themes in 1 week (April 1-8, 2023) of patients' portal messages about "rapidly read" pathology and radiology reports (viewed by patients within 6 hours of posting to the portal, as a proxy for viewing before discussing with physicians) at Memorial Sloan Kettering Cancer Center in New York City. Results: Five notable themes emerged across a total of 48 messages about rapidly read radiology and pathology results: Interpretation (24/48, 50%): Half of the messages contained questions like, "What does this mean?" Patients sought explanations of pathology and radiology findings, reflecting a need for clear, accessible interpretations. Implications (14/ 48, 29%): With questions like, "What are the next steps?" patients often asked how findings might alter treatment plans, highlighting a need for guidance on the care implications of their reports. Concern (5/48, 10%): Some patients expressed worry or pessimism about pathology and radiology reports: "I am very worried" and "Maybe it's time to give up." Such statements indicated a need for supportive communication. Relief (3/48, 6%): In other messages, patients shared positive emotions regarding favorable results – "It is a huge weight off my mind." These responses offer clinicians opportunities to reinforce patient satisfaction. Errors/Omissions (3/ 48, 6%): Occasionally, patients perceived errors or omissions in their reports – "The radiologist totally misread the size of the lesion" – which impacted their trust in the information. Addressing these concerns promptly can help strengthen the patient-provider relationship. **Conclusions:** This novel study highlights opportunities for AI-enhanced tools to triage messages and facilitate timely, effective responses. This study found common themes in patients' diverse questions about rapidly read pathology and radiology reports. By implementing AI to categorize and triage message patterns, providers could support patients more efficiently. Methods in development could be used to classify the message content.³ For instance, AI-driven natural language processing tools could recognize queries related to "What does this mean?" and offer clear, accessible explanations of medical terms. Similarly, AI could be trained to flag highpriority messages based on distress signals, ensuring that these messages are addressed swiftly. Implementing such AI-based solutions could help meet patients' immediate needs while they await conversations with their providers. Research Sponsor: None.

Analysis of a large language model-based system versus manual review in clinical data abstraction and deduction from real-world medical records of patients with melanoma for clinical trial eligibility assessment.

Christine Vecchio, Stephanie Braley, Lucy Boyce Kennedy, James Isaacs, Thach-Giao Truong, Taylor Kuhn, Weiqi Sun, Eirini Schlosser, Jason Cannavale, Konstantinos Bakogiannis, Olga Tasopoulou, Aikaterini Iliana Karathanasopoulou, Vaibhav Mavi, Lara Jehi, Aaron Thomas Gerds; Cleveland Clinic Taussig Cancer Institute, Cleveland, OH; Cleveland Clinic Foundation - Taussig Cancer Institute, Cleveland, OH; Cleveland Clinic, Cleveland, OH; Dyania Health, Jersey City, NJ; Cleveland Clinic Taussig Cancer Center, Cleveland, OH

Background: Manual chart review (MCR) is the gold standard for assessment of information from electronic medical records (EMRs) for clinical trial eligibility. However, this method is labor-intensive, prone to error, and limited in scalability with high volumes of unstructured EMR data. Large language models (LLMs), have shown promise in natural language understanding, and automating chart review and abstraction would significantly improve efficiency and accuracy in data review for clinical research. In this evaluation project, we compared the performance of Synapsis LLM, a medically-specialized LLM, with medical professionals at answering questions tied to eligibility criteria of relevant clinical trials, by reading clinical notes of patients with melanoma. Methods: We conducted a comparative analysis using records of randomly selected patients with melanoma from the Cleveland Clinic. Two parallel processes were assessed: (1) MCR conducted by a melanoma and an oncology specialized research nurse (2) Automated chart review using the Synapsis LLM. Both processes ran on two cohorts: Cohort (A) consisting of 25 EMRs that were posed 23 eligibility questions each, and Cohort (B) consisting of 25 different EMRs, posed 22 eligibility questions each. In total, there were 1,125 questions answered by each of the research nurses as well as Synapsis AI. The questions addressed focused on melanoma-specific clinical characteristics, including but not limited to treatment approaches, related surgical procedures, imaging findings, and genetic testing. Performance metrics included accuracy of answers to the questions, and time required to complete the abstraction process. Discrepancies between the responses of the two research nurses and the LLM were analyzed in comparison to the established ground truth, which was determined through a consensus review by physicians to ensure the validity and reliability of the results. Results: Synapsis LLM performed the task with 95.73% accuracy in 2.5 minutes while the melanoma specialized nurse responded with 95.11% accuracy in 427 minutes. The oncology specialized research nurse's accuracy was 88.09%, and the tasks was completed in 540 min. The comparison demonstrated significant time savings and medical-grade accuracy for the application of this LLM-based technology compared to manual methods. Conclusions: This is the first project that compares an LLM-based system vs research nurses in deducing clinical characteristics from patients' EMRs for clinical trial eligibility. Synapsis LLM accurately completed the abstraction process, outperforming in accuracy and time the clinical personnel. This study highlights the potential of LLMs like Synapsis AI in scalable clinical research applications that currently rely solely on MCR. Research Sponsor: None.

Leveraging AI to enhance symptom capture and reduced hospitalizations.

Arman Koul, Mohana Roy, Tina Hernandez-Boussard; Cancer Center, Stanford Healthcare, Stanford, CA; Stanford Cancer Center, Stanford, CA; Stanford Cancer Center, Palo Alto, CA

Background: Unplanned hospitalizations and ED visits for cancer patients impose significant morbidity, financial costs, and reduced quality-of-life. Efficient resource allocation in oncology care requires proactive strategies to identify patients at high risk for preventable admissions, optimizing bed availability and outpatient management. CMS classifies acute care utilization (ACU), hospital stays or ED visits, within 30 days of chemotherapy for certain conditions, as "preventable" under OP-35, emphasizing the need for better risk stratification. By leveraging artificial intelligence (AI) including machine learning and large language models (LLM), predictive models can analyze the electronic health record (EHR) to identify patients who may benefit from early outpatient interventions. This study leverages AI to assess preventable admissions and quantify the benefits of proactive management, enhancing patient outcomes and care efficiency in oncology. Methods: This study analyzed data from 18,187 patients across a multisite cancer center to develop predictive models for ACU within 30 days of any systemic therapy following OP-35 criteria. Models incorporated structured data and clinical notes using LLMs. Using 2010–2019 data for training and 2020–2024 for validation, XGBoost and Random Forest models were developed to maximize sensitivity while maintaining acceptable specificity. Estimates of preventable hospital bed days were modeled to evaluate the impact of AI-driven risk stratification and targeted interventions on hospital resource utilization. Results: The 30day hospital visit prediction model demonstrated strong performance, with the XGBoost algorithm achieving an AUROC of 0.84 (95% CI: 0.83-0.86). Incorporating later therapy lines improved accuracy by accounting for the complexity of advanced disease. A threshold was set to prioritize sensitivity for identifying high-risk patients while maintaining specificity to minimize unnecessary interventions. Model implementation was estimated to prevent 22% of hospital visits when paired with timely intervention, saving 1,160 of the 5,370 bed days observed in the 2021–2024 cohort. Conclusions: This study underscores the potential of AIdriven prediction models to enhance precision oncology by identifying patients at risk for unplanned hospital visits following systemic cancer therapy—a critical quality indicator impacting patient outcomes, healthcare costs, and operational efficiency. By incorporating multi-line therapy data and leveraging advanced modeling techniques, the approach effectively captures disease progression and personalized treatment histories. Utilizing LLMs to structure fragmented data across care systems addresses a prevalent challenge in oncology. Accurate risk prediction of hospitalization facilitates proactive interventions, improves care coordination, reduces bed occupancy, and supports informed decision-making, ensuring timely and targeted support for high-risk patients. Research Sponsor: None.
The role of healthcare system distrust in shaping patients' attitudes and beliefs of artificial intelligence (AI) use in oncology.

Marco Santos Teles, Karolina Łucja Bryl, Susan Chimonas, Atif J. Khan, Andrew S. Epstein, Robert Michael Daly, Han Xiao, Jun J. Mao; Memorial Sloan Kettering Cancer Center, New York, NY

Background: AI offers significant potential to improve cancer care, yet little is known about patients' attitudes and beliefs around its use and which factors influence acceptance of this new technology. Distrust in healthcare is increasingly prevalent and may hinder patient perceptions of innovations such as AI. This study aimed to evaluate the relationship between healthcare system distrust and acceptance of AI in oncology. Methods: We conducted a cross-sectional survey study with patients at an urban academic cancer center. We developed an 8-item AI Patient Acceptance scale, where patients rated their comfort with AI in different aspects of oncologic care (e.g. diagnosis, treatment planning) on a 5-point Likert scale (range 8-40, higher scores indicate greater comfort; Cronbach's α = 0.94). The survey also included a 10item Health Care System Distrust (HCSD) scale (range of 10-50, higher scores indicate greater distrust). Multiple linear regression was performed to evaluate the association between HCSD and AI Patient Acceptance scores, adjusted for demographic and clinical factors. Results: Of 383 patients approached, 330 (86%) participated. Among these, 49.4% were age 65 or older, 55.9% male, 68.1% non-Hispanic white, 77.4% had a college degree or more. The most common tumor types reported were prostate (34.5%) and breast (26.4%) cancer, with 70.6% currently receiving treatment. Patients were most comfortable with AI use in cancer screening (80.2% somewhat or very comfortable), and supportive care applications, such as exercise (78.2%) and diet (74.8%). They were least comfortable with AI use to assist with diagnosis (70.4%) and other clinical decision-making applications, including treatment planning (64.8%) and prognosis (61.5%). Higher levels of distrust measured by the HCSD scale were negatively associated with the AI Patient Acceptance scale scores after adjusting for co-variates (B = -0.263, p = 0.002). Younger patients (age < 65) were more likely to report lower scores on the AI acceptance scale (B = -1.996, p = 0.021), while sex, race/ethnicity, and education level were not associated with AI acceptance. Conclusions: Higher distrust in the healthcare system is associated with lower acceptance of AI in cancer care. As we integrate new technologies like AI into oncology, mitigating distrust in the medical community will be essential to ensure patient-centered implementation. Research Sponsor: None.

Cross-sectional study on the impact of receiving potentially sensitive test results online on the emotional health of patients with breast cancer.

Anezka Carvalho Rubin de Celis Ferrari, Andrea Shimada, Andre Perina, Pedro Henrique Mendes Figueiredo Sr., Ana Carolina Muhlberger, Carolina Barauna Assumpcao, Maynara Zoppei, Denyei Nakazato, Natalia Fraile, Thomás Giollo Rivelli, Manuel Santos Cruz, Tiago Kenji Takahashi, Renata Arakelian, Angelo Bezerra de Souza Fede, Bruna M Zucchetti, Mariana Carvalho Gouveia, Gustavo Henrique Munhoz Piotto, Simone Klug Loose, Marcus Zanetti, Max S. Mano; Hospital Sirio Libanês, São Paulo, Brazil; Hospital Sírio Libanês, São Paulo, Brazil; DASA Oncoogia - Hospital Santa Paula, São Paulo, Brazil; DASA Oncologia - Hospital Santa Paula, São Paulo, Brazil; DASA Oncologia - Hospital Santa Paula, São Paulo, Brazil; DASA Oncologia - Hospital Santa Paula, Sao Paulo, Brazil; Sírio Libanês Hospital, São Paulo, Brazil; Hospital Santa Paula SA, Sao Paulo, SP, Brazil; DASA Oncologia, São Paulo, Brazil; DASA Oncology, Hospital 9 De Julho, São Paulo, Brazil; Hospital 9 de Julho- Dasa Oncologia, São Paulo, Brazil; Hospital Sírio-Libanês, São Paulo, Brazil

Background: Internet has changed the way people communicate. In healthcare, patients have now easy access to their test results online; however, this has been particularly challenging in oncology because of potentially sensitive results present in imaging and pathology reports and tumor markers. In breast cancer, survival rates have improved significantly and more people are getting screened regularly. Providing online access to test results to patients may have ambiguous outcomes, such as increasing their engagement, but also their anxiety levels. This study aims to investigate associations between online access to potentially sensitive test results and effects on the emotional health of patients with breast cancer, particularly for symptoms of anxiety and depression. Methods: We conducted a cross-sectional study with 385 patients who had been diagnosed with breast cancer in the past 5 years. Participants completed a printed questionnaire on their approach to receiving test results (whether or not they accessed the results online), their feelings of anxiety about the results, and validated questionnaires assessing symptoms of anxiety (GAD-7) and depression (PHO-9). Descriptive data analysis was performed using simple and cross tabulations for qualitative variables and measures such as mean, median, mode and standard deviation for quantitative variables. The normality of the data was checked using the Shapiro-Wilk test, while associations between qualitative variables were assessed using the Pearson chi-square test or Fisher's exact test. The significance level was set at 5%, using SPSS software version 22.0. Results: Partial results presented here include 329 patients, representing 85.45% of the total sample. A statistically significant association was found between the habit of accessing test results online and higher levels of anxiety (p < 0.05). Patients with positive screening for anxiety on GAD-7 reported greater anxiety while waiting for results (p < 0.05), while no such association was found for depression. In addition, online access to results showed a significant association with education level (p < 0.05) and patient age (p < 0.05), with younger patients and those with a higher level of education showing a greater propensity for this practice. However, no significant associations were found between tumor stage (early vs. metastatic) or time from diagnosis and the perception of anxiety (p > 0.05). **Conclusions:** There is an apparent association between the habit of receiving test results online and anxiety levels in patients with breast cancer. The recruitment is now complete, and results of the entire cohort will be available for presentation. Research Sponsor: None.

Utilization and impact of a digital care platform on cancer patients in India.

Vamshi Krishna Muddu, Indraja Siripurapu, Sujana Priya Vuba, V. Naga Avinash Bonda, Nanditha Sesikeran Boindala, Diksha Vatwani, Dhiraj Kumar Gautam, Arif Khan, Kausik Bhattacharya, Chanakya Chandra Kumar Konduri, Sridhar Dasu, Aaliya Basheer, Swetha Gurram, Arpit Lal, Rajdeep Ghosh; AIG Hospitals, Hyderabad, India; Svaas Wellness Limited, Hyderabad, India; Svaas Wellness Limited, Hyderabad, Telangana, India; Dr Reddys Laboratories, Hyderabad, India; Asian Institute of Gastroenterology Private Limited, Hyderabad, India

Background: Cancer patients experience complex symptoms and treatment-related side effects that impair quality of life (QoL) and increase healthcare utilization. Digital health tools have the potential to improve symptom management and patient outcomes by facilitating realtime communication and support, especially for patients with limited access to immediate care. This study aimed to assess the usability and impact of a digital cancer care platform (Alivius) among Indian cancer patients, their primary caregivers, and care teams. Methods: We conducted a prospective, interventional, real-world study at a single tertiary cancer center in India from Jan 30, 2024, to Jun 11, 2024. We enrolled 100 cancer patients aged 18-80 years who had access to a smart phone, can read English, had a confirmed cancer diagnosis and had undergone at least one cycle of chemotherapy or radiotherapy. Patients were asked to communicate their symptoms and concerns to the care team and got health education materials for their disease. Primary endpoints included the Monthly Active Users (MAU) and Net Promoter Score (NPS) a metric used to measure customer loyalty and satisfaction by asking customers how likely they are to recommend a company or product. Secondary endpoints included the number of chat interactions, patient-logged symptoms, and use of educational content. Data were collected through in-app user activity and user feedback surveys. Descriptive statistics summarized the data with chi-square test for categorical variables and t-tests or nonparametric tests for continuous variables. Results: Out of 100 registered patients (mean age 58.7 ± 12.5 years; 61% male), the majority had gastrointestinal (55%) and genitourinary (18%) cancers. 66 caregivers participated in survey, with 84.8% being immediate family members. Average MAU during the study period was 58. The NPS for recommending the hospital and the digital application was 30.9 and 32.4 respectively, indicating positive user perception. User engagement was high during the study period: 85% accessed educational content, 82% updated health status, and 78% tracked mood. A total of 2,825 app activities were recorded, including 888 health status updates and 436 chat interactions. 507 side effects alerts generated, 29.5% were high severity, primarily related to tiredness and fatigue (29.2%), gastrointestinal issues (27.2%), and pain (17.5%). Customer Satisfaction Score (CSAT) was 50 and 48.5 among care teams (Doctors & Nurses) and patients, respectively. The app facilitated real-time communication between patients, caregivers, and care teams. Conclusions: Digital platform demonstrated high user engagement and positive perceptions among both the patients and their caregivers. The app effectively facilitated communication, symptom tracking, and management of treatment side effects. Patient centered digital platforms hold promise for improving cancer care support. Research Sponsor: Dr reddys Laboratories.

Biologically interpretable pathomics-driven transformer model with self-supervised training for outcome prediction of immunotherapy in non-small cell lung cancer.

Butuo Li, Xiao Zhong, Qian Zhao, Taotao Dong, Linlin Wang; Shandong Cancer Hospital and Institute, Shandong First Medical University and Shandong Academy of Medical Science, China Institution or Organization, Jinan, China; Shandong Cancer Hospital and Institute, Shandong First Medical University and Shandong Academy of Medical Sciences, China Institution or Organization, Jinan, China; Department of Radiation Oncology, Shandong Cancer Hospital and Institute, Shandong First Medical University and Shandong First Medical University, Jinan, China; Cheeloo College of Medicine, Shandong University, Jinan, China; Shandong Cancer Hospital and Institute, Shandong First Medical University and Shandong Academy of Medical Sciences, Jinan, China; Cheeloo College of Medicine, Shandong University, Jinan, China; Shandong Cancer Hospital and Institute, Shandong First Medical University and Shandong Academy of Medical Sciences, Jinan, China; Cheeloo College of Medicine, Shandong University, Jinan, China; Shandong Cancer Hospital and Institute, Shandong First Medical University and Shandong Academy of Medical Sciences, Jinan, China

Background: Only a subset of non-small cell lung cancer (NSCLC) patients experiences durable benefit from immune checkpoint inhibitors (ICIs), and precise biomarkers remain scarce. Meanwhile, computational pathology, based on digital pathology, has led to significant advancements in NSCLC prognosis prediction. Yet limited generalization and interpretation remain critical challenges in current clinical practice. Self-supervised learning, pretrained on unlabeled data to comprehensively capture underlying biological information in pathological images, may enable expandable, interpretable pathomics models for outcome prediction of ICIs. Methods: H&E-stained slides from pan-cancer patients were digitized as whole slide images (WSIs), then segmented for preprocessing. A self-supervised foundation model (patho-GPT) were performed to extract WSI features, and further fine-tuned for outcome prediction of immunotherapy in NSCLC with progression-free survival (PFS) labels. Its performance was evaluated by accuracy, sensitivity, specificity, and AUC in internal and external validation. Patients were classified as immunotherapy-resistant (R) or immunotherapy-sensitive (S), and ROC/survival curves were generated. The model was also tested in an operable cohort on neoadjuvant immunotherapy. Finally, single-cell RNA (scRNA) sequencing analyses were performed to provide biological insights. Results: A total of 13770 whole slide images (WSIs) from 6589 patients were included to construct the self-supervised patho-GPT model, which utilizes a context encoder, target encoder, and predictor based on the Vision Transformer architecture. There were 771 WSIs from 511 NSCLC patients receiving immunotherapy, labeled using 5.23 months as the cut-off value. All patients were divided into training and validation sets at a 7:3 ratio. For downstream outcome prediction of immunotherapy, the weight of patho-GPT was fine-tuned in the training set, and performance was evaluated in internal and independent external validation sets. The accuracy was 0.828 (AUC 0.774) in the internal set and 0.758 (AUC 0.752) externally. Survival analyses showed the model's risk group was significantly associated with survival after immunotherapy. In contrast, the ViT-ViT model using initial weights achieved 0.677 accuracy (AUC 0.547) in the external set, which was significantly inferior. ScRNA sequencing and differential analysis between R and S groups were performed, and a high level of H1.2hi Teffs was found in R, linked to dysfunction of cytotoxicityrelated genes and immune pathways. **Conclusions:** The self-supervised patho-GPT can be used for the accurate prediction of immunotherapy outcome, with well generalization and biological interpretation. Research Sponsor: None.

Artificial intelligence based music therapy intervention in cancer patients undergoing chemotherapy in oncology day care (MUSICC).

Sujith Kumar Mullapally, Pankaj Kumar Panda, Kalaivani C, Gokulakrishnan T, Pavan Deepak Mandigala Venkata Ramana, Venkata Siva Kiran Kumar Dasapathi, Sridhar Pallia, Sujatha Visweswara; Apollo Proton Cancer Centre, Chennai, India; National Cancer Centre Singapore, Singapore, Singapore; DigiNxtHlt Solutions, Chennai, India

Background: Studies on the role of music therapy for improving the quality of life of cancer patients are scarce. Artificial intelligence (AI) is being increasingly utilised in healthcare universally. Echo Care ©DigiNxtHlt Solutions leverages AI technology multi-class neural networks to make personalised recommendations by learning continuously from patients' usage and interactions. We aim to study impact of this AI based music therapy in health-related quality of life (HR-QOL) in cancer patients undergoing chemotherapy. Methods: A pilot interventional study for 50 consecutive cancer patients being administered chemotherapy at daycare facility was conducted. After informed consent, each patient underwent assessments during chemotherapy on week 1, week 3 and week 6. Vitals assessment, FACT G7 and HADS assessment was done at baseline, 3rd week and 6th week.30 minutes experience of sounds rendered by "echo Care" AI based application ©DigiNxtHlt Solutions was provided at each session of chemotherapy at 1st week, 3rd week and 6th week. Vitals were checked on admission to daycare unit followed by HR-QOL assessments which were done on digital platform by patients using unique ID and password. After completing the FACT G7 and HADS assessment, option was given to select from multiple music modules generated by AI based on data entered by patients. Once they completed the 30min session, post session vitals were measured. Qualitative feedback also was collected. The primary objective was quality of life as defined by FACT G7/ HADS scores and secondary endpoint was change in physiological vital parameters at baseline, 3 weeks, 6 weeks. Statistical analysis done by SPSS version 22.0. Results: A total of 50 patients were enrolled for the study during study period from March 2023 to Dec 2024. Mean HADS score for depression was 10.2 + / - 4 and for anxiety was 7.5 + / - 3.40% patients had high HADS score for anxiety. 18% had high HADS score for depression.50% of patients had improvement in HADS score for anxiety and depression whereas 50% did not have much change in their scores. Mean FACT-G7 score is 13.5+/-2 with majority having value less than 16 (70%). From gualitative feedback, 25% reported "very satisfied", whereas 75% reported to be "satisfied" with music intervention. 54% patients felt less anxious, 50% had calming effect and masking of pain, 37.5% felt mood elevation, positivity and closer to their family. 30% patients felt muscle relaxing effect. 37.5% felt sleepy during music session with 25% not feeling any change in them during the sessions. **Conclusions:** Artificial intelligence-based music therapy intervention in cancer patient undergoing chemotherapy shows promising results in terms of health-related quality of life, satisfaction and experience and can be offered to cancer patients as a nonpharmacological intervention to improve their quality of life during their treatment. Clinical trial information: CTRI/2023/03/050509. Research Sponsor: None.

A randomized, controlled pilot trial of a neuromodulatory digital therapeutic for individuals with breast cancer.

Samantha Adler, Brett Colbert, Mariya Petrova, Shaheen Lakhan; Click Therapeutics, Inc, New York City, NY

Background: Fatigue, pain, and mood symptoms are common side effects of cancer therapy and cancer patients. Frontoparietal circuitry has been implicated in chemotherapy-induced cognitive impairment as well as post-treatment fatigue. We hypothesized that a smartphonebased multimodal multistable bias modification (MMBM) intervention could improve fatigue, mood, and pain-related attentional biases in breast cancer patients by correcting the neurocircuitry alterations caused by uncertainty stress induced by cancer diagnosis, as well as alterations resulting from chemotherapy, correcting frontoparietal circuitry changes resulting from cancer or its treatment. Methods: A randomized, single-blinded exploratory study in patients with breast cancer (n = 81) was conducted. Participants were randomized 1:1 to an active MMBM app or a control app and instructed to use it for 7 minutes daily over 4 weeks. Clinical endpoints included PROMIS-29+2, Brief Pain Inventory (BPI), and Pain Catastrophizing Scale (PCS). Feasibility and acceptability of app usage were also evaluated. Results: The MMBM app group showed significant improvements over control in PROMIS-29 fatigue (-3.4, p < 0.05), depressive symptoms (-2.8, p < 0.05), and symptoms of anxiety (-3.0, p < 0.05) domains. There were also several pain measures that showed significant improvement over time in the MMBM group, but not the control group, such as the PROMIS-29 pain intensity measure (-0.9, p < 0.001), the BPI average pain intensity (-0.7, p < 0.001) and current pain intensity (-0.7, p < 0.01), and the PCS total score (-3.3, p < 0.01). Conclusions: This study provides preliminary evidence that the MMBM intervention may alleviate fatigue and moodrelated symptoms in breast cancer patients, with potential for improving pain-related symptoms as well. These findings underscore the potential of digital neuromodulation as an innovative approach to enhance the quality of life of patients with complex conditions, specifically breast cancer. Clinical trial information: NCT06136923. Research Sponsor: None.

Exploring social determinants of health and immunotherapy utilization in patients with stage III non-small cell lung cancer following definitive chemoradiation.

Chaewon Hwang, Nathaniel Stambaugh, Josephine Levey, Kathryn Huber, Daphna Spiegel; Beth Israel Deaconess Medical Center, Boston, MA; Diverging Mathematics, Boston, MA

Background: Since the approval of immunotherapy (IO) for maintenance therapy in stage III non-small cell lung cancer (NSCLC) in 2018, its use has expanded rapidly. This study aimed to evaluate patterns of IO use among diverse patient populations who received definitive chemoradiation (CRT) followed by adjuvant IO for stage III NSCLC. Methods: A retrospective analysis was performed using the National Cancer Database for patients \geq 18 years old with stage III NSCLC diagnosed between 2018 to 2021. Patients receiving \geq 60 Gy of radiation in \geq 30 fractions and IO delivered 50-150 days from starting CRT were included. Patients who underwent surgery were excluded. Social determinants of health included race, ethnicity, insurance, treatment site, Charlson-Deyo comorbidity index (CCI), high school graduation rate (HSGR; lowest, low, mid, high per US Census data), income (categorized similarly to HSGR), sex, and age. Odds ratios (OR) were calculated for IO use. Logistic regression analyses were performed for each variable followed by multivariable analysis with statistically significant factors (P < 0.05). IRB exemption was granted. Results: 25,746 patients were included: 21,848 White, 3,236 Black, 558 Asian, and 104 Native American. 620 were Hispanic. On univariate analysis, the following were predictive of IO receipt: Black vs White race (OR 0.86, P < 0.001), Hispanic vs non-Hispanic ethnicity (0.72, P < 0.001), Medicare or other governmental insurance vs private (OR 0.94, P =0.037 and 0.85, P = 0.034), CCI 1 or 2 vs 0 (1.11, P < 0.001 and 1.13, P = 0.005), community site vs academic/research center (0.88, P = 0.007), lowest and low vs high HSGR (0.78, P < 0.001 and 0.87, P < 0.001, lowest vs high income (0.90, P = 0.005), female vs male sex (1.06, P = 0.028), and age (-0.88%/year, P < 0.001). On multivariate analyses, Black patients were 3.3% less likely to receive IO than White patients (0.88, P < 0.001). Hispanic patients were 8.2% less likely to receive IO than non-Hispanic patients (0.72, P < 0.001). Medicare insurance (0.93, P = 0.012) and treatment at community sites (0.86, P = 0.002) were associated with reduced IO use. Patients from areas with lower HSGR were less likely to receive IO than those with the highest HSGR (lowest: 0.75, *P* < 0.001; low: 0.83, *P* < 0.001; mid 0.91, *P* = 0.039). Higher CCI (CCI 1: 1.12, *P* < 0.001; CCI 2: 1.13, *P* = 0.004; CCI 3: 1.10, *P* = 0.046), lower income (lowest: 1.11, *P* = 0.048; low: 1.10, P = 0.041; mid: 1.10, P = 0.025), and female sex (1.05, P = 0.048) were associated with increased IO use. Conclusions: This study highlights disparities in IO use following CRT for stage III NSCLC patients. Black race, Hispanic ethnicity, Medicare or governmental insurance, treatment at community sites, and lower education were associated with decreased IO use. These findings emphasize the need for strategies to ensure equitable access to advanced cancer therapies. Research Sponsor: None.

Food insecurity and disparities in mental health symptoms and severity among breast cancer survivors.

Kent Schechter, Jincong Q. Freeman, Long C. Nguyen, Xinyi Li, Victoria Umutoni; Ben May Department for Cancer Research, The University of Chicago, Chicago, IL; Department of Public Health Sciences, The University of Chicago, Chicago, IL; Milken Institute School of Public Health, The George Washington University, Washington, DC

Background: Breast cancer survivors (BCS) often experience mental health challenges during survivorship. Food insecurity is a growing public health concern in the US, which may exacerbate the challenges faced by BCS. However, little is known about the associations between food insecurity and mental health symptoms and severity among BCS. Methods: We conducted a secondary analysis of the 2022 National Health Interview Survey that used stratified clustering sampling to interview US adults aged \geq 18. This study was limited to women with a breast cancer history. Food insecurity (secure/insecure) was measured using a 10-item questionnaire assessing past 30-day household food situations. Ever having anxiety was selfreported (yes/no), and the severity level in the past 2 weeks was examined using the 7-item Generalized Anxiety Disorder scale. Women reported ever having a depressive symptom (yes/ no), and the 8-item Patient Health Questionnaire depression scale was used to evaluate the severity level in the past 2 weeks. We compared weighted percentages using Rao-Scott Chisquared tests and computed P-trends using the Cochran-Armitage test. We performed weighted logistic regression to estimate adjusted odds ratios (AOR). All analyses accounted for survey weights. Results: We obtained an unweighted sample of 644 BCS (weighted sample 4,234,520). Overall, 7.6% experienced food insecurity. BCS who were food insecure were younger than those secure (mean age 61 vs 69 years; P < .002). Black (20.4%) or Hispanic (24.3%) BCS were more likely than White BCS (4.7%) to experience food insecurity (P<.001). BCS who were food insecure reported a higher percentage of depression than those secure (52.9% [95% CI: 35.5-70.3%] vs 24.4% [95% CI: 20.2-28.6%]; P<.001). The proportion of anxiety was higher among BCS who were food insecure than those secure (45.4% [95% CI: 27.7-63.1%] vs 19.8% [95% CI: 16.0-23.6%]; P<.001). After controlling for demographic and socioeconomic factors, BCS who were food insecure had greater odds of depression (AOR 3.19, 95% CI: 1.42-7.17) or anxiety (AOR 3.14, 95% CI: 1.34-7.34) than those secure. Compared with BCS who were food secure, those insecure were more likely to experience moderate (26.0% vs 6.0%) or severe (7.5% vs 0.6%) depression (P-trend<.001), as well as moderate (6.4% vs 4.4%) or severe (14.5% vs 1.3%) anxiety (P-trend<.001). BCS who were food insecure also reported a higher proportion of forgoing mental health counseling due to cost than those secure (6.8% vs 1.5%; P=.02). Conclusions: Our findings highlight food insecurity prevalence and associated disparities in mental health symptoms and severity among BCS. Interventions and policies, e.g., food pantries/meals programs and nutrition assistance, are needed to address food insecurity. Cancer centers should also consider routine mental health screening and offer proper services to reduce racial disparities among BCS. Research Sponsor: National Institute on Aging; T32AG000243; Susan G. Komen Breast Cancer Foundation; TREND21675016.

Real world treatment patterns and outcomes in metastatic EGFR mutation-positive NSCLC patients: A retrospective study from a tertiary care cancer center in India.

Jyothis P. Jose, Akhil Santhosh; MVR Cancer Centre & Research Institute, Calicut, India

Background: Lung cancer is the leading cause of cancer related mortality worldwide with Non small lung cancer (NSCLC) constituting the majority of cases. EGFR mutations, predominantly exon 19 and Exon 21 L858R are actionable targets in approximately 25–30% Indian patients. Third generation EGFR tyrosine kinase inhibitors have set new benchmarks in the treatment of metastatic EGFR mutation positive NSCLC. However real world adoption in India faces significant barriers including financial constraints and healthcare disparities. Methods: Our objective was to evaluate whether patients with EGFR mutation positive metastatic NSCLC receiving the standard of care treatment and analyze demographic, clinical and molecular characteristics of EGFR mutation positive lung cancer patients treated at our center and compare treatment patterns and survival outcomes with national and global data. This retrospective study analyzed 894 stage 4 NSCLC patients treated between 2018-2023 of these 252 (28.1%) were EGFR mutation positive. Data on EGFR types, treatment modalities and survival outcomes were collected and analyzed. Kaplan Meir survival analysis was performed to estimate progression free survival (PFS) and overall survival (OS). Results: First line Osimertinib was median OS was 30 months and PFS was 20 months. The standard of care at that time received by 13.5% only. Other TKI alone (Gefitinib, Erlotinib and Afatinib) median OS was 21 months while PFS was 12 months. Other TKI with chemotherapy median OS 27 months and PFS was 18 months. Mutation specific outcomes showed exon 19 deletions had better overall survival 27 months PFS 16 months compared to Exon 21 L858R (OS 16; PFS 11 months). T790M were identified in 71% patients progressing after first line treatment. Second line osimertinib achieved a median PFS of 9.5 months. Conclusions: Despite the efficacy of osimertinib demonstrated in global trials, its adoption was limited to 13.5% of eligible patients in this cohort due to economic barriers. These findings emphasize the urgent need for systemic interventions to improve access to advanced therapies in India. Policymakers and healthcare systems must address these gaps through measures like government subsidies, expanded insurance coverage and cost effective diagnostic platforms to ensure equitable access to precision oncology in resource limited settings. Research Sponsor: None.

Racial disparities in oncology clinical trials by absolute neutrophil count eligibility criteria: A single center retrospective analysis.

Arvind Suresh, Laura Ann Huppert, Patricia A. Cornett, Andrew D. Leavitt, Marina Heskel; Department of Medicine, University of California San Francisco, San Francisco, CA; University of California San Francisco, San Francisco, CA; Division of Hematology/Oncology, University of California San Francisco, San Francisco, CA

Background: Black individuals have been historically underrepresented in clinical trials. The Duffy-null phenotype leads to clinically insignificant lower absolute neutrophil counts (ANC) and is found in 66% of non-Hispanic Blacks (NHB) and < 1% non-Hispanic Whites (NHW) in the United States. Although the ANC lower limit of normal for Duffy-null individuals is estimated to be 1,210/µL, little is known about the impact of ANC criteria on racial underrepresentation in clinical trial eligibility and enrollment. Methods: We conducted a single-center retrospective study of patients newly diagnosed with five cancers (lung, breast, prostate, colorectal, non-Hodgkin lymphoma) between 1988-2024. Baseline organ function data (Hgb, ANC, platelets, AST, ALT, creatinine, and bilirubin) were compared between NHB and NHW. We also identified ANC thresholds above which eligibility proportions differ between NHB and NHW. Results: We identified 23,854 patients. 14,585 had available baseline lab data within one year prior to starting anti-cancer therapy. The table lists the percentage of NHW and NHB who meet ANC eligibility criteria at thresholds of 1,000, 1,500, and 2,000/ μ L. Among patients with breast cancer, the median ANC was 3,500 for NHB and 3,890 for NHW (p = 0.63) and fewer NHB were eligible at all ANC thresholds of $1,500/\mu$ L or greater (94.5% NHB vs 97.2% NHW, p = 0.03). For those with prostate cancer, the median ANC was 3,780 for NHB and 4,450 for NHW (p = 0.03) and significantly fewer NHB were eligible at all ANC thresholds of $1,400/\mu$ L or greater (97.6% NHB vs 99.6% NHW, p = 0.04). For those with non-Hodgkin lymphoma (NHL), the median ANC was 4,260 for NHB and 4,020 for NHW (p = 0.34) and significantly fewer NHB were eligible at all ANC thresholds of $1,600/\mu$ L or greater (90.4% NHB vs 97.1% NHW, p = 0.008). Patients with lung cancer (ANC NHB 4,820 vs NHW 4,920; p = 0.85) and colorectal cancer (ANC NHB 3,930 vs NHW 4,150; p = 0.27) did not have significant ANC eligibility differences between NHB and NHW. No significant differences were found for other baseline labs. Conclusions: Our findings provide further evidence that ANC criteria may contribute to differences in clinical trial eligibility between NHB and NHW for breast cancer, prostate cancer, and NHL. Further work is needed to identify optimal cutoffs for each disease group. Limitations include lack of Duffy status for most patients and race is an imperfect approximation. Future clinical trials should proactively address these differences by using ANC eligibility criteria based on Duffy phenotyping. Research Sponsor: UCSF Department of Epidemiology and Biostatistics.

Cancer (n=NHB; NHW)	NHB ANC >2000	NHW ANC >2000	p value*	NHB ANC >1500	NHW ANC >1500	p value*	NHB ANC >1000	NHW ANC >1000	p value*
Lung (n=73; 726)	90.4%	94.4%	0.27	93.2%	97.4%	0.10	95.9%	99%	0.08
Breast (n=237; 2,905)	86.1%	92.7%	<0.001	94.5%	97.2%	0.03	98.7%	99%	0.99
Prostate (n=124; 961)	88.6%	97.8%	<0.001	96.8%	99.4%	0.02	100%	99.9%	-
Colorectal (n=80; 800)	87.5%	93.5%	0.08	100%	98.6%	-	100%	99.9%	-
NHL (n=103; 1,414)	76.7%	85.6%	0.02	87.4%	90.2%	0.39	94.2%	93.6%	1.0

*Calculated by Chi-squared tests.

Factors associated with receipt of surveillance breast MRI among racially/ethnically diverse women with a personal history of breast cancer.

Preeti Kakani, Vicky Ro, Julia Elizabeth McGuinness, Katherine D. Crew; Columbia University Irving Medical Center, New York, NY; Columbia University Medical Center, New York, NY; Herbert Irving Comprehensive Cancer Center, Columbia University Medical Center, New York, NY

Background: Surveillance breast imaging among breast cancer (BC) survivors is recommended for early detection of local recurrence or contralateral BC. Breast MRI is increasingly used as a screening modality given its heightened sensitivity compared to mammography, and in 2018, the American College of Radiology released guidelines recommending supplemental breast MRI among women diagnosed with BC under age 50 or with dense breasts. We investigated demographic and clinical factors associated with receipt of surveillance breast MRI among women with a personal history of BC. Methods: We conducted a retrospective cohort study of women with stage 0-III BC between January 2018-June 2023 at Columbia University Irving Medical Center in New York, NY. We excluded women with bilateral mastectomies. The primary outcome was receipt of at least one breast MRI > 1 year after initial diagnosis. Data from the electronic health record included age at diagnosis, race/ethnicity, primary language, health insurance, first degree family history of BC, germline genetic testing results, stage at diagnosis, mammographic density (MD), and BC treatments (surgery, radiation, chemotherapy, and hormonal therapy). We performed multivariable logistic regression to assess factors associated with receipt of surveillance breast MRI. Results: Among 1,990 evaluable patients, mean age was 59.7 years (SD 12.2), and the cohort included 14% non-Hispanic Black, 33% Hispanic, and 6% Asian women. About 22% of women were diagnosed before age 50, 53% had dense breasts (BIRADS C-D), and 18% received at least one surveillance breast MRI > 1 year after diagnosis. On adjusted analysis, younger age at diagnosis, higher MD, first-degree family history of BC, receipt of germline genetic testing, and having a germline pathogenic variant were associated with receipt of breast MRI. Compared to non-Hispanic White women, Hispanic and non-Hispanic Black women had lower odds of receiving breast MRI (odds ratio [OR] = 0.44, 95% confidence interval [CI] = 0.31-0.63 and OR = 0.57, 95% CI = 0.38-0.86, respectively). However, compared to patients with commercial insurance, those with Medicaid were more likely to undergo breast MRI (OR = 1.57, 95% CI = 1.10-2.25). Results were similar when restricting the analysis to those diagnosed before age 50 or with dense breasts. Conclusions: Hispanic and non-Hispanic Black women with BC were less likely to receive surveillance breast MRI than their non-Hispanic White counterparts. Also, as patients with Medicaid were more likely to undergo breast MRI than those with commercial insurance, there may be varying health insurance coverage for breast MRI. These results highlight the need for more standardized guidelines surrounding surveillance breast MRI among BC survivors, which may inform public health initiatives aimed at promoting equitable breast imaging practices in this population. Research Sponsor: None.

Meeting enrollment targets in IMbrave152/SKYSCRAPER-14, a global phase 3 study in patients with unresectable hepatocellular carcinoma (HCC).

Christopher Cotter, Ruma Bhagat, Huwaida Bulhan, Patty Leon, Ya-Chen Lin, Nicole Richie, Renee Sims, Jessica Spahn, Michael Stamatis, Lisa Yalovsky, Huaqi Zhu, Yasmin Ibrahim; Genentech, Inc., South San Francisco, CA; Roche Kenya Limited, Nairobi, Kenya; Roche Products Limited, Welwyn Garden City, United Kingdom; Roche China, Shanghai, China; Hepatitis B Foundation, Doylestown, PA

Background: The FDA has released guidance that the patient population in clinical studies should be representative of the intended-use population and the epidemiology of the disease, particularly in terms of race and ethnicity. IMbrave152/SKYSCRAPER-14 (NCT05904886) is a global phase 3 trial in patients with HCC, a disease with a globally high Asian and African prevalence, and which significantly impacts underrepresented (including Black and Hispanic) patients in the USA. Enrollment goals (by race/ethnicity), as well as operational and protocoldriven tactics to meet those goals, were implemented for IMbrave152. As of January 2, 2025, the targets for Black and Hispanic patients were met. Methods: Global recruitment began on September 14, 2023. Operational tactics included: feasibility questions about the ability to recruit underrepresented populations; utilization of internal and external databases to identify sites that could enroll underrepresented patients; incorporation of patient input; and enhanced patient-support services to facilitate recruitment and retention. Protocol-driven tactics included: modifying inclusion and exclusion criteria (considering race/ethnicity); streamlining study assessments; flexibility to use decentralized processes; and inclusion of an Africa Extension Cohort, which allowed for the recruitment of patients in Africa beyond the intent-to-treat population. Results: As of January 2, 2025, the randomized, global population included 8% Black and 14% Hispanic patients (US recruitment included 16% Black and 19% Hispanic patients), exceeding other global HCC studies, which recruited 2% or fewer Black patients and 11% or fewer Hispanic patients. Only two out of seven phase 3 studies in recent years have reported on Hispanic patient recruitment. Conclusions: IMbrave152 recruited the highest percentage of Black and Hispanic patients to date in a global phase 3 HCC study. These results demonstrate that recruitment of an underrepresented population is feasible if operational and protocol-driven tactics are utilized. Clinical trial information: NCT05904886. Research Sponsor: F. Hoffmann-La Roche Ltd.

Study	White, %	Asian, %	Black, %	Hispanic, %	Global enrollment from Asia (excl. Japan), %
IMbrave152	32.7	54.7	8.0	13.6	46.7
IMbrave150 ¹	34.9	56.7	2.0	NR	40.1
REFLECT ²	28.9	69.2	NR	NR	67.1*
HIMALAYA ³	44.5	50.9	1.6	4.7	40.9
LEAP-002 ⁴	43.5	43.5	1.6 ⁺	11.2	30.7
CheckMate-459 ⁵	53.2	44.7	0.7	NR	25.3
RATIONALE-301 ⁶	NR	NR	NR	NR	63.1
COSMIC-3127	50.9	31.4	1.7	NR	28.8

¹Finn et al. NEJM 2020;

²Kudo et al. Lancet 2018;

³Abou-Alfa et al. NEJM Evid 2022;

⁴Llovet et al. Lancet 2023;

⁵Yau et al. Lancet Oncol 2022;

⁶Qin et al. JAMA Oncol 2023;

⁷Kelley et al. Lancet Oncol 2022.

NR, not reported.

*Asia-Pacific region.

[†]Multiple races, including 9 additional patients who were Black plus either Asian or White, were also reported.

Intervention adherence, engagement and tool utilization in the breast cancer weight loss (BWEL) trial by race and ethnicity (Alliance A011401).

Ashley Odai-Afotey, Linda Mackie McCall, Karla V. Ballman, Chao Cao, Pamela Jean Goodwin, Vanessa Bernstein, Linda Delahanty, Dawn L. Hershman, Judith O. Hopkins, Erica L. Mayer, Electra D. Paskett, Patricia Spears, Vered Stearns, Anna Weiss, Julia R. White, Thomas Wadden, Eric P. Winer, Lisa A. Carey, Ann H. Partridge, Jennifer A. Ligibel; Dana-Farber Cancer Institute, Boston, MA; Alliance for Clinical Trials in Oncology, Durham, NC; Mayo Clinic, Alliance for Clinical Trials in Oncology, Rochester, MN; Mount Sinai Hospital-Breast Medical Oncology, Toronto, ON, Canada; BC Cancer Agency Vancouver Island Centre, Victoria, BC, Canada; Massachusetts General Hospital, Boston, MA; Herbert Irving Comprehensive Cancer Center, Columbia University Irving Medical Center, New York, NY; Southeast Clinical Oncology Research Consortium and NCORP, Winston Salem, NC; Medical Oncology, Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA; Department of Internal Medicine, The James Comprehensive Cancer Center, College of Medicine, The Ohio State University Wexner Medical Center, Columbus, OH; Lineberger Comprehensive Cancer Center, The University of North Carolina at Chapel Hill, NC; Weill Cornell Medicine, New York, NY; Department of Surgery, University of Rochester, Rochester, NY; University of Kansas Medical Center Comprehensive Cancer Center, Kansas City, KS; University of Pennsylvania, Philadelphia, PA; Yale Cancer Center, New Haven, CT; Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA

Background: Black and Hispanic breast cancer (BC) survivors have a higher prevalence of obesity and experience less success with weight loss interventions (WLI) than White BC survivors. The BWEL trial (Alliance A011401; NCT02750826) is a phase III randomized trial evaluating the impact of a 2-year telephone-based WLI on invasive disease-free survival in participants (pts) with stage II-III HER2-negative BC and a BMI \ge 27 kg/m². At 12-months, the WLI induced significant weight loss across demographic factors, including race and ethnicity. However, Black and Hispanic pts lost less weight and completed fewer calls than White pts. Here, we evaluate intervention adherence, engagement and tool utilization in BWEL pts by race and ethnicity. Methods: BWEL randomized pts to a WLI plus health education (HE) or HE alone. WLI pts received semi-structured telephone-based health coaching, delivered in English or Spanish, and received an activity monitor and wireless scale. Pts self-reported race and ethnicity. Mean values for call duration, call density (time to complete the initial 12-week intensive intervention phase), intervention attrition, and frequency of Fitbit use and weight tracking over 12-months were compared by race and ethnicity, comparing least squares means with Tukey-Kramer adjustment for multiple comparisons with adjusted p-values. Results: Of 3181 pts randomized to the study between 08/2016 and 02/2021, 1591 pts were allocated to the WLI arm. 80.5% of pts were White, 12.8% Black, and 7.1% Hispanic. Average BMI was 34.5 (±5.7) kg/m2. Compared to White pts, Black pts had fewer days of Fitbit usage (113.6 vs. 159.8, p<0.0001) and weight tracking (77.9 vs. 135.6 days, p<0.0001). Hispanic pts had fewer days of Fitbit usage (108.8 vs. 154.9, p= 0.001) and weight tracking (87 vs. 129.5 days, p=0.0002) compared to non-Hispanic pts. There were no differences in attrition rate, average call duration, or call density by race or ethnicity. Conclusions: In a phase III WLI trial, engagement with tools designed to support weight loss was significantly lower in Black and Hispanic pts. Future work is needed to explore ways to enhance engagement and improve weight loss outcomes for racial and ethnic minority pts. Support: U10CA180821, U10CA180882, UG1CA189823; https://acknowledgments.alliancefound.org. Clinical trial information: NCT02750826. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health.

		Race		Ethnicity			
Measure of engagement	White N=1281	Black N=204	p-value	Non- Hispanic N=1459	Hispanic N=113	p-value	
Withdrew from intervention n (%)	58 (4.5%)	13 (6.4%)	0.56	70 (4.8%)	6 (5.3%)	0.51	
Call Duration (min) Mean (SD)	34.5 (7.6)	34.6 (9.1)	0.99	34.6 (7.8)	33.3 (7.9)	0.25	
Call density (weeks) Mean (SD)	14.2 (7.2)	14.2 (8.8)	0.99	14.2 (7.3)	14.2 (9.7)	0.99	
Days of Fitbit Use Mean (SD)	159.8 (132.2)	113.6 (124.7)	< 0.0001	154.9 (131.8)	108.8 (125.7)	0.001	
Days of weight tracking Mean (SD)	135.6 (109.5)	77.9 (87.5)	< 0.0001	129.5 (108.8)	87 (96.5)	0.0002	

Breast cancer optimal care timeframes for culturally and linguistically diverse populations and First Nations People: A regional centre experience in Australia.

Matthew Hon, Malar Htut, Amy Brown, Sabe S. Sabesan, Corinne Ryan, Zulfiquer Ali Otty, Joanne Tan, Nathan Bain, Jun Beng Kong, Shivanshan Pathmanathan, Abhishek Jagdish Joshi; Townsville University Hospital, Douglas, QLD, Australia

Background: Culturally and linguistically diverse (CALD) populations and First Nations People are at-risk communities who face unique challenges in cancer diagnosis and management resulting in inequities. Optimal Care Pathways (OCP) established by Cancer Council Australia aim to address these disparities. The Breast cancer OCP outlines an integrated model of care with optimal timeframes such as time from general practitioner (GP) referral to specialist surgical review, time from decision to treat to surgery or neoadjuvant chemotherapy (NAC), and time from completion of NAC to surgery. Methods: Retrospective data was collected for all CALD (migrant from non-English speaking country and/or primary language identified as not English) and First Nations patients diagnosed with breast cancer treated at a regional centre in Australia (Townsville University Hospital) from 2018 – 2022. A comparison cohort (control) of consecutive non-CALD, non-First Nations patients was included. Data collected included patient demographics, tumour characteristics, stage, and identified timeframes which were compared with OCP. Results: 133 patients were included with 43 CALD (32%), 41 First Nations (31%) and 50 control (37%). CALD and First Nations cohorts had higher rates of stage IV disease at diagnosis (12 v 15%) compared to control cohort (0%). They were also more likely to be diagnosed via emergency department admission (CALD 16 v First Nations 7%) compared to control cohort (0%) suggesting later presentation. Of those referred through OCP defined GP pathway, a similar percentage were reviewed by specialist surgeon within optimal 2-week timeframe in all groups (CALD 47%; First Nations 39%; control 44%). Median time from decision to treat to surgery were longer in CALD versus control groups (19 v 13 days; p = 0.03), and in First Nations versus control groups (22 v 13 days; p = 0.02). Less CALD (89%, n = 24) and First Nations (82%, n = 18) patients underwent surgery within optimal 5-week timeframe compared to control (98%, n = 40). Similarly, median time from decision to treat to NAC were longer in CALD versus control groups (19 v 14 days; p = 0.05), and First Nations versus control groups (20 v 14 days; p = 0.03). Most patients (91%, n = 29) commenced NAC within optimal 4week timeframe; 2 CALD and 1 First Nations patients did not. Median time from completion of NAC to surgery was longer in CALD versus control groups (29 v 24 days; p = 0.15), and in First Nations versus control groups (35 v 24 days; p = 0.04). Of those who recieved NAC, 100% CALD (n = 9), 69% First Nations (n = 9), and 89% control (n = 8) patients underwent surgery within optimal 4-week timeframe. Conclusions: Achievement of key OCP timeframes was lower in both CALD populations and First Nations People. Strategies need to be further developed to address the delays and health outcome disparities in these vulnerable cohorts. Research Sponsor: None.

Continuous financial toxicity screening in community oncology.

Thomas Gregory Knight, Beth York, Sangita Paul, Kayla Barlow, Declan Walsh; Atrium Health Levine Cancer Institute, Wake Forest University School of Medicine, Charlotte, NC; Atrium Health Levine Cancer Institute, Charlotte, NC

Background: Financial Toxicity (FT) has been repeatedly linked with adverse cancer clinical outcomes. However, screening practices vary widely, especially in community settings where < 50% routinely proactively engage patients to discuss care costs. This quality improvement pilot examined the feasibility and impact of continuous FT screening in a community-based clinical practice. Methods: Using PDSA methodology, an electronic distress screening (EDS) tool was implemented at each visit at two rural oncology practices. Evidence of FT was defined as answering "yes" to the question "Do you have insurance/financial problems or concerns?" The EDS tool would automatically email the financial navigation (FN) team on "yes" response and patients were contacted by FN within 48 hours. Contact was attempted at least 3 additional times if unable to be reached. Four successive monthly PDSA cycles ran from April to July 2024. In addition to demographic trends, success metrics were: % of screened patients with FT; % of FT patients new to the FN team; number and types of resolutions of FT concerns; and satisfaction and feasibility survey of clinical teams and patients. Results: In the 4-month study,1071 patients were screened using the EDS tool: 169 (16%) affirmed FT. Of those with FT concerns, 140 (83%) were new to FN. The FN team provided a primary resolution to 85 patients of 169 (50%) who alerted. Of the remainder, 45 (27%) could not be contacted after multiple attempts and 39 (23%) reported clicking in error. Primary resolutions included: Charity Care Program Referral (36%), Financial Teaching (29%), Billing Changes (11%), Social Work Referral (9%), Medication Assistance (6%), and Marketplace Insurance Obtained (5%). The patients receiving FN services were majority female (75%) and between 35 and 64 yo (57%). The most prevalent cancer types were Blood/Marrow (35%) and Breast (31%). 66% were white, 24% African American, and 14% Hispanic. Payors included 40% commercial insurance, 31% Medicare, 19% Medicaid, and 9% other. Geographically, 62% of patients resided in rural areas, 24% suburban, and 4% urban. Patient satisfaction with FN was high across all categories; 55% agreed or strongly agreed that FN services helped lower stress about bills. Scores were highest for "FN cared about my concerns and needs" (69%); "would recommend it to others in need" (63%); and "information from FN was clear and easy to understand" (61%). The clinic teams survey in participating locations felt the EDS screening tool was feasible in their practice environment (67%) and reported they felt routine FT screening was useful for patients (67%) (n=9). Conclusions: Structured implementation of routine FT screening with an EDS tool in a rural, oncology community practice is feasible with high patient and clinical team satisfaction and may allow for earlier identification of at-risk patients. Future directions include screening questionnaire refinements and expansion to other clinical sites. Research Sponsor: None.

Socioeconomic- and insurance-based inequities in Oncotype DX testing and scoreguided treatment.

Courtney Williams, Jessica M. Shuey, Joud El Dick, Nusrat Jahan, Erica Michelle Stringer-Reasor, Andres Azuero, Gabrielle Betty Rocque; University of Alabama at Birmingham, Birmingham, AL; University of Alabama at Birmingham, Division of Hematology and Oncology, Birmingham, AL

Background: Personalized approaches to breast cancer treatment are increasingly guided by expensive, lab-based genomic testing like Oncotype DX (ODX) Breast Recurrence Score Test.Little is known about how socioeconomic and insurance status may affect utilization of ODX testing and subsequent ODX score-guided treatment. Methods: This retrospective cohort study included women diagnosed with an early-stage, HR+/HER2- breast cancer from 2011-2023 within the nationwide Flatiron Health electronic health record-derived deidentified database. Socioeconomic status was measured by the Yost index, a census block-level measure of neighborhood deprivation. Insurance status was captured at time of diagnosis. Utilization of ODX testing was compared descriptively. Likelihood of receiving adjuvant chemotherapy by neighborhood deprivation or insurance status was estimated using relative risk, predicted probabilities, and 95% confidence intervals from adjusted Poisson models with robust variance estimates. Analyses were stratified by age due to differing recurrence risk score categorizations. ODX scores indicating low or low/medium recurrence risk suggests chemotherapeutic benefit will likely not outweigh risk of side effects, while scores indicating medium or high recurrence risk suggests chemotherapeutic benefit will likely outweigh risk of side effects. Results: Of 4,367 patients eligible for ODX testing, mean diagnosis age was 62 years (SD 12), 77% were white, 69% had stage I cancer, 8% had \geq 1 comorbidity, 48% were commercially insured, and 30% lived in a highly deprived neighborhood. Compared to those without, patients with an ODX test (46%, n = 2,026) were more often white (81% vs. 74%), commercially insured (51% vs. 45%), or lived in a neighborhood of low deprivation (73% vs. 67%). For patients aged \leq 50 with ODX testing (n = 370), 51%, 25%, 12%, and 12% had low, low/medium, medium, and high recurrence risk. Of those with low recurrence risk, patients who resided in neighborhoods of low vs. high deprivation had 9% higher probability of receiving potentially inappropriate overtreatment with adjuvant chemotherapy (15%, 95% CI 10-25% vs. 6%, 95% CI 2-24%). Of those with low/medium recurrence risk, publicly vs. commercially insured patients were 2.7x more likely to receive adjuvant chemotherapy (RR 2.71, 95% CI 1.00–7.39). For patients aged > 50 with ODX testing (n = 1,656), 83% and 17% had low and high recurrence risk. Of those with high recurrence risk, patients who resided in neighborhoods of high vs. low deprivation were 18% less likely to receive recommended adjuvant chemotherapy, suggesting undertreatment (RR 0.82, 95% CI 0.67-1.00). Conclusions: Socioeconomic- and insurance-based inequities, including both overtreatment and undertreatment, were observed in this national cohort of women with early stage breast cancer eligible for ODX testing, indicating opportunities to increase care quality. Research Sponsor: Flatiron Health.

Empowering minority patients: A tailored education initiative for clinical trial awareness in thoracic oncology.

Tadana Angelica Vazquez Rothschuh, Keishla Marie Arce-Ruiz, Steve Sutton, Avani Mira Singh, Jenifer Ryan, Ashley Oates, B. Lee Green, Jhanelle E. Gray, Shannon Christy, Vani Nath Simmons, Bruna Pellini; Ponce Health Sciences University, Ponce, PR, Puerto Rico; H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL; H Lee Moffitt Cancer Center, Tampa, FL

Background: Minority populations are underrepresented in clinical trials. Underrepresentation stems from multiple barriers that include restrictive eligibility criteria, systemic inequities, and patient-related factors. Effective educational interventions are needed to address barriers toward increasing minority patient understanding and participation in clinical trials. Despite their potential, video-based, culturally tailored interventions for minority patient education on clinical trials remain understudied and underutilized. Methods: We developed 3 brief (<5 min) culturally tailored educational videos about clinical trials in thoracic oncology for Black (English) and Hispanic/Latino patients (English and Spanish). Patients completed pre- and immediate post-video surveys to assess knowledge about, attitudes toward, and willingness to participate in clinical trials. Inclusion criteria included age \geq 18 years, diagnosis of stage I-IV lung cancer, ECOG performance status 0-2, self-identification as Black or Hispanic/Latino, proficiency in English or Spanish, and access to an electronic device. Feasibility was measured by participant recruitment rates, completion of pre-and post-video surveys, and video acceptability via self-reported satisfaction. Results: Between April and September 2024, 54 patients were approached, and 30 (56%) were successfully enrolled (Table). Among those approached, 4 were ineligible, and 20 declined participation. All enrolled patients completed the pre- and post-video surveys. Over 90% reported high satisfaction with the videos. The total knowledge score increased significantly following the intervention (p < .001). For specific items, significant improvements were observed in understanding pre-clinical studies (p = .012), placebo use (p = .001), and clinical trial registration (p = .012). After the videos, over 90% of patients believed that clinical trials are useful and play an important role in developing new drugs and improving lung cancer outcomes. Potential barriers were observed in ~50% of patients, including concerns with informed-consent language, randomization, costs, and healthcare team communication style. There was a significant increase in willingness to participate in a clinical trial after watching the educational videos (p=.04). Conclusions: Our culturally tailored, patient-centered educational videos on clinical trials in thoracic oncology were both feasible and well-accepted. Future studies should explore whether such interventions can increase minority patient enrollment in therapeutic clinical trials. Research Sponsor: Moffitt Cancer Center Foundation; Bristol Myers Squibb Foundation; Fundacion Intellectus; National Cancer Institute/U.S. National Institutes of Health; U54 CA163068.

Patient demographics.			
Variable	Level	N = 30	%
Preferred Language	English	23	76.7
	Spanish	7	23.3
Age Group	30-49	5	16.7
5	50-69	12	40.0
	70-89	13	43.3
Sex at Birth	Female	19	63.3
	Male	11	36.7
Race	White	10	33.3
	Black/AA	16	53.3
	Other	4	13.3
Ethnicity	Not Hispanic	15	50.0
-	Hispanic	15	50.0

Development of a culturally tailored educational tool designed to increase access to somatic testing among Black men with metastatic prostate cancer (mPCa).

Christopher Johns, Hala Borno, Samuel L. Washington III, Wesley Robinson, Miriam Perales, Rahul Raj Aggarwal, Rohit Bose, Jonathan Chou, Arpita Desai, Kelly N. Fitzgerald, Terence W. Friedlander, Vadim S Koshkin, Ivan de Kouchkovsky, Elizabeth Pan, Eric J. Small, Noah Spector Younger, Xiaolin Zhu, Franklin W. Huang, Daniel H. Kwon; University of California, San Francisco, San Francisco, CA; Helen Diller Family Comprehensive Cancer Center, San Francisco, CA; Department of Urology, University of California, San Francisco, CA; Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco, San Francisco, CA; University of California, San Francisco, San Francisco, CA; University of California, San Francisco, Helen Diller Family Comprehensive Cancer Center, San Francisco, CA; University of California, San Francisco, Medical Center, San Francisco, CA; University of California, San Francisco, San Francisco, CA; University of California San Francisco, CA; Department of Medicine, Division of Hematology/Oncology, University of California, San Francisco, San Francisco, CA

Background: Somatic testing (ST), also known as molecular profiling, has become increasingly important for therapy selection in men with mPCa. Interventions targeting known racial inequities in the use of ST are lacking. Our objective was to design a culturally tailored educational tool to augment patient education with the ultimate goal of increasing equitable access to ST for Black patients with mPCa. Methods: We used principles of human-centered design to develop a ST educational tool. We first designed a prototype with key stakeholders, then conducted a qualitative study of Black patients with mPCa at three sites – a tertiary care academic center, a VA medical center, and a safety net oncology clinic. Trained interviewers conducted semi-structured interviews to explore patients' perceptions of ST and elicit feedback about the educational tool until data saturation was met. Based on this feedback, we iteratively revised the tool. Interviews were transcribed, and two coders qualitatively analyzed transcripts using the COM-B framework to identify barriers/facilitators of tool use. Results: For the initial prototype, four physicians, one genetic counselor, and two patients contributed to the design of a 7-min video of a Black oncologist with informative animations followed by a text-based decision aid. We approached 18 patients, of whom 11 (61%) consented to review the tool then complete the interview. All participants expressed a positive perception of the tool and comprehension of the information. Tool facilitators included 1) trust in the tool, 2) actionability of the tool's content, and 3) appreciation for a Black physician featured in the video. Barriers included 1) difficulty navigating the electronic interface, 2) negative emotions from reflection on their cancer diagnosis or racial inequities, 3) too much information in the decision aid, particularly about biopsy risks and testing costs, and 4) content concerns on risks associated with ST/biopsy. For participants' perceptions of ST, facilitators included 1) desire to learn more about mPCa and 2) motivation to improve their health, their family's health, or the health of the Black community. Barriers included 1) misinformation about ST and mPCa, 2) difficulty accessing affordable healthcare, 3) mistrust of the healthcare system due to prior negative experiences, and 4) belief that mPCa and its treatments are emasculating. Overall, 10/11 patients reported planning to either discuss ST with their oncologist (7/11) or obtain ST (5/11). **Conclusions:** We successfully designed an educational tool for pre-test education about ST for Black men with mPCa. This educational tool was well received and may have contributed to PCa patients further pursuing somatic testing. Further evaluation of the feasibility, acceptability, and efficacy of this educational tool is warranted. Research Sponsor: Prostate Cancer Foundation.

Comparative analysis of demographics and outcomes in young versus average onset hospitalized gastrointestinal cancer patients in New York State.

Mrinalini Ramesh, Yasmin Fakhari-Tehrani, Sawyer Bawek, Guangwei Yuan, Han Yu, Lauryn Rudin, Nour Nassour, Beas Siromoni, Deepak Vadehra, Sarbajit Mukherjee; University at Buffalo, Buffalo, Buffalo, NY; Department of Internal Medicine, University at Buffalo, Buffalo, NY; Roswell Park Comprehensive Cancer Center, Buffalo, NY; Department of Medicine, Jacobs School of Medicine, University at Buffalo, NY; University of South Dakota, Vermillion, SD

Background: Recent studies have shown an increasing incidence of gastrointestinal (GI) cancers among young patients. This study investigates clinical outcomes and healthcare utilization among young (< 50) versus average onset (\geq 50) GI cancer patients admitted to hospitals in New York State (NYS). Methods: We performed a retrospective analysis using the Statewide Planning and Research Cooperative System (SPARCS) database from 2009 to 2022. Patients were divided into two groups: young-onset GI cancer patients (YOGIC, < 50 years) and average-onset GI cancer patients (AOGIC, \geq 50 years). GI cancers included anal, biliary tract, colorectal, esophageal, gallbladder, liver, pancreatic, peritoneal, small intestine, and stomach cancers. The study population was further stratified by demographic and clinical characteristics. All variables were compared using the Kruskal-Wallis test or Fisher's exact test, along with multivariate linear and logistic regression in RStudio version 4.4.2, with a significance level of $p \le 0.05$. Clinical characteristics, including severity of illness and risk of mortality, were defined using the All Patient Refined (APR) grading system. Results: A total of 256,924 patients were identified (26,071 YOGIC and 230,853 AOGIC) with a primary admitting diagnosis of a GI cancer from 2009 to 2022. The AOGIC group had a higher proportion of white and female patients, whereas the YOGIC group included a higher proportion of black and male patients (p < 0.001). Anal, peritoneal, and stomach cancers were more prevalent in YOGIC, while pancreatic and esophageal cancers were more common among AOGIC (p < 0.001). AOGIC patients were more likely to have extreme (13% vs. 9.7%) or major (39% vs. 32%) severity of illness compared to YOGIC (p < 0.001). However, the median total cost of stay for YOGIC was significantly higher than that for AOGIC (\$21,421 vs. \$19,658 respectively, p < 0.001). YOGIC patients were more likely to undergo procedures during hospitalization (95%) compared to AOGIC (93%) (p <0.001). YOGIC patients were more likely to be discharged home (66%) vs. AOGIC (48%) (p <0.001). Longer hospital stays were associated with patients diagnosed with esophageal, peritoneal, and stomach cancers (p < 0.001) versus the reference group (anal cancer), and in AOGIC [log fold-change 0.029 (95% CI: 0.021-0.038), p < 0.001]. Despite a higher mortality risk in AOGIC, mortality rates decreased faster over the study period [OR 0.97 (95% CI: 0.96-0.98), p < 0.001]. Conclusions: AOGIC patients experience a higher risk for mortality and longer hospital stays. However, YOGIC patients undergo further procedural interventions and have been found to have higher inpatient admission costs. Policies focused on earlier outpatient interventions may alleviate the burden on inpatient care. Research Sponsor: This work was supported by funding from the National Cancer Institute. The study's design and decision to publish were independent of any involvement from the funding sources.

CARE DELIVERY/MODELS OF CARE

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Assessing the effects of financial toxicity on quality of life among hematopoietic stem cell transplantation recipients.

Grace Ann Hanvey, Janae Kirsch, Eleshia Morrison, Christi A Patten, James Robert Cerhan, Tabetha Brockman, William J. Hogan, Shahrukh Hashmi, Shawna L. Ehlers; Mayo Clinic, Rochester, MN; Division of Hematology, Mayo Clinic, Rochester, MN; Department of Psychiatry & Psychology, Mayo Clinic Rochester, Rochester, MN

Background: "Financial toxicity" refers to the financial burden imposed by treatment costs on individuals with cancer, constituting a major barrier to achieving equitable cancer outcomes. Recent literature increasingly demonstrates the detrimental impacts of financial toxicity on quality of life (QOL) among individuals with cancer, including individuals who have undergone hematopoietic stem cell transplantation (HSCT). This study evaluates associations among treatment cost burden and various aspects of QOL following HSCT. Methods: Seven hundred one HSCT recipients completed a survey examining their biopsychosocial health one year following transplant. The survey included the Functional Assessment of Cancer Therapy – Bone Marrow Transplantation (FACT-BMT), a multifactorial measure of QOL specific to this population. Treatment cost burden endorsement was measured on a 5-item Likert scale. Hierarchical regression models were developed to assess the incremental effects of demographic characteristics (i.e., Block 1), clinical predictors (Block 2), and cost burden (Block 3) on physical, emotional, social, functional, BMT-specific, general, and composite QOL outcomes. Results: Significant model improvement was observed with the addition of clinical factors ($\Delta F(2,650) =$ 20.28, p < .001), and subsequently, treatment cost burden ($\Delta F(1,649) = 110.29$, p < .001). In the final model, higher cost burden was associated with poorer physical ($\beta = -0.323$, p < .001), emotional (β = -0.301, *p* < .001), social (β = -0.250, *p* < .001), functional (β = -0.317, *p* < .001), BMT-specific (β = -0.341, p < .001), general (β = -0.377, p < .001), and composite QOL (β = -0.381, p < .001). Poorer performance score was associated with each QOL indicator (p < .001), with allogeneic transplant type associated with poorer functional ($\beta = -0.001$, p = .002), but higher emotional ($\beta = 0.118$, p = .002), wellbeing. Older age ($\beta = 0.113$, p = .003) and female sex predicted higher ($\beta = 0.183$, p < .001), while Hispanic ethnicity predicted poorer ($\beta = -0.095$, p =.010), social wellbeing. Female sex was associated with poorer QOL specific to BMT concerns (β = -0.118, p = .001). **Conclusions:** Higher treatment cost burden is associated with poorer overall QOL and its physical, emotional, social, functional, and BMT-specific components one year following HSCT, after controlling for demographic and clinical characteristics. This reflects a critical barrier to equitable cancer care, suggesting that financial toxicity may perpetuate preexisting inequities in QOL, treatment, disease, and survival outcomes that disproportionately impact the underserved. Future research should prioritize 1) better understanding relationships among complex indicators of financial toxicity, QOL, and their underpinning mechanisms and 2) developing solutions to mitigate financial toxicity of HSCT and overall cancer care. Research Sponsor: U.S. National Institutes of Health.

Early post-operative opioid fills after cancer-directed surgery among Medicare beneficiaries by race and ethnicity.

Ashley Odai-Afotey, Xu Wang, Pang-Hsiang Liu, Inga Van Wieren, Mary Beth Landrum, Nancy Lynn Keating, Alexi A. Wright, Andrea Catherine Enzinger; Dana-Farber Cancer Institute, Boston, MA; Harvard Medical School, Boston, MA; Department of Health Care Policy, Harvard Medical School, Boston, MA

Background: Post-operative pain is often underestimated and undertreated. Researchers have shown that Black patients receive fewer opioids than White patients across multiple settings and conditions; however, little is known about whether post-operative opioid prescribing for cancer-directed surgery differs by race and ethnicity. We characterized racial and ethnic differences in opioid fills among Medicare beneficiaries undergoing cancer-directed surgery. Methods: Using 100% Medicare data for fee-for-service beneficiaries enrolled in parts A, B, and D, we identified episodes of cancer-directed surgeries from 2012-2021 among adults who survived > 30d after surgery and were discharged home. We used Part D claims to identify opioid prescriptions filled in the 30d after outpatient surgeries and the 30d after hospital discharge for inpatient surgeries, overall and among non-Hispanic White (NHW), Black (NHB), Hispanic, and Asian patients. Results: Among 981,702 surgical episodes (mean age 73 [SD 8] years, 36% male), 83% were NHW, 8% NHB, 4% Hispanic and 2% Asian patients. Most surgeries were for breast (38%), colorectal (15%), prostate (13%), or lung (10%) cancers. Most (67%) patients with surgical episodes had an opioid fill within 30d, with a mean dose of 246 morphine milligram equivalents (MMEs) in the first prescription, and a mean total dose of 360 MMEs filled within 30d of surgery or discharge. On average, patients filled 1.4 opioid prescriptions, with a mean of 9-days' supply in the 30d after surgery or discharge. NHB patients had the highest rate of opioid prescription, doses, and days' supply; Asian patients had the lowest rate of opioid prescriptions, doses, and days' supply (Table). Findings among Hispanic patients mirrored NHW patients. Conclusions: Among Medicare beneficiaries undergoing cancerdirected surgeries in 2012-2021, two-thirds of surgical episodes were associated with an opioid fill. In contrast to prior studies of opioid fills among cancer patients, we observed the highest opioid fills among Black patients. Future work is needed to understand the association of time and patient, physician, and healthcare factors on post-operative opioid prescribing and to understand the association of opioid prescribing with pain control. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health.

Outcome in 30d	Overall	NHW	NHB	Hispanic	Asian
Mean (SD)	(n=981702)	(n=815966)	(n=77932)	(n=42663)	(n=21087)
Filling an opioid n (%)	653883 (67%)	538183 (66%)	58323 (75%)	28866 (68%)	12937 (61%)
MMÈ, first prescription	246 (320)	245 (318)	271 (350)	243 (318)	211 (210)
Total MME in 30d	360 (566)	356 (563)	420 (620)	358.9 (565)	276 (374)
# of fills	1.4 (0.8)	1.4 (0.8)	1.5 (0.8)	1.4 (0.8)	1.3 (0.6)
Days prescribed	9 (9)	9 (9)	10 (10)	9 (9)	8 (7)

MME=morphine milligram equivalents.

Disaggregating Asian American and Pacific Islander subgroups to evaluate disparities in breast cancer characteristics and outcomes.

Shawn Michael Doss, Alicia H. Arnold, Daniel Milgrom, Danny Yakoub; Medical College of Georgia, Augusta, GA

Background: When Asian American and Pacific Islander (AAPI) subgroups are aggregated under the labels "AAPI" or "Asian," subgroup-specific differences in breast cancer (BC) presentation and outcomes may be masked. Potential overlooked disparities among these diverse groups remain understudied. We analyzed BC characteristics and outcomes among regional AAPI subgroups. Methods: From the National Cancer Database (2009–2020), we identified patients diagnosed with stage I–IV BC, excluding patients missing race or stage. Multivariate logistic regression examined odds of advanced stage (III-IV), high-grade histology, and triplenegative BC (TNBC) at diagnosis. Multivariate Cox regression assessed three-year overall survival (OS). Age, comorbidity index, diagnosis year, and zip code income quartile were analyzed to account for confounding. **Results:** Of 1,956,145 total patients, there were 61,731 pooled AAPI patients, comprised of East Asian (n=23,643), South Asian (n=13,642), Southeast Asian (n=19,000), and Pacific Islander (PI) (n=5,446) subgroups. Non-Hispanic White (NHW) (n=1,639,814) served as the reference group. Compared to NHW, pooled AAPI had higher odds of advanced stage (adjusted odds ratio [aOR] 1.09; 95% CI 1.07-1.12; p<0.001) and high-grade histology (aOR 1.21; 95% CI 1.17–1.25; p<0.001). There was no difference in odds of TNBC (0.98; 0.92-1.03; p=0.41). Despite this, AAPI had better three-year OS (hazard ratio [HR] 0.79 (0.76–0.82; p<0.001). Compared to NHW, each AAPI subgroup had higher odds of high-grade histology and better OS except for PIs, who had similar odds of both. South Asians and Southeast Asians had higher odds of advanced stage (aOR 1.27; 1.21–1.34; p<0.001 and 1.22; 1.17–1.27; p<0.001, respectively), while East Asians had lower odds (0.86; 0.83–0.90; p<0.001). South Asians showed increased odds of TNBC (aOR 1.11; 1.00-1.23; p=0.04), whereas Southeast Asians (0.82; 0.73-0.91; p<0.001) and PIs (0.81; 0.66-0.98; p=0.036) showed lower odds. Conclusions: Disaggregating AAPI subgroup data is necessary to understand disparities in BC among these heterogenous populations. Further studies are warranted to evaluate disparities in healthcare delivery and its efficacy in these subgroups. Research Sponsor: None.

reast cancer characteristics by AAPI and subgroup.								
	Advanced Stage	High-Grade	TNBC	Three-Year				
	(aOR, 95% CI)	(aOR, 95% CI)	(aOR, 95% CI)	OS (HR, 95% CI)				
NHW (Reference)	1.00	1.00	1.00	1.00				
AAPI	1.09 (1.07–1.12)**	1.21 (1.17-1.25)**	0.98 (0.92-1.03)	0.79 (0.76-0.82)**				
East Asian	0.86 (0.83–0.90)**	1.12 (1.07-1.18)**	1.06 (0.97-1.15)	0.71 (0.67-0.75)**				
Southeast Asian	1.22 (1.17–1.27)**	1.30 (1.24-1.38)**	0.82 (0.73-0.91)**	0.84 (0.78-0.89)**				
South Asian	1.27 (1.21–1.34)**	1.28 (1.21-1.36)**	1.11 (1.00-1.23)*	0.75 (0.69-0.82)**				
PI	1.31 (1.21–1.42)**	1.10 (0.99-1.21)	0.81 (0.66-0.98)*	1.06 (0.96-1.18)				

*p-value <0.05.

**p-value <0.001.

The development of the cost of cancer in 31 European countries.

Andrea Manzano, Nils Erik Wilking, Christer Svedman, Thomas Hofmarcher; IHE, Stockholm, Sweden; Karolinska Institutet, Stockholm, Sweden; Npowermedicine Inc., Redwood City, CA; IHE, Lund, Sweden

Background: The estimated number of new cancer cases in Europe has risen from 2.6 million in 1995 to 4.1 million in 2022. Around every fourth death is due to cancer, yet survival rates have been improving due to advances in early detection, diagnosis, and treatment. The implications of these epidemiological changes and medical advances for the overall cost of cancer are not well documented. Methods: This cost-of-illness study estimated the direct and indirect costs of cancer across 31 European countries (the EU-27 countries, plus Iceland, Norway, Switzerland, and the UK) from 1995 to 2023. For direct costs, information on cancer-specific health expenditure was searched for all countries and combined with data from Eurostat and the OECD. Extrapolations were made for countries with missing information. For indirect costs, productivity losses due to premature mortality were calculated using mortality data from the World Health Organization, Eurostat, and the Office for National Statistics, combined with labor market data from Eurostat. Productivity loss due to morbidity were estimated using data from prior studies and changes in population structure. The human-capital approach was employed to calculate indirect costs. Total costs, costs per capita, and costs per new case were estimated for Europe as a whole and for each individual country. Results: Between 1995 and 2023, the combined direct and indirect costs of cancer across all countries increased by 43% from EUR 159 billion to EUR 228 billion (all figures adjusted to 2023 prices). Direct costs grew by 135%, from EUR 62 to EUR 146 billion, while indirect costs, which fell below direct costs after 2005, decreased by 16% from EUR 97 to EUR 82 billion. The decline in indirect costs reflects a reduction in potential years of working life lost due to premature mortality of working-age patients. Direct costs of cancer accounted for 4-8% of total health expenditures in all countries, with modest increases over time in some but not all countries. Per capita costs for all countries combined rose by 35% from EUR 313 to 423. However, there was a seven-fold difference between countries in 2023 ranging from around EUR 150 in Bulgaria and Romania to EUR 1,011 in Switzerland. This disparity represents a reduction from the twelve-fold difference observed in 1995. The cost per new cancer case remained relatively stable in Europe as whole at around EUR 78,000 between 1995 and 2010, before declining slightly to EUR 72,000 in 2015 and stabilizing thereafter. **Conclusions:** The societal cost of cancer in Europe has been steadily increasing. The growing number of cancer patients is spurring this development, rather than changes in cost per patient, which has remained mostly stable for nearly 30 years. Although the direct costs of cancer have risen the most, this has been partially offset by reductions in indirect costs. Changes in indirect costs and epidemiological trends should be considered in debates about the rising costs of cancer. Research Sponsor: European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium (unrestricted grant).

Trends in female breast cancer among adolescent and young adults in Southeast Asia.

Jenny Chen, Frances Dominique Ho, James Fan Wu, Kara Magsanoc-Alikpala, Edward Christopher Dee, Erin Jay Garbes Feliciano; Memorial Sloan Kettering Cancer Center, New York, NY; College of Medicine, University of the Philippines, Manila, Philippines; Division of Hematology and Oncology, Department of Medicine, Medical College of Wisconsin, Milwaukee, WI; ICanServe Foundation, Manila, Philippines; Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, NY; Ateneo School of Medicine and Public Health, Ateneo de Manila University, Pasig City, Philippines

Background: Breast cancer is the leading cancer among women globally and poses a growing public health challenge, particularly in adolescents and young adults (AYAs), defined as individuals aged 15–39 years. In Southeast Asia (SEA), rising breast cancer rates among AYAs are compounded by unique biological, socioeconomic, and healthcare barriers, including latestage diagnosis and limited access to screening and treatment. However, regional data on incidence and mortality trends remain scarce. This study aims to analyze temporal trends in AYA breast cancer incidence and mortality across 11 SEA countries from 1990 to 2021 using data from the Global Burden of Disease (GBD) database. Methods: We extracted breast cancer incidence and mortality data for AYAs in SEA from the GBD database (1990-2021) for Brunei, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, the Philippines, Singapore, Thailand, Timor-Leste, and Vietnam. Age-standardized rates (ASRs) were calculated, and temporal trends were evaluated using Estimated Annual Percent Change (EAPC) based on log-linear regression. Results: Breast cancer incidence among AYAs increased significantly across SEA from 1990 to 2021. Thailand reported the highest ASR in 2021 (11.78 per 100,000) and the most pronounced rise in incidence (EAPC 4.06). Significant increases were also observed in Vietnam (EAPC 2.92), Cambodia (2.63), and Laos (2.57). Mortality trends were heterogeneous: Singapore achieved a significant decline (EAPC -2.00), attributed to advancements in early detection and treatment, while Thailand, Indonesia, Vietnam, and Cambodia experienced rising mortality rates. In 2021, the highest mortality rates were recorded in Myanmar (2.54 per 100,000), Thailand (2.36 per 100,000), and the Philippines (2.17 per 100,000). Conclusions: The growing burden of AYA breast cancer in SEA reflects a combination of epidemiologic transitions, socioeconomic shifts, and regional healthcare disparities. Rising incidence is linked to changes in reproductive behavior, lifestyle factors, and urbanization, while increased mortality highlights gaps in healthcare access and screening infrastructure. Urgent public health interventions tailored to AYA populations are needed to enhance early detection, improve treatment accessibility, and address disparities across SEA. Regional collaboration and investments in healthcare systems are critical to mitigating the growing burden of breast cancer among AYAs in this dynamic region. Research Sponsor: None.

The impact of race on the association between structural racism and the quality of non-small cell lung cancer (NSCLC).

Jacquelyne Janean Gaddy, Do Lee, Jeph Herrin, James B. Yu, Craig Evan Pollack, Lorraine T. Dean, Safraz Hamid, Shelli Feder, Maureen Canavan, Pamela Soulos, Cary Philip Gross; Yale School of Medicine, New Haven, CT; Yale University School of Medicine, New Haven, CT; Dartmouth Hitchcock Medical Center, Lebanon, NH; Johns Hopkins University, Washington, DC; Johns Hopkins University, Baltimore, MD; Yale University School of Nursing, New Haven, CT; Yale Cancer Outcomes, Public Policy and Effectiveness Research Center, New Haven, CT

Background: Structural racism encompasses multiple intricate systems that generate and reinforce inequities amongst minoritized communities. Given the complexities associated with measuring structural racism, we sought to evaluate the relationship between structural racism and racial inequities amongst Black and White patients with NSCLC using an established structural racism index. Methods: We conducted a retrospective analysis using Surveillance, Epidemiology, and End Results -Medicare data. Outcomes were: localized stage at diagnosis, stage appropriate evaluation and treatment, and 2-year survival. We used the County Structural Racism (CSR) index, which assesses racial inequity within counties across various domains including criminal justice, education, employment, housing, and health care. We categorized counties into quintiles of the CSR index and estimated multivariable mixed effects logistic regression models to determine the adjusted association between structural racism and each outcome. We included interaction terms between patient race (Black versus White) and CSR to determine whether structural racism moderates the association between patient race and outcomes. We used the results of the regression models to calculate the adjusted predicted probabilities of each outcome across strata of patient race and CSR quintile. Results: The cohort included 54,344 individuals (10.3% Black, 89.7% White) diagnosed with NSCLC from 2013-2019. When compared to White patients, Black patients were less likely to be diagnosed at a localized stage (30.9% vs 38.4%), undergo stage appropriate evaluation and treatment (20.3% vs 28.0%), and survive two years after diagnosis (29.2% vs 37.3%) (all p < 0.001). Black patients were more likely to live in counties with higher structural racism (8.2% of the population in lowest quintile vs 19.2% in highest quintile). We did not find a clear association between structural racism and our outcomes. However, we did find that patient race moderated the association between structural racism and two-year survival. Specifically, Black patients in areas in the lowest quintile of structural racism had a predicted probability of two-year survival of 28.3% (95% CI, 25.2-31.4) compared to 31.1% (95% CI, 29.8-32.4) amongst White patients, a difference of 2.8% (p = 0.08). In areas with the highest structural racism, Black patients had an even more pronounced reduction in the probability of two-year survival (27.4%, 95% CI, 24.6-30.2 vs. 37.5, 95% CI, 34.9-40.1 for White patients), resulting in a disparity of 10.1% (p < 0.001). **Conclusions:** Increased structural racism exacerbates the racial disparity in two-year survival experienced by Black patients with NSCLC. Research Sponsor: R01MD017569.

30 year trends in racial disparities for early stage lung cancer treatment.

Olivia Frances Lynch, Do Lee, Pamela Soulos, James B. Yu, Jeph Herrin, Cary Philip Gross; Yale School of Medicine, New Haven, CT; Yale Cancer Outcomes, Public Policy and Effectiveness Research Center, New Haven, CT; Smilow Cancer Hospital at Saint Francis Hospital, Hartford, CT; Yale University School of Medicine, New Haven, CT

Background: Racial disparities in lung cancer treatment have been recognized for over 30 years. Our prior work showed that among Medicare beneficiaries diagnosed during 1992-2002, Black patients were less likely to receive curative therapy than White patients. As treatment approaches have evolved and increased attention has been paid to healthcare disparities, it is unclear whether this pattern has changed over time. We assessed temporal trends in racial disparities in receipt of curative therapy from 2005 to 2019, and compared findings to estimates from over 25 years earlier. Methods: Using the SEER-Medicare data linkage, we conducted a retrospective cohort study of Medicare fee for service beneficiaries diagnosed with stage I-II NSCLC during 3 time intervals: 2005-07, 2011-13, and 2017-19. Consistent with the prior study, we restricted the sample to Non-Latinx Black and Non-Latinx White patients. Curative therapy was defined as either surgery and/or radiation within 6 months of diagnosis. In our prior study, curative treatment was limited to surgery, as radiation was rarely used as curative therapy at that time. We performed multivariable logistic regression with receipt of any curative therapy as our outcome, controlling for sociodemographic and clinical covariates. We included a time*race interaction to evaluate whether receipt of treatment differed by race over time, and calculated the predicted probability of treatment across time and race group. Results: We identified 28,287 patients (7.5% Black) for study inclusion. Black and White patients were similar across most demographic variables; however, Black patients were more likely to have \geq 3 comorbidities and to have been hospitalized in the year prior to diagnosis. Overall, receipt of curative therapy was lower among Black patients (69.9%) compared to White patients (83.3%) throughout the study period and across all time intervals (Table). In adjusted analyses, Black patients were less likely to receive curative treatment in all 3 time intervals, with a Black-White difference of -17.6% in 2005-07, -14.2% in 2011-13, and -9.7% in 2017-19 (p-value for time*race interaction = < 0.001). Compared to the 1992-94 and 2000-02 time intervals from the prior study where Black-White difference in receipt of treatment was -11.8% and -14.4% respectively, disparities have persisted. Conclusions: Racial disparities in receipt of curative treatment for early stage lung cancer in Medicare beneficiaries have persisted 30 years, with minimal improvement. Research Sponsor: None.

Receipt of curative treatment by race and time period, adjusted.								
	1992- 1994 ^a	2000- 2002 ^a	2005-2007 ^b	2011- 2013 ^b	2017- 2019 ^b			
Black	73.1	64.9	66.2 (59.6, 72 7)	71.6 (65.8, 77.3)	77.7 (72.3, 83.1)			
White	84.9	79.3	83.8 (82.4, 85.1)	85.8 (84.4, 87.1)	87.4 (86.2, 88.6)			
Black:White Difference	-11.8	-14.4	-17.6 (-24.3, -10.9)	-14.2 (-20.1, -8.3)	-9.7 (-15.2, -4.2)			

^aData from prior 2008 study

^bCurrent Study.

At-risk cancer genetic syndrome identification (ARCAGEN-ID): Novel EHR integrated system to overcome disparities in identification and testing for cancer genetic syndromes.

Vinit Singh, George Chen, Amanda Sena, Thomas Rafter, Rosa Xicola, Mohamad Sharbatji, Jing Liu, Quiana Brown, Karina Brierley, Claire Healy, Michelle Hughes, Nitu Kashyap, Xavier Llor; Roswell Park Comprehensive Cancer Center, Buffalo, NY; Yale School of Medicine, New Haven, CT; Yale New Haven Health, New Haven, CT; Advent Health, Orlando, FL; Yale New Haven Hospital, New Haven, CT; Emory University School of Medicine, Atlanta, GA

Background: Identifying individuals at-risk for a hereditary cancer syndrome (HCS) is crucial to prevent cancer deaths. While there are established guidelines for genetic testing, less than 30% eligible individuals are tested, with consistently worse rates among underserved. The complexity of guidelines and providers' unconscious bias contribute to these disparities. This project aimed to enhance the identification and testing of at-risk individuals, focusing on underserved populations. Methods: NCCN/ACMG criteria for genetic testing were translated into three distinct rule-based conditional logic statements in the EHR. A total of 218 rules that serially evaluate each aspect of an individual criteria, and together roll up into a logic statement of "at-risk for HCS. The rules evaluate personal and/or family history, determine age at onset, and categorize family relationships. A proof-of-concept automated outreach initiative was developed that allowed patients to opt into genetic testing after an informational video was watched was developed. Relevant data were extracted and compared using chi-square test. Results: Out of 1.3 million individuals, ARCAGEN-ID identified 59,377 (4.8%) at-risk of an HCS. Of those, 47,000 (79.2%) had not been previously evaluated: 43,051 (79.3%) at-risk for Breast, Ovarian, Pancreas, Prostate related mutation; 3,308 (70.2%) at-risk for Lynch syndrome, and 1,144 (80.5%) at-risk for other HCSs. Among previously identified individuals, 2,340 (18.9%) had a pathogenic variant (PV). Compared to overall population in health system, ARCAGEN group had a higher proportion of female (82% vs 55%, p < 0.01), White (78% vs 65%, p < 0.01) and non-Hispanic (89% vs 84%, p < 0.01) individuals, and had less often Medicaid (16.7% vs 28%, p < 0.01). Within ARCAGEN, comparing previously identified individuals with newly identified ones, the latter were significantly more often male (19.9 vs 11.13%, p < 0.01), younger (≤45y) (33.6% vs 27.2%, p < 0.01), Non-White (22.9& vs 20.5%, p < 0.01), and more often on Medicaid (31.5% vs 13%, p < 0.01). For the pilot, 126/504 outreached individuals (25%) viewed the video and completed a questionnaire. 43/504 (8.5%) pursued testing, and 7 (16%) had a PV. A total of 7% had prior testing not recorded in discrete fields; 2% declined testing; and 6% sought genetic counseling prior to testing. A higher proportion of African American (AA) individuals opted for testing through this strategy (11%) compared to the overall percentage of this population that was outreached (6%, p = 0.05). **Conclusions:** Through this automated system, we were able to identify more non-White individuals and add more Medicaid-insured individuals for testing. Uptake after outreach was higher among AA. Thus, a system like ARCAGEN can help overcome disparities in HCS identification without a relevant increase in resources. Research Sponsor: None.

CARE DELIVERY/MODELS OF CARE

1601

Clinical implications and prevalence of benign ethnic neutropenia (BEN) in breast cancer patients of Middle Eastern ethnicity.

Shruti Prem Sudha, Atef Shehata, Fatema Sajjad, Nabil Mahmoud Abdelfattah, Taif Najeebi, Lateefa Daraj, Fatima Sabri Al-Ali, Shahad AlOmari, Cigdem Ozturk, Tarkan Yetisyigit, Maha Alsindi, Zeki Surmeli, Özge Keskin, Burcu Cakar, Burcak Erkol, Baran Akagunduz; Bahrain Oncology Center, Muharraq, Bahrain

Background: Benign ethnic neutropenia (BEN) commonly affects patients of African and Middle-Eastern descent and is not a true neutropenic state. Patients with BEN have the Duffy-null phenotype on red cells and Duffy phenotyping has been used as a surrogate marker for diagnosis. There is evidence that cancer patients with BEN are not at increased risk of infection with chemotherapy. The primary aim of this study was to assess the prevalence of BEN among breast cancer patients in Bahrain using Duffy antigen phenotyping on red cells. The secondary aims were to study treatment delays and infectious complications in BEN patients. Methods: We conducted this retrospective study after obtaining IRB approval. We reviewed records of 493 consecutive breast cancer patients treated in our setting from January 2018 to January 2024. We included patients with neutropenia at presentation (defined as having an absolute neutrophil count [ANC] of $< 1.5 \times 10^3 / \mu$ L). Patients with Duffy-null phenotype and no identifiable secondary causes of neutropenia were presumed to have BEN. Clinical details studied included drug, and family history, treatment interruptions for neutropenia, filgrastim responsiveness, and episodes of febrile neutropenia. Overall survival (OS) and progression-free survival (PFS) estimation using the Kaplan-Meier method and Cox regression analysis of prognostic factors were performed using R software version 4.2.0. Results: Of 493 patients, 72 (14.6%) had a presumed diagnosis of BEN. The median age at presentation was 45 yrs, and the median follow-up duration was 3.6 yrs. 13% patients had metastatic disease at presentation and 11% had triple-negative breast cancer (TNBC). The median ANC at diagnosis was 1.2×10^3 / μ L (range 0.4–2.1 × 10³/ μ L). The 4-yr OS was 95% (95% CI, 89–100%) and the 4-yr PFS was 75% (95% CI, 63–89%). Treatment was interrupted due to low ANC in 65% of patients, and the median ANC at which treatment was delayed was $0.8 \times 10^3 / \mu L$. 89% patients had received filgrastim and all were filgrastim responsive. Only one patient had uncomplicated neutropenic fever. On multivariable analysis, inferior PFS was seen in patients with metastatic disease (HR, 6.2; 95% CI, 2.17–17.9; p < 0.001), and TNBC (HR, 7.73; 95% CI 1.79–33.3; p = 0.006). We did not find any effect of treatment delay on the PFS. Conclusions: Ethnic neutropenia is prevalent among breast cancer patients in Bahrain. Duffy phenotyping can be used in place of more invasive tests to identify these patients. Treatment delays due to apparent neutropenia are common, however, response to filgrastim is universal, and febrile neutropenia episodes are rarely seen. Since these patients are not at increased risk of infection, larger studies to identify unique neutrophil thresholds for holding chemotherapy in BEN can help avoid compromising therapy. This can have far-reaching implications in populations with a high prevalence of BEN. Research Sponsor: None.

Community-based patient navigation and preventative care among women surviving breast cancer.

Anthony Zisa, Marcelo Sleiman Jr., Muriel Rose Statman, Duye Liu, Adina Fleischmann, Kenneth Tercyak; Lombardi Comprehensive Cancer Center, Georgetown University Medical Center, Washington, DC; Lombardi Comprehensive Cancer Center, Washington, DC

Background: Routine physical exams, mammograms, and Pap smears are essential to longterm follow-up for breast cancer survivors, enabling detection of recurrence and guiding overall health maintenance. Barriers to preventive care adherence over time can be addressed by community-based organizations (CBOs) by providing information and supportive services, including navigation to screening. We studied adherence to preventive care and screening among breast cancer survivors who engaged a national cancer control CBO-examining how sociodemographics, cancer care factors, and quality of life (QoL) were associated with adherence. Methods: A secondary data analysis was conducted among N = 777 breast cancer survivors who contacted a CBO for resources, including no-cost patient navigation. Patient-reported outcomes were assessed after 30 days, along with survivorship care planning (SCP) and QoL. An index score was created based upon women's self-reported adherence to receiving routine physical exams, mammograms, and Pap smears at recommended intervals. Results: Among survivors, 37% were age < = 46, 19% were non-white, 63% were in a partnered relationship, 23% rated their QoL (general health) as fair/poor, and 47% carried a pathogenic variant in BRCA. Medical providers caring for these survivors included primary care physicians (53.6%) and oncology specialists (46.4%). For index scores, 66% were adherent to all 3 recommendations for follow-up, 29% to 2 recommendations, and 6% to < = 1 recommendation. The most adhered to recommendation was a physical exam (97%), and the least was a Pap smear (73%): 88% of survivors reported mammograms at recommended intervals. At the bivariate level, breast cancer survivors who were younger (t, df = 4.59, 711, p < .001), non-white, (t, df = -3.27, 267, p < .001), in a partnered relationship (t, df = 1.76, 54, p < .05), and with better QoL (r = -.09) p < .01) were more adherent to guideline-based care. A trend was observed for SCP: survivors who received care summaries (56%), including follow-up instructions (64%), and in written form (45%), were more likely to adhere (r = 0.05, p < .10). In a multivariable regression model adjusting for partnership status and SCP, younger survivors (B = 1.13, p < .001), who were nonwhite (B = 1.0, p < .01), and with better QoL (B = .09, p < .05) were more adherent. **Conclusions:** Survivors can benefit from guideline-based cancer prevention and screening with CBO-led support. Tailored SCP is essential to reinforce life-saving health behaviors and enhance follow-up adherence. Research Sponsor: Centers for Disease Control and Prevention #U58DP005408; #P30CA051008.

Mutation rate differences across populations and association with performance disparities in pathology AI diagnostic models.

Po-Jen Lin, Shih-Yen Lin, Pei-Chen Tsai, Fang-Yi Su, Chun-Yen Chen, Fuchen Li, Junhan Zhao, Yuk Yeung Ho, Tsung-Lu Michael Lee, Elizabeth Healey, Ting-Wan Kao, Irene Tai-Lin Lee, Eric Chongze Ma, Jung-Hsien Chiang, Kun-Hsing Yu; Department of Biomedical Informatics, Harvard Medical School, Boston, MA; Department of Computer Science and Information Engineering, National Cheng Kung University, Tainan, Taiwan; Department of Computer Science and Information Engineering, Southern Taiwan University of Science and Technology, Tainan, Taiwan; Emory University, Atlanta, GA; Western Connecticut Medical Group, PC., Danbury, CT; Department of Computer Science and Information Engineering, National Cheng Kung University, Tainin, Taiwan

Background: Previous studies have established artificial intelligence (AI) algorithms to classify cancer types, providing real-time diagnostic support. In addition, AI models have identified previously unknown pathology patterns associated with cancer genomic profiles. However, these models exhibit variable performance in different demographic groups, and the causes remain largely unknown. To address this challenge, we investigated the relationships between biases in AI diagnostic models and mutation rate disparities across populations and evaluated the efficacy of a fairness-aware contrastive learning (FACL) framework in reducing performance disparities. Methods: We obtained whole-slide pathology images, mutation rates of the 5 most frequently mutated genes in each cancer type, age, sex, and race from 9,217 patients in The Cancer Genome Atlas across 10 cancer types. We identified tasks with performance disparities across demographic groups, and employed generalized linear models to quantify the relationship between mutation rates and model bias in each cancer type. We further developed an FACL framework, and evaluated its effectiveness in mitigating these disparities using metrics including differences in accuracy (DIA) and equal opportunity. Results: Six genomic profile prediction tasks showed significant performance disparities across population groups (Table). Variations in TP53 mutation are associated with differential error rates in serous UCEC v. nonserous UCEC, mixed IDC v. ILC, LUAD v. LUSC, and GBM v. LGG classification tasks. Differences in CDH1 mutation rates were linked to racial disparity in mixed IDC v. ILC and age discrepancy in IDC v. ILC classification tasks. Our FACL framework mitigated performance disparities across demographic groups in 5 out of 6 tasks where standard AI model exhibited significant bias (p < 0.05). **Conclusions:** Biases in AI-driven cancer pathology diagnosis stem from disparities in somatic mutation prevalence across demographic groups. Addressing these biases is critical to ensuring fairness and the global applicability of AI tools. Our findings demonstrate that the FACL-based framework effectively reduces performance disparities, making AI-powered cancer diagnostics more reliable. Research Sponsor: None.

Tasks	Mutation	Sensitive Attribute	C Mi	Groups a utation ra	nd ates	Standard (S) v. FACL (F) models DIA
SUCEC v. nSUCEC	TP53	Race	W B	0.34 0.45	p<0.001	S: 0.13±0.10, p<0.001 F: 0.10±0.05, p=0.088
Mixed IDC v. ILC	CDH1	Race	W B	0.29 0.46	p<0.001	S: 0.07±0.02, p<0.001 F: 0.11±0.04, p=0.233
	TP53	Race	W A	0.15 0.11	p=0.047	S: 0.12±0.02, p=0.023 F: 0.10±0.05, p=0.196
IDC v. ILC	CDH1	Age	≥59 yrs <59 yrs	0.11 0.17	p=0.038	S: 0.05±0.02, p=0.001 F: 0.05±0.05, p=0.370
LUAD v. LUSC	TP53	Sex	F M	0.75 0.58	p=0.002	S: 0.12±0.02, p<0.001 F: 0.01±0.01, p=0.154
GBM v. LGG	TP53	Race	W B	0.50 0.33	p=0.021	S: 0.20±0.01, p<0.001 F: 0.29±0.02, p=0.005

W: White; B: Black:

A: Asian.

Gentian violet compared with methylene blue for sentinel lymph node biopsy in breast cancer: A retrospective analysis from a resource-limited setting.

Mehwish Mooghal, Zakia Madad Ali, Lubna Saleem, Anam Yaqoob, Faiza Ahmed, Saad Nasir, Abid Jamal; Cancer Foundation Hospital, Karachi, Pakistan; Cancer Foundation Hospital, Gulshan-E-Iqbal, Pakistan; Cancer Foundation Hospital Karachi Pakistan, Karachi, Pakistan; AKUH, Karachi, Pakistan; Aga Khan University Hospital, Karachi, Pakistan

Background: Sentinel lymph node biopsy (SLNB) minimizes morbidity in breast cancer surgeries compared to axillary lymph node dissection. Standard tracers like vital blue (VB), methylene blue (MB) and radioisotopes (RI) are effective but often costly and logistically challenging in low- and middle-income countries (LMICs). Gentian violet (GV), a low-cost alternative, offers potential for resource-constrained settings. Methods: A retrospective cohort study was conducted at Cancer Foundation Hospital Karachi, Pakistan between January 2023 -December 2024. The study included 28 patients with breast cancer who underwent SLNB using GV and RI. Sentinel lymph node (SLN) detection rates, concordance between GV and RI, and safety profiles were assessed. Detection was analyzed across tumor grades, histology, receptor statuses, and neoadjuvant chemotherapy (NACT) status. Results: The majority of patients were aged 41-50 years (n = 8) and > 70 years (n = 8) and had a BMI in the range of 21-30. Tumor size analysis revealed that T2 tumors were most common (57.1%, n = 16), followed by T3 tumors (21.4%, n = 6). Neoadjuvant chemotherapy (NACT) was administered to 35.7% (n = 10) of patients and all patients were clinically node-negative (cN0) at diagnosis with no distant metastases. Stage II disease predominated (78.6%, n = 22), and invasive ductal carcinoma (IDC) was the most common type (71.4%, n = 20), and 53.6% (n = 15) of tumors were poorly differentiated (Grade 3). Receptor status analysis showed ER/PR positivity in 64.3% (n = 18) of cases, triple positivity in 21.4% (n = 6), while HER2/neu-positive and triple-negative subtypes each accounted for 7.1% (n = 2). GV successfully identified SLNs in 96.4% of cases, with moderate concordance with RI (Kappa = 0.512). GV identified more nodes in 32.1% of patients, while RI identified more in 14.3%; both identified the same number in 50%. The falsenegative rate for GV was low (4.2%). Detection rates were consistent across histological types (e.g., invasive ductal carcinoma: 1.94 nodes by GV vs. RI), tumor grades (Grade 3: 1.78 by both), and receptor statuses (triple-positive cases: \sim 2.4 nodes by GV vs. 2 by RI), with no significant differences. NACT did not impact SLN detection (p = 0.844). No complications or adverse events related to GV dye were observed intraoperatively or during the postoperative follow-up at days 0, 3–7, and 30. The safety profile of GV dye demonstrated no staining-related complications, dermatitis, tattooing, or skin necrosis. Conclusions: Gentian violet is a safe, effective, and affordable alternative to MB/VB for SLNB in breast cancer. It demonstrates high detection rates and a favorable safety profile, making it particularly suitable for LMICs. Broader studies are encouraged to validate these findings and further its clinical adoption. Research Sponsor: No funding received.

Comparison of mobile mammography versus urban hospital-based breast cancer screening.

Carla Zeballos Torrez, Christine E. Edmonds, Brian S. Englander, Linda White Nunes, Amissa Brewer-Hofmann, Stephany Perez-Rojas, Jiarui Yan, Oluwadamilola Motunrayo Fayanju, Leisha C. Elmore; Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA; The University of Pennsylvania, Philadelphia, PA; University of Pennsylvania, Philadelphia, PA; Division of Breast Surgery, Department of Surgery, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

Background: Breast cancer screening via mobile mammography units (MMU) is used to improve access in medically underserved communities. This study aims to evaluate factors associated with site of screening, recall rates and time to diagnostic resolution for MMU vs hospital-based sites. Methods: This retrospective study analyzed screening mammography examinations performed in a MMU and at our large, urban hospital sites during overlapping 2week periods in 2022 and 2023. BI-RADS, recall and cancer detection rates were assessed. For BI-RADS 0 patients, time intervals between screening and diagnostic imaging and, when indicated, between diagnostic imaging and biopsy, were collected. Area of Deprivation Index (ADI), an index of socioeconomic status for communities, was calculated for each patient. Diagnostic resolution was defined as time from screening to completion of diagnostic work-up. Statistical analyses were performed with chi-square, analysis of variance, and Kruskal-Wallis tests. Cox regression analysis was used to assess factors associated with diagnostic resolution. **Results:** In the MMU cohort (n=516) vs the hospital-based cohort (n=2401), more patients identified as Non-Hispanic Black (68% vs 40%, p < 0.001), reported no insurance (71% vs 2.1% p < 0.001), had no PCP (35% vs 9.8%, p < 0.001), and were in the highest ADI percentile (70% vs 27%, p < 0.001). Regardless of screening site, most patients with longer time to diagnostic resolution had a higher ADI percentile; 58% of patients with > 80 ADI percentile (p < 0.001) had diagnostic resolution in > 60 days. The MMU cohort had a higher recall rate (18.8% vs 9.9%; p <(0.001) and trend towards a higher cancer detection rate (13.6 vs 8.7 per 1000 examinations, p = 0.32) than the hospital-based cohort. Among BI-RADS 0 patients (n=333), there were longer delays to diagnostic resolution in the MMU vs the hospital-based cohort (Table 1). Patients with no insurance were less likely to have diagnostic resolution compared to insured patients (HR: 0.43, 95%CI [0.26,0.71], p = 0.001). Conclusions: Compared to hospital-based screening, MMU-screened patients experienced longer times to diagnostic resolution and had higher recall rates. Although MMU offers an effective strategy to improve screening access, our study highlights opportunities for improved patient navigation, social work support, and financial assistance to promote more equitable follow-up of abnormal screening mammograms. Research Sponsor: None.

BI-RADS 0 outcomes.				
	Facility N = 236	Mobile N = 97	Overall N = 333	p-value
Median Days from Screening to Diagnostic (IQR)	11 (7, 20)	28 (13, 43)	13 (7, 28)	< 0.001
Median Days from Diagnostic to Biopsy (IQR)	12 (7, 18)	11 (6, 24)	12 (7, 19)	0.5
Median Days to Diagnostic Resolution (IQR)	14 (7, 29)	29 (16, 52)	17 (8, 34)	< 0.001
Days to Diagnostic Resolution		(, ,		< 0.001
<=30	178 (75%)	42 (43%)	220 (66%)	
30-60	33 (Ì4%)́	20 (21%)	53 (Ì6%)	
60+	16 (6.8%)	17 (18%)	33 (9.9%)	
No Follow up	9 (3̀.8%)	18 (19%)	27 (8.1%)	

Radiotherapy utilization at the fourth most populous province in Indonesia: A single centre study.

Vito Filbert Jayalie, Sudibio Sudibio, Hendrik Hendrik, Hendriyo Hendriyo, Julijamnasi Julijamnasi, Rudiyo Rudiyo, Julius Oentario, Harriyo Utomo, Montesqieu Silalahi, Muhammad Fauzi Siregar, Sry Widjaja, Gregorius Ben Prajogi, Tiara Bunga Mayang Permata, Handoko Handoko, Soehartati Gondhowiardjo; Murni Teguh Memorial Hospital, Medan, North Sumatra, Indonesia; Murni Teguh Memorial Hospital, Medan, Indonesia; Murni Teguh Memorial Hospital, Medan, Sumatera Utara, Indonesia; Adam Malik Central General Hospital, Medan, Sumatera Utara, Indonesia; Biochemistry Department, Medical Faculty, Universitas Sumatera Utara, Medan, Sumatera Utara, Indonesia; Universitas Indonesia, Cipto Mangunkusumo Hospital, Jakarta, Indonesia; Faculty of Medicine Universitas Indonesia - Dr. Cipto Mangunkusumo National General Hospital (Indonesia), Jakarta Pusat, Indonesia; Dr. Cipto Mangunkusumo National Hospital, Jakarta, Indonesia; Cipto Mangunkusumo Hospital-Faculty of Medicine, Universitas Indonesia, Jakarta, Indonesia

Background: Cancer continues to grow as a health burden in Indonesia, with the current cumulative cancer risk at 14.0%. Along with the rising rate of cancer discovery, treatment effectiveness should be constantly improved. This study was conducted to explore the actual radiotherapy utilization rate (aRUR) of the 10 most common cancers at Murni Teguh Memorial Hospital (MTMH), a cancer referral hospital in North Sumatra. Methods: This was a retrospective study utilizing MTMH medical records in 2019. Data on the 10 most common cancers in Indonesia (based on GLOBOCAN 2020) were collected. Completed data underwent double filtering and cleaning before analysis with the Statistical Package for the Social Sciences (SPSS) and Microsoft Excel to calculate aRUR. Further elaboration was made to compare with the Collaboration for Cancer Outcomes Research and Evaluation (CCORE) RUR data. Results: A total of 3,928 samples were collected with 74% of patients being female; the mean age is 50 (0,6 to 96) years old; 38% of cancer staging reported (6% stage I; 32% stage II; 34% stage III; and 28% stage IV). The most to least common cancers are breast, colon, rectal, nasopharynx, cervix, ovary, leukemia, prostate, lung, and lymphoma. Out of 457 irradiated cases, radiotherapy was most used in breast (36%), nasopharyngeal (23%), and cervical cancer (23%). There was gap between these three cancers' aRUR to their optimal RUR (oRUR) calculated by CCORE (54.4% for cervix; 52% for nasopharynx; 41.27% for rectum). Optimal radiotherapy utilization was reached only for colon and ovarian cancers. **Conclusions:** Our study shows that a gap between aRUR and oRUR was observed for most cancers treated at MTMH. Several factors may contributed to this result, including patient factors, clinical factors, and administrative/bureaucracy factors. Further study is needed to address the cause and to plan any measures to shorten the gap and optimize radiotherapy. Research Sponsor: None.

Rates and predictors of cancer screening in California (CA) prisons.

Christopher Manz, Angela C. Tramontano, Emma Voligny, Marcus Dahlstrom, John Dunlap, Amanda Johnson, Vikrant Rathore, Michael Selby, Richard Sun, Joseph Bick; Dana-Farber Cancer Institute, Boston, MA; California Correctional Health Care Services, Elk Grove, CA

Background: Cancer is the leading cause of death in state prisons. Patients diagnosed with cancer in prison are more likely to have Stage IV diagnoses and have worse survival. Rates and predictors of cancer screening in prison and the relationship to stage at diagnosis are unknown. Methods: This retrospective study evaluated patients incarcerated in CA prisons in 2014-2023 who met screening criteria for breast, cervical, colon, liver and lung cancers during periods tracked by the prison system (Table). Correctional data were used to identify screening-eligible patients incarcerated during the study period, screening eligibility dates, receipt of screening and periods of incarceration. These data were matched to CA cancer registry data from 2014-2021 using name and date of birth; cancers were identified between the start of the tracking period for each cancer and 2021. For each cancer, we calculated the proportion of: patients who ever received cancer screening, time covered by a screening test (sum of non-overlapping time of screening intervals [e.g., 10 years for colonoscopy] divided by time eligible for screening), and patients diagnosed at Stage IV (stratified by ever-receipt of screening prior to diagnosis). Generalized estimating equations models with logit link adjusted for demographic and incarceration characteristics (e.g. incarcerated in the past year) clustered at the prison+yard level were used to determine predictors of receipt of screening for each cancer and the association of ever-receipt of screening with Stage IV diagnosis. Results: The study included 83,174 individuals who were 79% male, had a median age of 51 when first eligible for any screening, and were 33% Non-Hispanic White. Rates of ever receiving cancer screening ranged from 43-87%, and mean proportion of time covered ranged from 30-75% (Table). In adjusted models, receipt of outpatient mental health services, higher security level and recent change in prison or primary care clinician were associated with higher screening rates for most cancers. 597 screenable cancers were diagnosed from the start of each screening tracking period through 2021. 17% of cancers were diagnosed as Stage IV. In the adjusted model including all cancers, patients who ever received screening prior to diagnosis were 60% less likely to be diagnosed with Stage IV disease (OR 0.40, 95% CI 0.24-0.69). Conclusions: Cancer screening rates in CA prisons are high and may explain why rates of Stage IV diagnoses in CA prisons are comparable to the general population and lower than in other state prisons. Research Sponsor: None.

	Breast	Cervical	Colon	Liver	Lung
Start of tracking period (all end 6/2023)	1/2014	1/2016	1/2014	10/2015	7/2022
Ever screened, n (%)	2,408 (75)	11,326 (70)	49,023 (72)	5,044 4,935 (87)	3,406 1,479 (43)
Mean proportion of time covered	72%	74%	62%	75%	30%
Cancer diagnosed, n	58	12	280	247	-
Stage IV at diagnosis, screened, %	5% 7%	0%	21%	12%	-
Stage IV at ulagilosis, not screened, %	1 /0	0 /0	55%	21/0	

Implementation of a clinical trial navigation program for cancer patients: Barriers and facilitators identified through stakeholder perspectives.

Milica Paunic, Dana Morgan Inglis, Salah Alhajsaleh, Anthony Luginaah, Gregory Charalambos Anagnostopoulos, Depen Sharma, Mahmoud Hossami, Olla Hilal, Ria Patel, Christina Trieu, Michael Touma, Swati Kalia, Anaam Jaet, Pratham Gupta, Govana Sadik, Laurice Togonon Arayan, Renee Nassar, Roaa Hirmiz, Megan E. Delisle, Caroline M. Hamm; Temerty Faculty of Medicine, University of Toronto, Toronto, ON, Canada; Max Rady College of Medicine, University of Manitoba, Winnipeg, MB, Canada; University of Windsor, Windsor, ON, Canada; Western University, London, ON, Canada; University of Ottawa, Faculty of Medicine, Ottawa, ON, Canada; Clinical Trials Navigator, Windsor, ON, Canada; Windsor Regional Hospital, Windsor, ON, Canada; University of Manitoba, Winnipeg, MB, Canada; University of Western Ontario, Windsor, ON, Canada

Background: Patient navigation has been highlighted as a solution to improve clinical trial access. The Clinical Trial Navigator (CTN) Program is a Canadian cancer clinical trial navigation program that can be accessed online by patients or healthcare professionals (HCP). Trained individuals search and provide patients and/or oncologists a report of potentially eligible trials for free. Over 550 patients have used the Program since its launch in 2019, but systemic implementation within cancer centers has yet to occur. We aimed to identify facilitators and barriers to implementing the CTN Program in Canadian cancer centers by gathering insights from key stakeholders. Methods: Thirty-three 45-minute, virtual, semi-structured interviews were conducted with healthcare/clinical research professionals (CRP; n = 9) and patientfocused stakeholders (n = 24). Interviews were guided by the Consolidated Framework for Implementation Research (CFIR) and analyzed by two independent researchers using thematic analyses with deductive and inductive coding. Results: Participants highlighted the importance of patient navigation to address barriers related to the limited availability of clinical trials and difficulty in identifying them, noting that navigation can significantly reduce this workload. CRP: "We need a program dedicated to look at trials across the board. [The clinical trial unit team] has no time or tools to be able to do this for patients." Key barriers to implementing navigation were the financial and logistical stressors for patients who may want to enroll onto trials that the navigator finds, particularly when only available in another institution. HCP: "[Our province] covers only travel for the consultation, so [financing] is a big barrier and needs to be thought through." Another commonly cited barrier was obtaining the required medical information for the CTN Program to perform high quality clinical trial searches. Cancer advocacy group leader: "It's got to be very physician structured because [the CTN Program intake form] needs patient records. I'll ask patients what stage they are at and they don't know, so asking them for their medical information [to perform a clinical trial search], they just don't know that." When the clinical trial search is initiated by patients and the report of potential eligible trials returned to them, patients felt they needed extra support in discussing the report with their oncologist. Patient: "Every oncologist is different. Some are very easy to talk to...one was extremely difficult...so to have a discussion is very difficult." Conclusions: Our findings provide critical considerations for the successful implementation of the CTN Program in cancer centers across Canada. We have planned program adaptations to address these results and will evaluate changes in uptake and effectiveness of the CTN Program. Research Sponsor: None.

Association of West African ancestry, reproductive factors, and deprivation with incidence of triple-negative breast cancer among Black women in the U.S.

Neha Hippalgaonkar, Gregory Sampang Calip, Zain Akbar, Kent Hoskins; University of Illinois Chicago, Chicago, IL; University of Southern California, Los Angeles, CA

Background: Black women have the highest incidence of triple negative breast cancer (TNBC) of any racial or ethnic group in the U.S. The TNBC incidence rate among Black women varies substantially by state of residence (Sung H, et al, JAMA Oncol 2023), and the underlying factors driving state level variation are unknown. Genetic ancestry of West Africans and U.S.-born Black Americans (whose ancestry is primarily admixed West African) is significantly different from East Africans, and approximately 10% of the U.S. Black population identify as African immigrants. We used state level data on the number of Black residents who identify as East African immigrants to estimate the proportion of the Black population in that state with West African ancestry (defined as not East African immigrant), and we conducted a mediation analysis of state TNBC incidence data to investigate whether West African ancestry, reproductive patterns, and socioeconomic deprivation influence the relationship between race and TNBC incidence. Methods: We obtained state level TNBC incidence rates for Black women (2011-2021) from the U.S. Cancer Statistics Public Use database. State level data on country of birth from the 2020 U.S. census, rates of breastfeeding and fertility for Black residents, and socioeconomic indicators (the 2015 official poverty measure (OPM) and Multidimensional Deprivation Index (MDI)) were obtained from the U.S. Census Bureau. Correlations between TNBC incidence rates and variables of interest were tested with Spearman's correlation test. Causal mediation analysis of TNBC incidence rate differences was performed by estimating coefficients for direct and indirect effects with linear regression models. We calculated estimates of the proportion mediated with 95% confidence intervals (CI) accounting for a priori confounders and potential effect modification at the state level. Results: State TNBC incidence rates among Black residents were inversely correlated with the proportion of residents identifying as East African immigrants (r = -0.42, p = .006) and the rate of breastfeeding (r = -0.35, p = .03). There was no correlation with fertility rates, OPM or MDI. In unadjusted analyses, East African immigrant proportion at the state level mediated 15.3% (p = 0.01) of the differences in TNBC incidence rates. After adjustment for rates of breastfeeding, fertility, and socioeconomic indicators, East African immigrant proportion was associated with 30.1% (p = 0.02) of the difference in TNBC incidence rates for Black women at the state level. Conclusions: Proportion of East African immigrants and rate of breastfeeding are inversely correlated with TNBC incidence rates in Black women. These factors transmit a portion of state level differences in TNBC incidence, suggesting that West African ancestry partially mediates the higher incidence of TNBC in Black women. Research Sponsor: None.
Effects of socioeconomic status on access to next generation sequencing in patients with metastatic breast cancer.

Conchita Martin de Bustamante, Christine Zhang; UT Southwestern Medical Center, Dallas, TX

Background: Metastatic breast cancer is difficult to treat and a major cause of mortality related to breast cancer. Standard treatment includes therapeutic options that target specific molecular signals and pathways responsible for cancer growth. For metastatic breast cancer, focused next-generation sequencing (NGS) on DNA isolated from the tumor tissue or circulating tumor DNA in the blood has quickly become standard of care to create actionable and personalized treatment plans. In ER+ disease, NGS helps to determine potential second-line therapies. However, these tests are often expensive, limiting their clinical implementation. We hypothesized that limited access to these therapies increases health disparities in clinical oncology. Methods: Data from 187 patients with recurrent MBC were obtained from the Dallas Metastatic Breast Cancer Study, a clinical database that was established in 2021 at a single academic medical system to track patient demographics, area deprivation index (ADI), treatments, and other variables. Commercial NGS testing was performed on patient tumor tissue or tumor DNA from blood samples by Tempus and FoundationOne between the years 2014 through 2022. Results: Overall, 39% of patients in our dataset received NGS testing. Patients who are not Hispanic/Latino (n=140, OR: 3.99, 95% CI: 1.66–9.61) are 4 times more likely to receive NGS compared to those who are Hispanic/Latino. We then explored whether ADI correlated with access to NGS testing. ADI measures education level, employment, housing quality, and income to rank neighborhoods by SES disadvantage; a higher quartile ADI equates to a greater disadvantage. Our data showed that patients in the lowest quartile ADI are 2.5 times more likely to have NGS testing compared to those in the highest quartile (OR: 2.54, 95% CI 1.07-6.20). To account for different clinical indications for receiving NGS testing, we then looked at NGS trends between tumor molecular subtypes. We observed that ER+ patients were 3 times more likely to have NGS testing compared to ER- patients (n=118, OR: 2.77, 95% CI: 1.45-5.29) and that TNBC patients were less likely to receive NGS testing compared to ER+ patients, however this difference was not significant (n=113, OR: 0.36, 95% CI: 0.13-1.01). In ER+ patient population, we found that Hispanics/Latinos were 79% less likely to undergo NGS testing compared to their non-Hispanic counterparts (n=76, OR: 0.21, 95% CI: 0.06-0.73). Conclusions: These results suggest that even in clinically indicated ER+ disease, NGS testing is disproportionately offered to patients with a higher SES, particularly those who are not Hispanic/Latino. Whether these discrepancies stem from the recent adoption of NGS as standard of care or from actual barriers to accessing care should be defined in future studies. However, identifying that these disparities exist promotes awareness for clinicians to offer NGS more broadly. Research Sponsor: None.

Trust and communication among sexual and gender minority (SGM) cancer survivors.

Brandon M. Godinich, Narges Khanjani, Clifton Dave Fuller, Fumiko Chino; Texas Tech Health Science Center El Paso, El Paso, TX; The University of Texas MD Anderson Cancer Center, Houston, TX

Background: Trust and effective communication in healthcare are essential for delivering high-quality cancer care, especially for marginalized groups like SGM patients. This study examines the differences in trust and communication among LGBTQIA cancer survivors and those without (w/o) a cancer history to inform strategies for improving cancer care equity. Methods: Data from the nationally representative Health Information National Trends Survey (HINTS) from 2018-2022 was used to evaluate questions on communication, quality of care, and trust in those who self-identified as homosexual, gay, or lesbian, bisexual, or "something else" for sexual orientation. Two cohorts compared SGM participants with prior cancer diagnosis (survivors) and those w/o cancer. Demographic data included: age, gender, race/ ethnicity, education, employment, and household income. Analysis was done in STATA with Chi-squared and T-tests testing between SGM survivors and those w/o cancer and multivariate analysis (MVA) focused on SGM survivors. Results: In total, 1,258 SGM participants were included, of which 144 (11.4%) were SGM cancer survivors. SGM survivors were older than those w/o cancer history (median 64 vs. 46, p < 0.001) but had no significant differences in employment (25.0% vs. 47.2%) or race (White: 79.9% vs 69.5%; Black 21.9% vs 19.6%) (p = NS). Less than half of SGM survivors (44.9%) reported they always or usually had the chance to ask all of their health-related questions during provider visits, this was better than SGM w/o cancer (36.8%, p = 0.03). About a third reported that providers always/usually gave adequate attention to their emotions and feelings (37.2% survivors vs 37.5% w/o cancer, p = NS). Most felt they were always/usually adequately involved in decisions about their health care (82.5% survivors vs 82.0% w/o cancer, p = NS). Only 33.1% SGM survivors rated their overall quality of care as excellent/very good within the past year; this was slightly better than surveyed SGM w/o cancer (24.6%, p = NS). Half of SGM survivors (50.9%) trusted information about cancer from doctors, slightly more than for those w/o cancer (46.2%, p = NS). In a MVA limited to SGM survivors, only education was associated with decreased trust of cancer information from a doctor; those with at least some college (OR = 0.51 95%CI 0.26-0.99, p = 0.048) or postgraduate education (OR = 0.3695%CI 0.14-0.92, p = 0.034) had less trust compared to those with a high school degree or less. Conclusions: This national study shows that patient-reported overall healthcare to SGM survivors is poor. Less than a third of SGM survivors reported good quality of care and less than half felt providers answered all their questions; only half trusted cancer information from a doctor. Concerningly, those with higher education levels were less likely to trust doctors. Future efforts should focus on ensuring that all patients benefit from high quality cancer care and communication. Research Sponsor: None.

Quantifying financial toxicity in oncology: A comprehensive analysis of prescription cost disparities using public data from 2022.

Charishma Bhimineni, Shivani Modi, Sindhu Chandra Pokhriyal, Brian Gillespie, John Charles Leighton; Jefferson Einstein Montgomery, East Norriton, PA; Albert Einstein Healthcare Network, Philadelphia, PA; One Brooklyn Health System/interfaith Medical Center, Brooklyn, NY; Jefferson Einstein Medical Center, Philadelphia, PA

Background: Financial toxicity in cancer care poses a significant burden for patients and healthcare systems. This study analyzed public data to evaluate the financial impact of oncology treatments, focusing on factors such as demographics, insurance type, gender disparities, or geographics. Methods: The 2022 Medical Expenditure Panel Survey (MEPS) data was analyzed, focusing on antineoplastic and immunologic agents. Cost distributions, payment sources, and financial burden—defined as prescription costs exceeding 20% of annual household income were assessed across various insurances and demographic groups (age, gender, race, income, and education). Geographic analyses utilized Federal Information Processing Standard (FIPS) state codes. Results: The study included 1,379 oncology prescriptions. Prescription costs averaged 1,569 per prescription (median 388), ranging from 19 to 7,208. Annual costs spanned 2,507 (25th percentile) to 26,857 (75th percentile), with a median of 3,561 and a mean of 14,138. Non-prescription medical costs, such as procedures and hospitalizations, had a median of 45,475 and a mean of 47,509, with some exceeding 132,396 annually. Uninsured patients faced the highest average costs (78,439 annually), followed by Medicare patients (67,979). Medicaid patients had the lowest total costs (53,469). VA/TRICARE patients showed moderate costs (56,619) but higher prescription expenses (16,758). Low-income patients faced the greatest financial burden, spending 11.71% of their income on prescriptions, compared to 5.89% for middle-income and 2.66% for high-income patients. Private insurance beneficiaries faced the highest costs (5,500-6,000), particularly among Black and White patients, followed by Medicare (4,500-5,000). Medicaid beneficiaries incurred lower costs (3,500-4,000), while uninsured patients had the lowest mean costs (2,500-3,000), reflecting limited access to comprehensive treatments. Female patients had higher costs for breast and lung cancer treatments. Black and Hispanic patients relied more on Medicaid. Patients with graduate degrees had higher average costs (4,226) than those with a high school education or less (3,707). Geographically, financial burden was highest in the Midwest, moderate in the Northeast, and mixed in coastal and Southern states. Conclusions: Significant disparities in financial toxicity exist across demographics, insurance types, and regions. The gap between mean and median costs underscores the disproportionate financial strain faced by some patients. Policy interventions, including expanded insurance coverage, capped out-of-pocket costs, and targeted subsidies, are needed to improve equity and affordability in cancer care. Research Sponsor: None.

Racial differences in cardiovascular outcomes among cancer patients receiving immune checkpoint inhibitors.

Cho Han Chiang, Xiaocao Xu, Yu-Cheng Chang, Junmin Song, Chun-Chiao Yu, Yu Chang, Shuwen Lin; Department of Medicine, Mount Auburn Hospital, Harvard Medical School, Cambridge, MA; Department of Hematology and Oncology, University of Vermont Medical Center, Burlington, VT; Department of Medicine, Danbury Hospital, Danbury, CT; Department of Medicine, Jacobi Medical Center, Albert Einstein College of Medicine, Bronx, NY; Kaohsiung Medical University, Kaohsiung, Taiwan; Department of Surgery, National Cheng Kung University College of Medicine, Tainan, Taiwan; Montefiore Einstein Comprehensive Cancer Center/Albert Einstein College of Medicine, Bronx, NY

Background: Immune checkpoint inhibitors (ICIs) increase the risk of major adverse cardiovascular events (MACE). We aimed to evaluate disparities in MACE across racial groups. Methods: We conducted a propensity score-matched study using the TriNetX Analytics Network database, which includes de-identified data from over 140 healthcare institutions. Adult cancer patients treated with ICIs were included and those with prior MACE were excluded. Patients were grouped into White, Black, Asian, and Hispanic cohorts. The primary outcome was incident MACE, defined as the composite of myocarditis, pericarditis, myocardial infarction, ischemic stroke, heart failure, atrial fibrillation, and venous thromboembolism (VTE) within 12 months of ICI. Matching was performed using variables: age, sex, cancer type, metastatic disease, comorbidities, and cardiovascular medication. Results: A total of 58,217 eligible patients were identified, including 44,151 White, 5,876 Black, 5,347 Asian, and 2,843 Hispanic individuals. After matching, cohorts were adequately balanced. Black patients had the highest risk for MACE, with an 18% increased risk compared to White (HR 1.18 [95% CI: 1.06-1.30]) and Hispanic patients (HR 1.18 [95% CI: 1.03-1.35]) and an 80% increased risk compared to Asian patients (HR 1.80 [95% CI: 1.57-1.35]). This increased risk among Black patients appeared to be driven by higher rates of heart failure and VTE. The risks of MACE were similar between White and Hispanic individuals while Asian patients had the lowest risk. Conclusions: There were racial differences in immune-related MACE, with Black patients experiencing the highest risk of cardiotoxicity following ICI treatment. Research Sponsor: None.

Hazard ratio for effects of race on cardiovascular outcomes.						
	Black vs. White	Black vs. Hispanic	Black vs. Asian	White vs. Asian	White vs. Hispanic	Hispanic vs. Asian
Outcomes	n=5,109 each	n=2,636 each	n=3,095 each	n=2,842 each	n=4,876 each	n=2,157 each
MACE	1.18 (1.06-1.30)	1.18 (1.03-1.35)	1.80 (1.57-2.07)	1.44 (1.28-1.62)	0.98	1.60 (1.35-1.91)
Myocarditis	0.50	0.16	0.61 (0.15-2.57)	1.85	1.08	1.66 (0.61-4.58)
Pericarditis	1.10	1.36	2.31 (0.71-7.51)	2.99 (1.09-8.21)	1.20	0.99 (0.20-4.91)
Myocardial infarction	1.09 (0.86-1.39)	1.18 (0.83-1.67)	1.80 (1.28-2.53)	1.42 (1.06-1.91)	1.18 (0.84-1.65)	1.47 (0.96-2.24)
Ischemic stroke	1.23	1.13 (0.83-1.54)	1.34 (1.00-1.80)	1.17 (0.91-1.50)	0.81 (0.59-1.10)	1.45 (1.01-2.08)
Heart failure	1.33	1.32 (1.01-1.73)	1.78 (1.37-2.31)	1.38 (1.10-1.73)	1.05 (0.80-1.39)	1.33 (0.96-1.84)
Atrial fibrillation	0.96	1.19	1.29	1.36	1.26	0.95
Venous thromboembolism	1.28	1.19	2.34 (1.92-2.84)	1.62	0.97	2.09

Impact of sociodemographic factors and Medicaid expansion on postoperative outcomes for glioblastoma, 2004-2021.

Bhav Jain, Pragat Patel, Gabriela D. Ruiz Colón, Lily H. Kim, John Choi, Edward Christopher Dee, Tej D. Azad, Laura M. Prolo, Gordon Li, Michael Lim; Stanford University School of Medicine, Stanford, CA; University of Pennsylvania, Philadelphia, PA; Massachusetts General Hospital, Boston, MA; Stanford University Medical Center, Stanford, CA; Department of Radiation Oncology, Memorial Sloan Kettering Cancer Center, New York, NY; Johns Hopkins University, Baltimore, MD; Stanford University, Stanford, CA

Background: Glioblastoma (GBM), the most aggressive primary brain tumor in adults, has a median survival of ~15 months despite treatment and exhibits significant disparities in care access. Sociodemographic factors and policy interventions, such as Medicaid expansion under the ACA, show potential to mitigate inequities in other cancers. However, their impact on GBM outcomes remains underexplored. Methods: Using the National Cancer Database, we conducted a retrospective study of 85,631 GBM patients treated with surgery between 2004. and 2021. Multivariate regression models and Kaplan-Meier survival analyses evaluated associations between sociodemographic factors (e.g., race, income, education, rurality, insurance status) and outcomes, including postoperative hospital stay, 30-day readmission, 90-day mortality, and overall survival. All models adjusted for key clinical (e.g., tumor size, comorbidities, receipt of chemotherapy/radiation therapy) and patient (e.g., age, sex) covariates. A difference-in-differences analysis assessed the effects of Medicaid expansion on these outcomes. Results: Regarding postoperative length of hospital stay, disparities were observed by race (Black vs. White β = 1.45 days [1.22–1.68]; Asian American and Pacific Islander [AAPI] vs. White $\beta = 0.86$ days [0.50–1.22]), rurality (urban vs. metro $\beta = -0.31$ days [-0.47 to -0.15]), insurance status (private vs. uninsured β = -1.10 days [-1.41 to -0.80]), and education (highest vs. lowest quartile β = -0.28 days [-0.48 to -0.09]). Unplanned 30-day hospital readmission rates demonstrated disparities by race (Black vs. White OR = 1.19 [1.04 - 1.35]), income (highest vs. lowest quartile OR = 0.84 [0.75-0.96]), and education (highest vs. lowest quartile OR = 1.19[1.05-1.34]). Moreover, 90-day mortality indicated disparities by race (Black vs. White OR = 0.85 [0.77-0.95]; AAPI vs. White OR = 0.64 [0.53-0.77]), income (highest vs. lowest quartile OR = 0.81 [0.74 - 0.89], education (highest vs. lowest quartile OR = 1.13 [1.03 - 1.23]), and insurance status (private vs. uninsured OR = 0.71 [0.62-0.82]). Finally, overall survival demonstrated disparities by race (Black vs. White HR = 0.88 [0.85-0.91]; AAPI vs. White HR = 0.77 [0.73-0.82]), income (highest vs. lowest quartile HR = 0.83 [0.81-0.86]), education (highest vs. lowest quartile HR = 1.12 [1.09–1.15]), rurality (rural vs. metro HR = 1.06 [1.00–1.12]), and insurance status (Medicaid vs. no insurance HR = 1.09 [1.04–1.15]). Medicaid expansion did not significantly impact any outcomes, including overall survival (DID HR = 0.95 [0.84-1.07]). **Conclusions:** Significant sociodemographic disparities persist in GBM postoperative outcomes, with no improvement from Medicaid expansion. Targeted socioeconomic interventions are needed to address inequities in access to specialized neuro-oncological care and improve outcomes for underserved populations. Research Sponsor: None.

Symptom burden, quality of life (QoL), social and behavioral characteristics in young patients (<40 years old) with cancer: A prospective cohort of 7323 patients across 110 sites in France and Belgium.

Kaïssa Ouali, Christophe Massard, Antoine Hollebecque, Yohann Loriot, Aurelien Marabelle, Capucine Baldini, Ivan Panico, Younes Youssfi, Arlindo R. Ferreira, Alexandre Yazigi, Charles Ferté, Fabrice Barlesi, Fabrice Andre, Maria Alice Franzoi; Gustave Roussy, Drug Development Department (DITEP), Villejuif, France; Gustave Roussy, Department of Drug Development (DITEP), Villejuif, France; Drug Development Department (DITEP), Institut Gustave Roussy, Villejuif, France; Resilience Care, Paris, France; Resilience Care, Lisbon, Portugal; Gustave Roussy Institute, Villejuif, France; Gustave Roussy, INSERM U981, Université Paris-Saclay, IHU-National PReclSion Medicine Center in Oncology, Villejuif, France; Cancer Survivorship Program, INSERM Unit 981, Gustave Roussy, Villejuif, France

Background: Cancer in individuals under 40 years old is increasingly recognized as a public health concern, characterized by unique etiologies, biology, and clinical behaviors compared to older populations. Young patients may also face specific physical, psychosocial, and socioeconomic challenges that can influence outcomes which are often suboptimally addressed in routine care. Digital health and specifically remote patient monitoring (RPM) offer a way to track and manage these challenges effectively, increasing access to supportive care. Methods: Prospective, observational cohort of 7323 adult patients with cancer participating in an RPM pathway across 110 hospitals in France and Belgium between Jun-2022 and Dec-2024. Patients were grouped by age (< 40 vs. ≥ 40). At baseline, demographic, clinical, and social and behavioral data were collected. Longitudinal symptom burden (e.g., anxiety, pain, nausea) was assessed using validated patient-reported outcomes (PRO-CTCAE). High symptom burden was defined as PRO-CTCAE grade \geq 3. QoL was measured by EORCT QLQ-C30 summary score. Linear mixed models, adjusted for relevant covariates, were used to compare changes in symptom burden over 12 weeks between age groups. Results: Younger patients (n = 350 pts < 40 years) were more often female (77 vs 62%, p < 0.001) and with localized disease (55 vs 45%, p < 0.001). The rate of breast, lung, colorectal and pancreatic cancers represented respectively 157%, 27%, 57% and 17% of the proportion in older adults (p < 0.001). Younger patients also presented with more unfavorable social and behavioral characteristics including higher alcohol consumption (26.3 vs. 15.3%, p= 0.005), tobacco consumption (23.2 vs. 13.8%, p < 0.001), unemployment (17.7 vs 7.2%, p < 0.001) and financial insecurity (23.2 vs 10.9%, p <0.001). Similar QoL was found at baseline (mean [SD] 76.9 [16.8] vs 76.1 [17.0], p = 0.84). Adherence to RPM surveys was lower in the younger group (74 vs 84%, p = 0.001), who took also on average longer to answer (22 vs 10h, p<0.001). Younger patients had higher early (week 1 to 3) symptom burden (anxiety 16.7 vs 10.6%, p = 0.001], fatigue [36.1 vs 30.6, p = 0.05], nausea [30.4 vs 18.6%, p < 0.001], anorexia [16.7 vs 10.6, p = 0.004] and performance status decline [26.8 vs 18.7%, p = 0.012). At 12 weeks, symptom burden improved in both groups, and the between-group difference was no longer significant. Conclusions: In this large, multiinstitutional cohort, younger patients faced unique physical, psychological and behavioral challenges and experienced higher early symptom burden. Interestingly, by 12 weeks, both groups demonstrated symptomatic improvement, with no remaining differential across age groups. These findings suggest that RPM and supportive interventions may help mitigate disparities in symptom burden over time. Research Sponsor: Resilience Care.

Prevalence of and factors associated with financial toxicity among gastrointestinal cancer patients in Pakistan.

Sehar Salim Virani, Tayyab Siddiqui, Fatima Shaukat, Asfia Khursheed, Lubna Saleem, Abid Madad Jamal, Juliet Lumati, Muhammad Rizwan Khan, Syed Nabeel Zafar; Aga Khan University Hospital, Karachi, Pakistan; Patel Hospital, Karachi, Sindh, Pakistan; Cyberknife And Tomotherapy Centre, Jpmc, Karachi, Sindh, Pakistan; Cancer Foundation Hospital, Gulshan-E-Iqbal, Pakistan; Cancer Foundation Hospital, Karachi, Pakistan; Northwestern University Feinberg School of Medicine, Chicago, IL; Aga Khan University, Karachi, Pakistan; University of Wisconsin–Madison, Madison, WI

Background: Financial toxicity (FT) impacts cancer care in low- and middle-income countries (LMICs), affecting treatment adherence and quality of life. This study assesses FT prevalence and associated factors among gastrointestinal (GI) cancer patients across distinct healthcare systems in Pakistan. Methods: A cross-sectional study was conducted across three tertiary care centers in Karachi: Aga Khan University Hospital (AKUH, private, fee-for-service), Jinnah Postgraduate Medical Center (JPMC, public, free), and Cancer Foundation Hospital (CFH, private-philanthropy, subsidized). FT was assessed using the Urdu version of the Comprehensive Score for Financial Toxicity-Functional Assessment of Chronic Illness Therapy (COST-FACIT). Multivariable negative binomial regression identified factors linked to high FT. Results: Of 375 patients, 44.5% were from AKUH, 33.6% from JPMC, and 21.9% from CFH. Mean age was 50.8 ± 14.4 years, with 62.4% males. Only 8.3% had health insurance, and the median International Wealth Index (IWI) was 79.9 (IQR: 57.1–95.1). Catastrophic healthcare expenditure affected 41.7%. The mean COST-FACIT score was 16.0 \pm 7.4, with 46.1% experiencing mild FT (score: 14–26) and 41.9% moderate FT (score: \leq 14). Patients delaying or forgoing care had higher FT (p < 0.001). Borrowing money, selling assets, or cutting essential expenses were strongly associated with increased FT (p < 0.001). Patients at AKUH reported higher FT than JPMC (IRR = 0.84, 95% CI: 0.74–0.97). Younger patients (21–50 years) (IRR = 0.66, 95% CI: 0.46-0.95) and those receiving chemotherapy (IRR = 0.89, 95% CI: 0.81-0.98) experienced higher FT. Females (IRR = 1.36, 95% CI: 1.17-1.58) and higher socioeconomic status (IRR = 1.39, 95% CI: 1.06-1.83) were associated with lower FT. Conclusions: Nearly 85% of GI cancer patients faced FT. Younger age, male gender, lower socioeconomic status, and systemic therapy were associated with higher FT. Subsidized care, financial support, and institution-specific strategies are critical to mitigating FT in LMIC healthcare systems. Research Sponsor: None.

Patient characteristics and treatment costs across hospitals.					
	AKUH	JPMC	CFH		
Gender, n (%)					
Male	109 (65.3)	73 (57.9)	52 (63.4)		
Female	58 (34.7)	53 (42.1)	30 (36.6)		
Age (yrs), mean (SD)	54.3 (1.1)	44.2 (1.3)	53.6 (1.4)		
IWI score, mean (SD)	84.0 (1.5)	52.8 (2.6)	80.4 (2.0)		
COST-FACIT score, mean (SD)	16.7 (7.9)	15.3 (7.6)	15.7 (5.8)		
EORTC QLQ summary score	78.1 (15.5)	79.3 (17.9)	75.1 (16.0)		
(Quality of Life score), mean (SD)					
Monthly household income	358.4 (179.2-716.8)	107.5 (43.0-	233.0 (71.7-358.4)		
(USD), median (IQR)		179.2)			
Out of pocket costs (USD), median					
(IQR)	2509.0 (1003.6-	0 (0-0)	1433.7 (1075.3-		
Surgery and associated inpatient	4569.89)	0 (0-304.7)	1792.1)		
Chemotherapy	1433.7 (573.5-3225.8)	0 (0-0)	1469.5 (358.4-1881.7)		
Radiotherapy	896.1 (255.4-2150.5)		1075.3 (716.8-1792.1)		

*Costs converted using 1 USD = 279 Pakistani Rupee.

The effect of a vertically integrated health system on the disparity of socioeconomic status seen in cancer stage at presentation.

Robert Michael Cooper, Quyen Ngo-Metzger, Reina Haque; Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA; Kaiser Permanente Bernard J. Tyson School of Medicine, Pasadena, CA; Kaiser Permanente Southern California, Pasadena, CA

Background: Earlier stage of diagnosis may lead to more curable disease and less intensive treatment. Vertically integrated health care systems through screening and integrated care delivery model may provide benefit in identifying cancer patients at earlier stage of disease. Methods: We examined an insured Southern California cohort of 503,279 patients diagnosed with invasive cancer between Jan 1 2015 and Dec 31 2020 provided by the state SEER Cancer Registry. Stage at diagnosis provided was SEER summary stage in which patients were defined as having local disease or advanced (regional or metastatic) disease. We used geocoded socioeconomic status, race/ethnicity, and hospital of diagnosis as independent variables. For hospital of diagnosis, patients were divided into those diagnosed in Kaiser Foundation Hospitals or not. The first cohort was for cancers with robust screening programs and included breast, cervical and colon (CBC group). The second cohort was all other cancers (non CBC group). We evaluated each of these groups independently. The prevalence of local disease was determined and multilinear regression was used to determine the adjusted odd ratios of being diagnosed with local disease. Results: Compared to patients not diagnosed in Kaiser Foundation hospitals (non KFH), patients diagnosed in Kaiser Foundation hospitals (KFH) were more likely to be diagnosed with local disease. 1.14 (95% Confidence Intervals 1.13, 1.16) for the total cohort. We looked at the adjusted interaction of being diagnosed in KFH for each quintile: Highest SES 1.03 (1.00, 1.07), Upper Middle SES 1.11 (1.08, 1.14), Middle SES 1.21 (1.18, 1.25), Lower-Middle SES 1.25 (1.21, 1.29) and Lowest 1.34 (1.29, 1.38). Compared to patients not diagnosed in Kaiser Foundation hospitals (non KFH), patients diagnosed in Kaiser Foundation hospitals (KFH) were more likely to be diagnosed with local disease in the CBC cohort 1.12 (1.09, 1.16) and in the non CBC cohort 1.16 (1.14, 1.17). **Conclusions:** Vertically integrated health care systems have shown advantages in preventive care. We show that insured patients diagnosed in Kaiser Foundation hospitals present with more localized and less advanced disease than patients diagnosed in non KF hospitals. This advantage was seen in a group of patients with established screening program and was also seen in diseases without screening programs. A sub analysis showed that the advantage more pronounced the lower the SES. How a vertically integrated care delivery system provides these advantages deserves further study. Research Sponsor: None.

Dihydropyrimidine dehydrogenase (DPD) deficiency-related variants among Mexican patients with gastrointestinal (GI) malignancies.

Enrique Soto Pérez de Celis, Andrea Morales Alfaro, Óscar B. Jiménez, Paula Cárdenas-Reyes, Jaime Ivan Mercado-Camacho, Mauricio Rodríguez-Dorantes, Vanessa González-Covarrubias; University of Colorado Anschutz Medical Campus, Aurora, CO; Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Mexico City, DF, Mexico; Instituto Nacional de Medicina Genómica, Mexico City, Mexico; Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Mexico

Background: DPD deficiency is the most important risk factor for developing fluoropyrimidinerelated adverse events. Genetic variants causing DPD deficiency are found in 6-8% of Caucasian patients. However, there is limited information on their prevalence in underrepresented ethnic groups, such as Hispanics and Latinos, and testing for these variants is not routinely recommended in Latin America. Our goal was to assess the allele frequency of clinically actionable dihydropyrimidine dehydrogenase (DPYD) risk variants defined by the Clinical Pharmacogenetics Implementation Consortium (CPIC) and the European Medicines Agency (EMA) among admixed Mexican patients with GI malignancies. Methods: Patients with recently diagnosed GI cancer candidates for fluropyrimidine therapy were recruited from a single institution in Mexico City. After providing informed consent, a blood sample and clinical characteristics were collected. We utilized the Illumina Infinium Global Screening Array (GSA)-to genotype 34 DPYD variants, six of which are known to lead to an increased risk of fluoropyrimidine toxicity and are considered clinically actionable. Results: Two hundred and eight patients with a mean age of 62 years (SD 13.2) were included. 47% were female. The most common type of cancer was colorectal (38%) followed by pancreas (22%) and biliary tract (18%). DNA samples from 192 patients passed quality control, of which 156 (62%) received fluoropyrimidines during followup. Only 2 patients (1%) were heterozygous for actionable DPYD intermediate metabolizer risk variant alleles: one with c.2846A > T (rs67376798, D949V) and one with c.1129-5923C > G[rs75017182; HapB3 SNP c.1236G > A; rs56038477]. No patients were found to have other CPIClisted DPYD risk variants. Additionally, we investigated the allele frequencies of other 30 DPYD variants and observed low-frequency variation (between 0.260 and 0.0032) in rs56038477, rs1801160, rs17376848, rs1801159, rs1801158, rs45589337, rs2297595, rs200562975, and rs1801265. Several of these may be related to decreased DPYD activity and warrant further analysis regarding their impact on adverse drug reactions. Conclusions: In contrast with reports from Caucasic populations, we found a very low allele frequency of DPYD actionable variants. Our findings highlight the limitation of current pharmacogenomic testing recommendations and panels, which may not be appropriate for admixed ethnic populations such as Hispanics/Latinos due to disparities in representation. There is a need to study the role of other DPYD variants in larger patient samples to understand their role in the toxicity risk of admixed populations in Mexico and Latin America, to explore the use of novel techniques such as Next Generation Sequencing, and to investigate the effect of other related genes on toxicity risk. Research Sponsor: AGA Research Foundation.

State-level trends and associated disparities in melanoma burden in the United States.

Furkan Bahar, Mehmed Taha Dinc, Chinmay Jani, Betul Ibis, Ann W. Silk, Elizabeth Iannotti Buchbinder, Karam Khaddour; Mount Auburn Hospital/Harvard Medical School, Cambridge, MA; Boston Medical Center, Boston University, Boston, MA; University of Miami Sylvester Comprehensive Cancer Center, Miami, FL; Mount Auburn Hospital, Harvard Medical School, Cambridge, MA; Dana-Farber Cancer Institute, Boston, MA

Background: Melanoma, an aggressive skin cancer, poses a significant public health challenge in the United States despite advancements in detection and treatment due to its high mortality. This study analyzes trends in melanoma incidence, mortality, and disease burden in the US from 1990 to 2021. Methods: Data on incidence rates (IR), mortality rates (MR), disabilityadjusted life years (DALYs), and estimated annual percentage changes (EAPCs) from 1990 to 2021 were extracted from the Global Burden of Disease 2021 database. Regional trends within the US were evaluated to identify state-level patterns and disparities. Results: In 2021, melanoma IR in the US was 27.2 per 100,000, far exceeding the global average of 3.8. Between 1990 and 2021, IR increased by 64.8%, compared to a global rise of 28.8%. Among US states, Maine had the highest IR at 37.8 per 100,000, while the District of Columbia reported the lowest IR at 8.3. Alaska showed the largest relative increase (EAPC of 81.5%), while New Jersey was the only state to report a decline in incidence, with an EAPC of -1.6%. The US melanoma mortality rate was 3.0 per 100,000 in 2021, compared to the global rate of 0.78. US mortality increased by 5.5%, while the global mortality rate rose by 25.8%. West Virginia recorded the highest mortality rate at 4.49 per 100,000, whereas the District of Columbia had the lowest rate at 1.20 and the most significant improvement, with an EAPC of -43.5%. In terms of DALYs, the US reported a rate of 79.2 per 100,000 in 2021, significantly higher than the global average of 21.27. Between 1990 and 2021, DALYs in the US declined by 14.4%, contrasting with an 8.5% increase globally. The DALY/incidence ratio in 2021 was 2.9 in the US, compared to 5.6 globally, indicating notable differences in disease burden across populations. Melanoma disproportionately affected males, with an IR of 33.9 per 100,000 compared to 20.7 in females (male-tofemale ratio: 1.6). Mortality rates followed a similar pattern, with males experiencing a rate of 4.0 per 100,000 vs. 2.1 for females, consistent with global trends. Conclusions: Despite the decrease in DALYs, melanoma incidence and mortality continue to rise in the US, exceeding global averages. Significant disparities persist across states and genders, reflecting the complex interplay of risk factors and behavioral patterns. The lower DALY/incidence ratio in the United States highlights the likely effectiveness of US treatment options in mitigating disease burden per case. Variations among states may also be attributed to differences in ethnic distribution, which influence genetic susceptibility, healthcare access, and prevention efforts. Research Sponsor: None.

Association of allostatic load (AL) and residential segregation with breast biopsy outcomes after screening mammography.

Braelyn Wekwerth, Niam Abeysiriwardena, Nathaniel Mercaldo, Sarah Bell, Ruth C. Carlos; Massachusetts General Hospital, Boston, MA; University of Michigan, Ann Arbor, MI; Columbia University, New York, NY

Background: Allostatic Load (AL) and residential segregation have been associated with the risk of breast cancer (BC). However, the independent effects of AL and measures of residential segregation (MRSs) on cancer detection and the false positive (FP) biopsy rate in a screening mammography population have not yet been assessed. Methods: We retrospectively identified women aged ³40 who underwent screening mammography between 1/1/2021-12/31/2021 and subsequent breast biopsy from the Mass General Brigham Biobank. We collected age and selfreported race/ethnicity. Each participant's zip code was geocoded to the corresponding census tract. We computed five MRS indices: Dissimilarity (DD), Isolation (BI), Delta (D), Absolute Centralization (AC), Spatial Proximity (SP). We collected the following biomarkers obtained within two years before the index screen: cardiovascular, metabolic, immunologic, renal lab values. AL was assigned one point for each lab value in the worst quartile and summed (continuous). We collected diagnostic breast imaging and biopsy encounters within 12 months after the index screen. Multiple imputation accounted for missing data. Multivariable logistic regression assessed age, race, AL and each of our MRSs association with cancer detection and FP rates. We applied Rubin's rules to estimate overall odds ratios (OR), confidence intervals (CI), and p-values for all covariates. Results: Of the 418 eligible women, 59.6% (N=249) had an FP biopsy, and 66.3% (N=277) had breast cancer, including cases of ductal carcinoma in situ. On average, women were 62 years old (SD=13); 85.6% White. DD was associated with a reduced risk of benign high-risk lesions (OR=0.69, 95% CI:[0.49-0.95]; p=0.025), and homogeneous, affluent census tracts—whether predominantly Black or White—were similarly protective (OR=0.85, 95% Cl:[0.72, 0.99]; p=0.041). MRS indices were linked to lower benign high-risk outcomes (e.g. SP, OR=0.53, 95% CI:[0.31, 0.91]; p=0.021). Age and race significantly predicted adverse events (AEs). Older age was consistently associated with increased AEs across all models (OR = 1.09, 95% CI:[1.00, 1.18]). Cancer detection also increased with age (OR = 1.20, 95% CI: [1.10, 1.30]; p < 0.001). AL was significantly linked to cancer detection (OR = 1.13, 95% CI:[1.00, 1.28]). Conclusions: Some MRSs are associated with cancer detection and high-risk FP. AL remains associated with these cancer and high-risk FP, even accounting for these segregation measures. These factors may contribute to an increased risk of cancer, highlighting the significance of spatial and socioeconomic influences on screening outcomes. Clinical Relevance Statement: AL may serve as a biomarker to enhance biopsy selection following screen-detected mammographic abnormalities, potentially improving cancer detection rates. Research Sponsor: None.

Racial differences in serious immune-related adverse events among cancer patients receiving immune checkpoint inhibitors.

Cho Han Chiang, Xiaocao Xu, Yu-Cheng Chang, Junmin Song, Chun-Chiao Yu, Yu Chang, Shuwen Lin; Department of Medicine, Mount Auburn Hospital, Harvard Medical School, Cambridge, MA; Department of Hematology and Oncology, University of Vermont Medical Center, Burlington, VT; Department of Medicine, Danbury Hospital, Danbury, CT; Department of Medicine, Jacobi Medical Center, Albert Einstein College of Medicine, Bronx, NY; Kaohsiung Medical University, Kaohsiung, Taiwan; National Cheng Kung University Hospital, Taibei, Taiwan; Montefiore Einstein Comprehensive Cancer Center/Albert Einstein College of Medicine, Bronx, NY

Background: Immune checkpoint inhibitors (ICIs) are associated with an increased risk of adverse events (irAEs). We aimed to evaluate disparities in serious irAEs among patients from different racial backgrounds. Methods: We performed a propensity score-matched study using the TriNetX Analytics Network database, which includes de-identified data from over 140 healthcare institutions. We included adult cancer patients treated with ICIs and grouped patients into White, Black, Asian, and Hispanic cohorts. The outcomes were incident composite irAEs, which included pneumonitis, colitis, thyroiditis, hypophysitis, adrenal insufficiency, Stevens-Johnson syndrome (SJS) / toxic epidermal necrolysis (TEN), and hepatitis within 12 months of ICI. Patients were matched using variables: age, sex, ICI type, cancer type, metastatic disease, and underlying comorbidities. Results: We identified 72,501 cancer patients who received ICIs, including 56,937 White, 7,027 Black, 5,623 Asian, and 2,914 Hispanic patients. Cohorts were adequately balanced across covariates after matching. White and Hispanic patients showed similar risks of irAEs, both having approximately 30% higher risk of developing serious irAEs compared with Black and Asian patients. Compared with Black patients, White and Hispanic patients had higher risks of colitis and adrenal insufficiency. Compared with Asian patients, White and Hispanic patients had higher risks of pneumonitis, colitis, and thyroiditis. Conclusions: White and Hispanic patients have the highest risks of developing serious irAEs. Further research is needed to explore the underlying causes and develop targeted interventions to mitigate these disparities. Research Sponsor: None.

Hazard ratio for the effects of race on irAEs.						
	White vs. Black	White vs. Asian	White vs. Hispanic	Black vs. Asian	Hispanic vs. Black	Hispanic vs. Asian
Outcomes	n=7,207 each	n=5,562 each	n=3,314 each	n=3,839 each	n=2,680 each	n=2,224 each
Composite irAE	1.28	1.30	1.03 (0.91-1.18)	0.95	1.30 (1.11-1.52)	1.39 (1.16-1.67)
Pneumonitis	1.55 (0.77-3.12)	1.93	1.01 (0.42-2.44)	0.68	2.86 (0.78-11.1)	4.35 (0.96-20.0)
Colitis	1.44 (1.27-1.63)	1.72 (1.47-2.00)	1.04 (0.88-1.23)	1.12 (0.91-1.34)	1.22 (0.99-1.52)	1.69 (1.32-2.17)
Thyroiditis	1.01 (0.81-1.25)	` 1.61 (1.19-2.17)	`1.09 (0.81-1.47)	`1.31 (0.91-1.89)	`1.41 (0.98-2.04)	`1.85 (1.19-2.86)
Hypophysitis	0.34 (0.07-1.67)	0.50 (0.05-5.56)	0.68 (0.11-4.04)	2.00 (0.37-10.9)	`0.65 (0.11-3.85)	`1.47 (0.24-9.09)
Adrenal insufficiency	1.70 (1.13-2.55)	1.18 (0.79-1.75)	1.10 (0.69-1.77)	0.64 (0.36-1.11)	2.50 (1.20-5.26)	0.89 (0.48-1.67)
SJS/TEN	0.61 (0.15-2.54)	0.05 (0.01-0.40)	0.76 (0.17-3.40)	0.51 (0.15-1.68)	1.43 (0.24-8.33)	0.33 (0.07-1.61)
Hepatitis	1.11 (0.88-1.40)	0.74 (0.59-0.93)	0.88 (0.67-1.16)	0.68 (0.50-0.91)	1.41 (0.99-2.00)	0.97 (0.69-1.37)

Survival disparities between patients with breast cancer with and without HIV at Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH).

Harriet Fridah Adhiambo, Thomas A Odeny, Dorothy Imbuka Mangale, Phiona Awuor Adagi, Everline Nyandieka, Angela Awino Mcligeyo; Kenya Medical Research Institute, Nairobi, Kenya; Washington University in St. Louis, St. Louis, MO; Washington University School of Medicine, St. Louis, MO; Jaramogi Oginga Odinga Teaching and Referral Hospital, Kisumu, Kenya; Research Care Training Program, Center for Microbiology Research, Kenya Medical Research Institute, Kisumu, Kenya; Kenya; Kenyatta University, Nairobi, Kenya

Background: Breast cancer and HIV/AIDS pose significant public health challenges. Women living with HIV face higher mortality rates when diagnosed with breast cancer than HIVnegative women. Although advancements in treatment have improved survival outcomes, limited evidence exists on the impact of HIV on breast cancer outcomes in low-resource settings. This study examines survival disparities between breast cancer patients with and without HIV. Methods: We conducted a retrospective cohort study of breast cancer patients diagnosed at JOOTRH between January 2013 and September 2024. Data from paper-based records included demographics, clinical data and outcomes (survival status). Survival, defined as time from diagnosis to death or last follow-up, accounted for transfer out, death, being alive, or lost to follow-up. Variables with >20% missingness were excluded. Survival disparities by HIV status were estimated using Kaplan-Meier, with mortality relationships analyzed via Cox Proportional Hazards Model. Results: Out of 494 breast cancer patients, 101(20%) were HIV+, 219 (44%) had unknown HIV status, and 174(36%) were HIV-. At diagnosis, HIV+ patients were younger (median: 48, [IQR 40-56]) compared to HIV- patients (median: 51, [IQR 40-64], p=0.030) and had a lower median BMI (23.2 vs. 25.4, p=0.008). HIV positive patients had a longer median time to treatment initiation (56 days, IQR 25-127) compared to HIV-negative patients (44 days, IQR 20-94), although the difference was not statistically significant (p=0.4). In this cohort, 12% (60) of patients had died, with a higher mortality rate among HIV+ patients (17%, 17 out of 101) compared to HIV- patients (14%, 24 out of 174), while loss to follow-up was substantial in both groups (43% HIV+ vs. 37% HIV-, p<0.001). The crude 5-year survival probability was 14% lower in HIV+ patients (59%, [95% CI 38 – 91]) than HIV- patients (73%, [61–87]). Survival, adjusted for age, smoking, employment, and cancer stage, did not vary significantly by HIV status (HR for HIV+ vs. HIV-: 1.13, 95% CI: 0.51-2.50, p = 0.8). However, survival was significantly lower among patients with health insurance (HR = 0.35, 95% CI: 0.12-0.97, p = 0.044) and those with > primary/elementary school education (HR: 0.13, 95% CI: 0.02, 0.88, p = 0.037) compared to those with primary education only. Patients who did not receive treatment had a significantly higher mortality risk (HR = 3.52, 95% CI: 1.54-8.04, p = 0.003. Conclusions: In this study, breast cancer patients living with HIV had poorer crude 5year survival probabilities compared to their HIV-negative counterparts, although the adjusted survival did not differ significantly by HIV status. Factors associated with significantly lower survival included lack of treatment, lower education levels, and absence of treatment. These findings underscore the need for targeted interventions to improve breast cancer outcomes among HIV-positive patients, particularly in low-resource settings. Research Sponsor: None.

Association between Geriatric 8 frailty, guideline treatment, treatment adherence, and overall survival in older patients with cancer (PROGNOSIS-G8).

Helena Møgelbjerg Ditzel, Ann-Kristine Weber Giger, Jesper Ryg, Cecilia Margareta Lund, Per Pfeiffer, Henrik Jorn Ditzel, Sören Möller, Marianne Ewertz, Trine Lembrecht Jørgensen; Department of Oncology, Odense University Hospital, Odense, Denmark; Department of Geriatric Medicine, Odense University Hospital, Svendborg, Denmark; Department of Geriatric Medicine, Odense University Hospital, Odense, Denmark; Department of Clinical Medicine, Copenhagen University Hospital, Herlev-Gentofte, Denmark; Department of Oncology, Odense University Hospital, Odense, Denmark; OPEN- Open Patient data Explorative Network, Odense University Hospital, Odense, Denmark; Department of Clinical Research, University of Southern Denmark, Odense, Denmark

Background: Frailty is frequent among older adults with cancer and may affect oncologic treatment tolerance. Frailty screening, with tools such as the Geriatric 8 (G8), is recommended to help guide clinical decision-making. While the G8 has been strongly associated with survival, its relationship with treatment adherence remains less clear. This study aimed to evaluate the association between G8-identified frailty and treatment outcomes in a large cohort of older adults with diverse cancer types. Methods: This single-center prospective cohort included adults, age \geq 70 years, with solid cancers who underwent G8 screening at their initial oncology consultation. Treatment-related outcomes included one-year overall survival, first-line oncologic treatment adherence within 9 months, and whether patients were offered guideline treatment. Guideline treatment was defined as regimens consistent with recommendations from national guidelines for first-line oncologic treatment, allowing add-on protocol treatment, while less-than-guideline treatment referred to regimens not among first choices, often deemed inferior. Adherence to the doctor-patient selected treatment plan was defined as the absence of discontinuations, dose reductions after treatment initiation, or un-administered treatments (i.e., excluding delays). Data on demographics, comorbidity, cancer diagnosis, treatment, and survival were extracted from medical records. Associations between G8 frailty $(\leq 14/17 \text{ points})$ and outcomes were analyzed using multivariate logistic regression and Cox proportional hazards regression, adjusting (adj.) for confounders. Results: Among the 1,398 patients screened, 65% were frail. Frailty doubled the risk of death at one year (adj. HR 2.0, 95% CI 1.7-2.4, p < 0.001). Frail patients who adhered to less-than-guideline treatment had a 69% lower mortality risk compared to frail patients unable to adhere to guideline treatment (adj. HR 0.31, 95% CI 0.21-0.47, p < 0.001). Non-frail patients were more likely to adhere to treatment (adj. OR 2.38, 95% CI 1.49-3.81, p < 0.001) and were more often offered guideline treatment (adj. OR 1.98, 95% CI 1.28-3.06, p = 0.002) compared to frail patients. Lastly, when receiving guideline treatment, non-frail patients had significantly better adherence than frail patients (adj. OR 3.08, 95% CI 1.72-5.52, p < 0.001). Conclusions: G8 frailty screening effectively identifies older adults at a higher risk of treatment non-adherence and mortality, facilitating tailored treatment approaches. Our findings suggest that frail patients may benefit from initial less-intensive treatments with potential escalation to improve adherence and survival. Implementing G8 screening in routine practice addresses the unique challenges associated with frailty, ensuring more effective, equitable care for at-risk older adults. Research Sponsor: The Danish Cancer Society; Odense University Hospital; University of Southern Denmark; Agnes and Poul Friis Fond; Dagmar Marshalls Fond; Academy of Geriatric Cancer Research (AgeCare).

Prognostic awareness in older adults with metastatic cancer: Secondary analysis of a randomized controlled trial.

Cristiane Decat Bergerot, Paulo Gustavo Bergerot, Marianne Razavi, Marcos V.S. Franca, Jonas Ribeiro Gomes Silva, Jose Adolfo Cerveira, William Hiromi Fuzita, Gabriel Marques dos Anjos, Renata Ferrari, Sarah Ananda Gomes, Errol James Philip, Murilo Buso, Mariana Laloni, Carlos Gil Ferreira, Sumanta Kumar Pal, Ryan David Nipp, Areej El-Jawahri, Enrique Soto Pérez de Celis, William Dale; Oncoclínicas&Co, Sao Paulo, Brazil; Oncoclínicas&Co, Medica Scientia Innovation Research (MEDSIR), Sao Paulo, Brazil; City of Hope Comprehensive Cancer Center, Duarte, CA; Oncoclínicas&Co - Medica Scientia Innovation Research (MEDSIR), Sao Paulo, Brazil; Loiversity of California, Los Angeles, Los Angeles, CA; Oncoclínicas&Co, Sao Paulo, SP, Brazil; Department of Medical Oncology, City of Hope Comprehensive Cancer Center, Duarte, CA; The University of Oklahoma, Oklahoma City, OK; Division of Hematology and Oncology, Department of Medicine, Massachusetts General Hospital; Harvard Medical School, Boston, MA; University of Colorado Anschutz Medical Campus, Aurora, CO; City of Hope National Medical Center, Duarte, CA

Background: Prognostic awareness plays a key role in patient outcomes, particularly among older adults with metastatic cancer. This secondary analysis of a randomized controlled trial (RCT) evaluated the effect of a Geriatric Assessment-guided Intervention (GAIN-S) on patient responses to prognosis items over time between two arms. Methods: Eligible participants, aged 65+, diagnosed with metastatic solid cancers, and undergoing treatment across multiple Brazilian states, were randomized 1:1 into two arms. The GAIN-S included a geriatric assessment (GA), which devised tailored treatment based on identified impairments. Patients in the usual care (UC) arm received standard care. Both arms completed the Illness and Prognostic Awareness Impact Questionnaire (PAIS) at baseline (T1) and 12 weeks (T2), assessing Emotional (10 items; range 0-30) and Adaptive (12 items; range 0-36) domains; each rated on a 4-point Likert scale The change in PAIS (T2 - T1) was calculated for each participant in both the GAIN-S and UC arms, and then the mean changes in PAIS between the two arms were compared via independent t-test. Results: Eighty-six patients were approached; 80 provided consent (93% enrollment rate). At 12 weeks, the analytic sample included 77 patients. Demographic characteristics were well-balanced between arms, with a mean age of 74.5 years (SD=6.1), primarily female (55.8%), self-identified as White (71.4%), and 50.4% had at least a college education. The most common cancer types were genitourinary (29.9%), breast (24.7%), and gastrointestinal (22.1%). At T1, no significant differences were noted in PAIS between arms. However, there was significant improvement in PAIS Emotional (UC: mean change=-0.26, SD=1.6 vs GAIN-S: mean change=0.87, SD=1.4; P=0.002) and Adaptive (UC: mean change=-0.07, SD=0.6 vs GAIN-S: mean change=0.74, SD=1.7; P=0.008) domains between in the GAIN-S arm (Table). **Conclusions:** This secondary analysis highlights the impact of GA-guided care on improving prognostic awareness in older adults with metastatic cancer. GAIN-S resulted in significant improvements in Emotional and Adaptive domains compared to UC. Tailored interventions addressing the specific needs of older adults with metastatic cancer may enhance understanding of prognosis and improve adaptive responses. Studies are needed to determine whether these differences translate into meaningful improvements in outcomes. Research Sponsor: None.

Impact of GAIN-S intervention on prognostic awareness.					
	Change over time				
	Arm 1 (T2-T1) Mean (SD)	Arm 2 (T2-T1) Mean (SD)	Difference Arm 2 - Arm 1 (SE)	p-value	
Emotional Domain 10 items (range: 0-30)	-0.263 (1.62)	0.872 (1.44)	1.135 (0.35)	0.002	
Adaptive Domain 12 items (range: 0-36)	-0.079 (0.67)	0.744 (1.73)	0.823 (0.30)	0.008	

National cancer system characteristics and global pan-cancer outcomes.

Edward Christopher Dee, James Fan Wu, Erin Jay Garbes Feliciano, Frederic Ivan Leong Ting, Jonas Willmann, Frances Dominique Ho, Bhav Jain, Urvish Jain, Jenny Chen, Fabio Moraes, Nancy Y. Lee, Puneeth Iyengar, Paul Nguyen; Memorial Sloan Kettering Cancer Center, New York, NY; Division of Hematology and Oncology, Department of Medicine, Medical College of Wisconsin, Milwaukee, WI; Department of Medicine, NYC Health + Hospitals/Elmhurst, Icahn School of Medicine at Mount Sinai, Queens, NY; University of St. La Salle College of Medicine, Manila City, Philippines; College of Medicine, University of the Philippines, Manila, Philippines; Stanford University School of Medicine, Stanford, CA; University of Pittsburgh, PA; Queen's University, Kingston, ON, Canada; Dana-Farber Cancer Institute, Boston, MA

Background: Approximately 29.9 million cancer cases and 15.3 million deaths are anticipated by 2040 globally. Health systems must invest in cancer system strengthening. A greater understanding of health system factors that can be leveraged to improve cancer control may guide health system planning. Therefore, we conducted a pan-cancer ecological study making use of most recent available national health system metrics for cancer outcomes and health system metrics, spanning the breadth of global income levels across 185 countries. Methods: Estimates of age-standardized mortality-to-incidence ratios were derived from GLOBOCAN 2022 for patients with cancer of all ages. Health spending (% of gross domestic product [GDP]), physicians/1000population, nurses and midwives/1000population, surgical workforce/ 1000population, GDP per capita, Universal Health Coverage Service Coverage Index (UHC index), availability of pathology services, human development index, gender inequality index, radiotherapy centers/1000population, and out-of-pocket expenditure as percentage of current health expenditure were collected. The association between MIR and each metric was evaluated using univariable linear regressions. Metrics with P < 0.0045 (Bonferroni corrected) were included in multivariable models. Variation inflation factor allowed exclusion of variables with significant multicollinearity. R2 defined goodness of fit. Results: On univariable analysis, all metrics were significantly associated with MIR of cancer (P < 0.001 for all). After including metrics significant on univariable analysis and correcting for multicollinearity, the final multivariable model had R2 of 0.8729. Therefore, the following variables were associated with lower (improved) MIR for cancer: 1) nurses/midwives per 1000 population (β = -0.0049, P < (0.057), 2) UHC index ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, 2000), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, 2000), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, 2000), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, 2000), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, 2000), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, 2000), 3) radi -11.21, P = 0.072), and 4) GDP per capita (β = -1.7x10-6, P < 0.001). On analysis stratified by sex, the following were associated with improved MIR for all cancers among females: 1) UHC index ($\beta = -0.0042$, P < 0.001), 2) GDP per capita ($\beta = -9.9x10-7$, P = 0.02), and 3) gender inequality index (β = 0.13, P = 0.084) (R2 0.8699). The following were associated with improved MIR for all cancers among males: 1) nurses/midwives per 1000 population ($\beta = -0.0053$, P = (0.066), 2) UHC index ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, P < 0.001), 3) radiotherapy centers per 1000 population ($\beta = -0.0042$, and (-12.37, P = 0.076), 4) GDP per capita (β = -2.31x10-6, P < 0.001) (R2 0.8485). Conclusions: This comprehensive pan-cancer analysis of health system metrics suggests progress towards UHC, strengthening the nursing/midwifery workforce, facilitating access to services such as radiotherapy, and mitigating gender inequality are key priorities in cancer control. These generalizable findings may guide efforts to strengthen cancer systems throughout the world. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health; P30 CA008748; Prostate Cancer Foundation; National, Heart, Lung, and Blood Institute; 1R38HL167238-01 grant.

Validating Navya Earthshot: An AI-enabled point-of-care solution for guidelineadherent treatment planning in a decentralized cancer care model.

Umesh Mahantshetty, Raviteja Miriyala, Padmanaban Srinivasan, Motepalli Panduranga Kumari, Raghavendra Naik, Shveta Sharma, Dolorosa Fernandes, Shilpa Kandipalli, Rajendra A. Badwe; Tata Memorial Hospital, Homi Bhabha National Institute, Homi Bhabha Cancer Hospital & Research Centre, Visakhapatnam, India; Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, India; Rangaraya Medical College, Kakinada, Andhra Pradesh, India; Andhra Medical College/King George Hospital, Visakhapatnam, Andhra Pradesh, India; Andhra Medical College, Visakhapatnam, Tirupati, India; Homi Bhabha Cancer Hospital and Research Centre, Visakhapatnam, Andhra Pradesh, Visakhapatnam, Andhra Pradesh, India; King George Hospital, Tirupati, India; Tata Memorial Hospital and Homi Bhabha National Institute, Mumbai, India

Background: Adherence to guidelines increases overall survival, globally. In resourceconstrained settings, ~ 30% of patients receive undertreatment or overtreatment. Despite significant investment in decentralized cancer care—with tertiary hub centers providing support to non-specialized spoke centers-shortage of oncologists creates a knowledge gap, which may be partially addressed by clinically validated AI solutions. Navya is a clinically validated AI solution for cancer patients in use since 2014 which matches patient-specific data to evidence and generates treatment recommendations vetted via asynchronous expert review. Navya Earthshot is a new, provider facing solution for point of care cancer treatment planning for non-specialized providers, and is built as an AI driven search interface on Navya's validated domain model supporting subspecialized expert opinions in oncology. Methods: This multicenter, prospective validation took place at 25 hospitals across India participating in a decentralized cancer care model. All patients with breast, oral and lung cancerbetween January and June 2024 with all decisions (curative and palliative; local and systemic therapies) were included. Navya Earthshot matched input patient data available in the patient medical record with National Cancer Grid (NCG) guidelines, and output evidence based treatment plans at the point of care. The output was shared at each center, and concordance was scored by the tumor board/treating oncologists, as well as by a group of domain experts experienced in analyzing NCG guidelines. Results: Navya Earthshot processed 1787 decisions in a decentralized cancer care system, pertaining to 40% (725) breast, 20% (351) oral, 40% (711) lung cancer diagnoses respectively. Patients were well represented with respect to age (< 45 years (23%) and >45years (77%), and early stage (24%); advanced stage (58%) and incomplete diagnostic workup (18%)). Of the 1787 decisions, Navya Earthshot output referred 27% (478) to hub center tumor boards due to presence of uncommon histologies or scenarios not covered by the NCG guidelines (3rd line therapy etc.). In the remainder 73% (1309) decisions, Navya Earthshot output diagnostic or treatment plans. Of these, 85% (1114/1309) were scored concordant with NCG guidelines, and adopted by the local treating oncologist. The remaining 15% (195) decisions were referred to a hub center for treatment planning. Conclusions: Navya Earthshot can improve capacity of oncologists in resource-constrained settings and enhance adherence to guideline-driven care in a decentralized cancer care model. In a majority of cases, this pointof-care solution can improve access to care locally, reduce reliance on tertiary hub centers, and improve patient outcomes, globally. Research Sponsor: None.

Advancing global equity in cancer care: Comparative environmental impacts of radiotherapy in Brazil and the U.S.

Katie Lichter, Genevieve Silva, Samuel Avelino, Chirjiv Anand, Osama Mohamad, Shearwood McClelland III, Katherine Van Loon, Surbhi Grover; Department of Radiation Oncology, University of California, San Francisco, San Francisco, CA; University of California San Francisco, San Francisco, CA; VITTA Centro Avançado de Radioterapia, Brasília, Brazil; Department of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX; The University of Oklahoma Health, Oklahoma City, OK; University of Pennsylvania, Philadelphia, PA

Background: Climate change poses a significant threat to global health, necessitating efforts to address the environmental impacts of oncology care, particularly in low- and middle-income countries (LMICs). Radiation therapy is a cornerstone of cancer treatment, yet its delivery often involves high energy consumption and resource use, contributing to environmental degradation and inequities in health outcomes. Despite these challenges, the environmental footprint of radiotherapy in the Global South remains largely unexplored. This study quantifies the environmental impacts of radiotherapy in Brazil, compares these findings to external beam radiation therapy (EBRT) delivery in the U.S., and explores how sustainable practices may promote equity by reducing operational costs and expanding access to radiation therapy in underserved regions. Methods: A life cycle assessment (LCA) of EBRT for ten cancer disease sites was conducted at a radiation oncology clinic (Vitta) in Brasília, Brazil, following ISO 14040 and 14044 standardized methodology. Data on medical supplies, equipment usage, building energy consumption, and staff and patient travel from 2018-2023 was analyzed to assess environmental impacts across nine categories, including greenhouse gas emissions, air pollution, and carcinogenic potential. These results were compared with a previously published LCA of EBRT across four U.S. healthcare centers. Results: Radiotherapy at Vitta had a lower environmental impact across all categories compared to U.S. centers. Transit-related emissions were the largest contributor at Vitta, though they remained lower than those in the U.S. due to shorter travel distances (median 15 miles/week by public transit at Vitta vs. 48–90 miles/week by car in the U.S.). Vitta's reliance on hydroelectric energy eliminated emissions from building heating and reduced cooling-related emissions to 9.3% of the clinic's total footprint, compared to 74.0% at U.S. sites using mixed-grid electricity and natural gas. However, impacts from medical supplies at Vitta were higher across all categories, reflecting opportunities for resource optimization. Conclusions: This study provides novel insights into the environmental impact of radiotherapy in an LMIC context, underscoring the importance of regional differences in care delivery. The reduced environmental footprint at Vitta highlights the value of sustainable practices, such as renewable energy and public transit, in mitigating the health sector's climate impact while reducing operational costs. These findings support the development of adaptable, scalable models for global radiation oncology, particularly in publicly funded and rural clinics, to expand access and promote equity in cancer care. Future research should prioritize environmentally sustainable strategies that align with the unique needs of LMICs and underserved populations. Research Sponsor: None.

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Achieving global breast cancer initiative key performance indices for breast cancer patients in Botswana by HIV status.

Tara Friebel-Klingner, Tlotlo Ralefala, Darya A. Kizub, Lebogang Laletsang-Mokokwe, Babe Gaoleabale, Nkhabe Chinyepi, Peter Vuylsteke, Dipho Irene I Ikanyeng Setlhako, Scott Dryden-Peterson, Mosepele Mosepele, Robert Gross, Yehoda M. Martei; Johns Hopkins University, Baltimore, MD; Ministry of Health and Wellness, Gaborone, Botswana; University of Texas MD Anderson Cancer Center, Houston, TX; Botswana University of Pennsylvania Partnership, Gaborone, Botswana; Princess Marina Hospital, Gaborone, Botswana; University of Botswana, Gaborone, Botswana; Sir Ketumile Masire Teaching Hospital, Gaborone, Botswana; Botswana; Botswana, Philadelphia, PA; Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

Background: Low- to middle-income countries have disproportionately higher breast cancer (BC) mortality rates, partly due to late-stage diagnosis. In people with HIV (PWH), BC mortality is worse compared to those without HIV. The WHO's Global Breast Cancer Initiative (GBCI) proposes to reduce mortality through 3 identified pillars: (1) health promotion for early detection with at least 60% of invasive BC diagnosed at stage 1 or 2; (2) timely diagnosis, where evaluation, imaging, and pathology are completed within 60 days from first doctor's appointment; and $(3) \ge 80\%$ of patients completing treatment. Few real-world data exist on these key performance indices in PWH. Understanding the influence of clinical and demographic factors associated with achieving the GBCI pillars can inform tailored interventions to increase BC survival. We aimed to assess pillars 1 and 2 in BC patients presenting to a referral hospital in Botswana, by HIV status. Methods: This prospective BC cohort included patients >18 years, presenting for BC care at Princess Marina Hospital between 2015 and 2023. Patients with unknown HIV status and/or unknown stage were excluded. Pillar 1 was assessed using the cancer stage documented in the medical chart. Pillar 2 was assessed using patient recall of firstcontact with health facility and pathology report date. We characterized socioeconomically disadvantaged districts as those with poverty rate \geq 20% and < 100% of the population living within 5km from a health facility. Descriptive statistics and logistic regression were used. Results were stratified by HIV status. All p-values were two-sided. Data was analyzed using STATA 18.5. Results: 655 patients (median age: 51.2, IQR 42.4, 63.4) met eligibility criteria. 212 (31.8%) were PWH and 11 (1.7%) men. 180 (27.1%) attained pillar 1, and 59 (9.3%) attained pillar 2. PWH were younger (48.9 vs. 58.6; p < 0.001) and more likely to be single (70.3% vs. 47.3%; < 0.001). There was no significant difference between rates of PWH and those without HIV achieving both pillar 1 (23.1% vs 28.9%, p = 0.12) and pillar 2 (11.4% vs 8.3%, p = 0.2). However, PWH had a significantly shorter interval from first contact with the health facility to completed pathology (11.9 months vs. 20.1 months, p = 0.013). There was no significant difference between residents of socioeconomically disadvantaged districts versus non-residents in achieving pillar 1 (29.7% vs. 27.0%, p = 0.72) or pillar 2 (8.3% vs. 9.3%, p = 0.84). Conclusions: Majority of BC patients presenting to the referral hospital in Botswana did not achieve the GBCI pillars 1 and 2. However, PWH had significantly less diagnostic interval, which may be reflective of frequent contact for PWH in established care and may present an opportunity for care integration for PWH. Early detection and patient navigation interventions may potentially help Botswana achieve the WHO's GBCI goals and reduce BC mortality. Research Sponsor: Fogarty International Center K01TW011481 Award; Doris Duke Charitable Foundation Fund to Retain Clinical Scientists at Penn/CHOP.

Disparities in exercise referral practices and barriers among oncologists in public and private institutions in Latin America.

Paulo Gustavo Bergerot, Cristiane Decat Bergerot, Pamela Muniz, Maria Natalia Gandur-Quiroga, Regina Barragan-Carrillo, Lucia Viola, Errol James Philip, Jasmin Hundal, Livia Mega, Dr. Paulo Sergio Lages, Renata Ferrari, Angela S. Morabito, Carolina Bernabe, Mariana Laloni, Carlos Gil Ferreira, Murilo Buso, Gilberto Lopes, Enrique Soto Pérez de Celis, Narjust Florez, Kathryn H. Schmitz; Oncoclínicas&Co, Medica Scientia Innovation Research (MEDSIR), Sao Paulo, Brazil; Oncoclínicas&Co, Sao Paulo, Brazil; Oncoclínicas&Co - Medica Scientia Innovation Research (MEDSIR), Sao Paulo, Brazil; Oncoclínicas&Co, Sao Paulo, Brazil; Oncoclínicas&Co - Medica Scientia Innovation Research (MEDSIR), Sao Paulo, Brazil; Department of Medical Oncology, Genitourinary Tumors, Institute of Oncology Angel H Roffo, Buenos Aires, Argentina; City of Hope Comprehensive Cancer Center, Duarte, CA; Fundación Neumológica Colombiana, Bogotá, Colombia; University of California, Los Angeles, Los Angeles, CA; UConn Health (Farmington, CT), West Hartford, CT; Dana-Farber Cancer Institute, Boston, MA; Montefiore Einstein Comprehensive Cancer Center, Bronx, NY; Oncoclínicas&Co, Sao Paulo, SP, Brazil; University of Miami Sylvester Comprehensive Cancer Center, Miami, FL; University of Colorado Anschutz Medical Campus, Aurora, CO; Lowe Center for Thoracic Oncology, Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA; Penn State College of Medicine, Hershey, PA

Background: Exercise offers significant benefit for patients with cancer, improving physical function, quality of life, and treatment-related outcomes. However, barriers such as limited referral practices and insufficient knowledge hinder its integration into care. This study compared referral practices, exercise assessment, and physicians' perceptions in public (PUB) and private institutions (PRI). Methods: A cross-sectional survey of 454 physicians from 21 Latin American countries was conducted using a 25-item questionnaire on referral practices, patients' exercise habits, and perceived barriers and facilitators to implementing exercise programs. Descriptive statistics summarized respondent characteristics and adherence to exercise-related practices. Chi-square tests were used to compare differences in referral practices and perceived barriers/facilitators between physicians working in PUB versus PRI institutions. Results: Out of 454 participants, most were from PUB (52%), mainly from Mexico (17%), Brazil (12%), and Colombia (10%). In the PRI (48%), Brazil led with 51%, followed by Argentina (18%), and Peru (8%). Female representation was higher in PUB compared to PRI (57% vs. 43%, P = 0.01). Physicians in PUB were less likely than those in PRI to assess exercise habits (53% vs. 18%, P = 0.001), refer patients (72% vs. 36%, P = 0.001), or provide guidance (56% vs. 12%, P = 0.001). Resource limitations were more common in PUB (e.g., no referral location: 86% vs. 70%, P = 0.04). Barriers included treatment side effects (PUB: 66% vs. PRI: 40%, P = 0.001) and lack of knowledge on prescribing exercise (PUB: 63% vs. PRI: 27%, P = 0.001). Physicians in PUB emphasized facilitators like access to qualified professionals (90% vs. 66%, P = 0.001) and personal experience (90% vs. 80%, P = 0.01). Conclusions: This study reveals significant disparities in cancer exercise practices between oncologists in public and private institutions across Latin America. Oncologists in public institutions were less likely to assess exercise, refer patients to exercise programs, and provide guidance. They also reported greater barriers, such as treatment side effects and lack of knowledge on exercise prescription and resources. Facilitators such as access to qualified professionals were less prominent in public institutions. These findings highlight the need for targeted interventions to improve exercise integration in cancer care, particularly in resource-limited settings. Research Sponsor: None.

Investigating gender demographics and equity among hematologists.

Florence Broussais, Judith Trotman, Eliza Anne Hawkes, Anna Sureda, Clémentine Sarkozy, Michelle Dawson, Nina Shah, David Wright, Carla Casulo; Institut Carnot CALYM, Lyon, France; Concord Hospital, Concord, Australia; Austin Health, Heidelberg, Australia; ICO, Hospital Duran i Reynals, L'Hospitalet de Llobregat, Barcelona, Spain; Institut Curie, Saint Cloud, Paris, France; AstraZeneca, Gaithersburg, MD; University of California San Francisco, San Francisco, CA; ZS, Toronto, ON, Canada; James P. Wilmot Cancer Center, University of Rochester Medical Center, Rochester, NY

Background: Despite a substantial number of women in the field of hematology, representation in leadership roles remains inconsistent with ~50% of women among medical graduates in many countries. This survey of hematologists sought to examine gender demographics and explore experiences with professional development including mentorship, involvement in and leadership of clinical trials, and opportunities for career advancement. Methods: An international online survey of hematologists was developed collaboratively with the Women in Lymphoma (WiL) global organization in partnership with the HERmatology initiative (Astra-Zeneca). It was distributed to and by the membership of WiL. All participants were licensed medical practitioners, self-characterized on gender, age, years of practice, country of practice, and seniority of role. Statistical differences between males and females were calculated by pairwise z-tests with a significance level of 90%. Results: From October to December 2024, 237 hematologists from 34 countries were surveyed: 182 female and 55 male. The proportion of females to males in hematology practices significantly favored females (53% [51, 56] vs. 47% [44, 49]). Heads of Department (60% [55, 66] vs. 40% [35, 45]) and direct supervisors (59% [54, 64] vs. 41% [36, 46]) were significantly more likely to be male. Females reported serving as Principal Investigator significantly less frequently for industry-sponsored clinical trials over the past 12 months than males (2.1 vs 0.9, p < 0.1), but no significant differences as a Site Investigator (3.4 vs 2.4, p = 0.2). No differences were observed in female vs. male participation or leadership in cooperative group / academic clinical trials. There was a trend for fewer female physicians invited to write an article or publication in the past 12 months compared to males (2.7 vs. 4.2, p = 0.15), as well as fewer opportunities to receive public recognition from a senior colleague (1.1 vs. 1.9, p = 0.15). Females overall were significantly less likely to have clinical (p < 0.15). 0.1) or career mentors (p < 0.1), but earlier-career females were more likely than later-career females to have both (p < 0.1). 'Family or caregiving responsibilities' was the top factor discouraging women from pursuing careers in hematology (86% agreed), followed by a 'Lack of representation of women in leadership positions' (59% agreed). Conclusions: Differences were noted between males and females across several career dimensions, including representation in leadership roles, involvement in industry-sponsored clinical trials, and access to mentorship. These results underscore the continued need for systematic efforts to reduce unconscious bias and promote greater diversity within hematology. Providing additional structured support, particularly to boost female leadership in industry-sponsored trials, will help advance gender equity, ultimately benefiting both medical progress and patient outcomes. Research Sponsor: None.

Clinical profiles, patient expectations and outcomes from an integrative oncology clinic in India: A novel integrated model of care in oncology.

Kanakavalli K. Kundury, Maa Vama Bhavani Balakrishnan, Karthick J., Aparna Vasudev, Pragya Singh, Sujith Kumar Mullapally; JSS Academy of Higher Education & Research, Mysuru, India; Isha Health Solutions, Isha Yoga Centre, Coimbatore, Coimbatore, India; Apollo Proton Cancer Centre, Chennai, India

Background: Integrative approaches are used in Oncology care, often as an auxiliary measure to the Standard of Care (SoC). There is paucity of data regarding Integrated oncology model approach combining alternate systems of medicines like Ayurveda & Siddha, Yoga and Dietary modification recommendations along with SoC. In this study, we present an audit of this novel Integrated oncology model of care provided by online and in-patient consultations at Isha Integrative Oncology Clinic (IIOC), Isha Health Solutions (IH), Coimbatore, India. Methods: A clinical audit was conducted for 514 patients who have received care through Integrated oncology consultations (in-person or online) at IIOC from January 2016 to July 2024. This abstract focuses on the statistical analysis of data of the initial 196 consecutive patients based on descriptive data from clinical proformas and follow-up visits for symptomatic response outcomes. Updated data will be presented at the conference. Results: Among 196 patients analysed, 99% of patients had online consultations. The median age was 52yrs (7-81yrs) and Male: Female ratio was 1: 1.3. 50% belonged to age group 40-60 yrs whereas 29% were between 60-85 yrs. Most common cancers in males were hematological cancers (20%), prostate cancers (11%), GI cancers (11%) and in females were breast (26%), ovary (10%) and colon (5%). The most common stage was Stage 4 (58%) followed by Stage 3 (40%). Most common symptoms were pain (49%), anorexia (43%), fatigue (42%), lack of sleep and anxiety (39%). Most common side effects of chemotherapy were fatigue (32%), constipation (25%), anorexia/ weight loss (25%), pain (16%) etc. Most common expectations were cure/avoid relapse (32%), symptomatic relief (15%), reduction from chemotherapy side effects (11%), integration of Yoga (10%) etc. Only 6% of patients wished to avoid chemotherapy. Integrated oncology model based on complementary systems of medicine (Ayurveda & Siddha), dietary changes and yoga was provided to all patients (100%). After using this model of care, improvement in cancer-related symptoms was reported by 90% of patients and compliance seen in 73% of patients. **Conclusions:** Our study is one of the largest clinical audits in Integrative oncology in published literature. Younger patients and advanced cancer patients more often seek integrative oncology care and main expectation is to achieve better cure rates and symptomatic relief. In this study, all patients were provided a novel integrated oncology model with alternative medicines (Ayurveda & Siddha), yoga, and dietary modifications in addition to their ongoing SoC resulting in good symptomatic relief and high compliance rates. Integrative oncology model incorporating alternative medicine, yoga, and dietary changes can be effectively offered to cancer patients alongside standard treatment. Further prospective studies are warranted. Research Sponsor: None.

How do health concerns present in cancer survivors who require interpreters? Database analysis of a structured survivorship clinic for early-stage cancer.

Lawrence Kasherman, Vu Quang Do, Sim Yee Tan, Angela Liao, Lachlan Huynh, Krishna Suryadevara, Ashanya Malalasekera, Joanne Shaw, Janette L. Vardy; Concord Clinical School, Faculty of Medicine and Health, University of Sydney, Concord, NSW, Australia; New South Wales Ministry of Health, St Leonards, NSW, Australia; Sydney Cancer Survivorship Centre, Concord, NSW, Australia; Concord Repatriation General Hospital, Concord, NSW, Australia; Concord Cancer Centre, Sydney, NSW, Australia; The University of Sydney, School of Psychology, Psycho-Oncology Cooperative Research Group, Camperdown, NSW, Australia

Background: Cancer survivors (CS) of Culturally and Linguistically Diverse (CALD) backgrounds face disparities in care. We aimed to compare demographics and health concerns of CALD CS with non-CALD CS following completion of primary treatment. Methods: The Sydney Cancer Survivorship Centre (SCSC) database was analyzed to compare baseline differences in demographics and health concerns between early-stage CS of solid tumor or hematologic cancers requiring interpreters (CALD CS) during initial consultations to those who did not (non-CALD CS). Descriptive statistics were used to illustrate distribution by age, gender and tumour type. Survivors completed questionnaires on symptoms, quality of life (QoL), distress, exercise time and were assessed by a psychologist for fear of cancer recurrence (FCR). Univariate analyses were used to determine differences at presentation to the survivorship clinic between CALD and non-CALD groups. Results: From September 2013 to April 2024, 939 initial consultations (median 10.9 months from diagnosis) with consenting CS were conducted at SCSC. 15% (n = 137) required interpreters in 21 different languages (Mandarin (n = 48, 35%), Korean (n = 26, 35%)19%) and Cantonese (n = 19, 14%): 83 (61%) used professional interpreters, 25 (18%) family/ friends. CALD CS were more likely to be female (58%), aged 40-64 (51%) and have colorectal cancer (55%). Common symptoms in CALD CS of at least moderate severity included fatigue (39%), numbness (32%), and pain (31%), not significantly different to non-CALD CS. Significantly lower proportions of CALD CS reported trouble concentrating (19 vs 29%, p = 0.023), hot flashes (14 vs 23%, p = 0.017) and problems with sexual function (12 vs 20%, p = 0.032). CALD CS were significantly more likely than non-CALD CS to report less minutes/week doing vigorous (13.2 vs 32.8; p < 0.001), moderate (32.3 vs 73.0; p < 0.001) and resistance exercise (4.6 vs 18.7; p < 0.001), but more light exercise (219.6 vs 115.5; p = 0.041). Mean global FACT-G QoL score for CALD CS was 77.4 (SD 20), with physical (mean 21.4, SD 6) and emotional (mean 17.6, SD 5) domains most impacted; these were not significantly different from non-CALD CS scores. There were no significant differences between groups in mean distress thermometer scores (3.09 vs 3.39/10; p = 0.288), rates of moderate-to-severe distress (36 vs 41%; p = 0.952) or rates of psychologist-assessed moderate-to-severe FCR (19 vs 28%; p = 0.228). Conclusions: CALD CS experience similar physical and psychosocial health concerns to non-CALD CS at initial survivorship clinic consultations but are less likely to report issues with sexual function, concentration and hot flashes, and are more likely to exercise less. Future work should focus on longitudinal effects and comparisons over time, with particular focus on addressing cultural sensitivities and increasing exercise intensity. Research Sponsor: Australian Government, National Health and Medical Research Council; 2021964; Cancer Institute New South Wales; 2021/ CBG0002; Australian Government, National Health and Medical Research Council; APP1176221.

Living beyond cancer: The long-term impact of breast cancer diagnosis on cognitive function.

Cheng Peng, Bernard Rosner, Jae Hee Kang, Erica T. Warner, Liang Liming, Francine Grodstein, Michelle D. Holmes, Wendy Y. Chen, Rulla Tamimi, Walter C Willett, Olivia I. Okereke, A. Heather Eliassen; Brigham and Women's Hospital, Boston, MA; Channing Laboratory, Brigham and Women's Hospital and Harvard Medical School, Boston, MA; Massachusetts General Hospital, Boston, MA; Harvard T. H. Chan School of Public Health, Boston, MA; RUSH Alzheimer's Disease Center, Boston, MA; Dana-Farber Cancer Institute, Boston, MA; Weill Cornell Medicine, New York, NY; Harvard T.H. School of Public Health, Boston, MA; Mass General Hospital, Boston, MA

Background: While some clinical studies report greater cognitive difficulties in middle-aged women diagnosed with and treated for breast cancer over the short-term, observational studies of older persons, with longer follow-up, found that a history of cancer was associated with lower Alzheimer's disease risk. We estimated the relation of breast cancer and treatment history with cognitive status and rate of decline among older women. We further divided breast cancer survivors by: (1) time since cancer diagnosis (assessing recency), (2) age of cancer onset (reflecting body aging at diagnosis), and (3) stage (capturing disease aggressiveness). To evaluate any overlap in shared or opposing genetic risk, we estimated cognitive status by breast cancer polygenic risk score (PRS). Methods: A cognitive sub-study was initiated in 1995-2001 in the Nurses' Health Study, including 1,378 breast cancer survivors and 14,196 cancer-free women. Breast cancer diagnoses were self-reported and confirmed by medical records; treatment was self-reported. Cognitive function was assessed up to 4 times (over a mean of 6.6 years) and combined into 4 outcomes: global composite score, Telephone Interview for Cognitive Status (TICS), verbal memory, and working memory. We used linear models to assess breast cancer history and treatment with cognitive status (averaged across follow-ups). We used mixed-effects models to assess breast cancer history and treatment with rate of cognitive decline. We computed a breast cancer PRS and evaluated cognitive function across quartiles of PRS. Results: The mean age of breast cancer diagnosis was 65.4 years, and the mean time between cancer diagnosis and baseline cognitive assessment was 8.6 years. We observed similar distributions of key risk factors for AD between women with and without history of breast cancer, including age, education, depression, and physical activity. No significant differences in global cognitive status were noted comparing women with a history of breast cancer with those who were cancer-free. Associations did not differ by age of cancer onset (< 65 vs. ≥ 65 years), time since diagnosis (< 5 vs. ≥ 5 years), or stage. Genetically predicted breast cancer risk was not associated with the global cognitive status. Women with breast cancer and treated with hormone therapy, chemotherapy, and/or radiation therapy had similar global cognitive status compared to cancer-free women. No significant differences by breast cancer history were observed for TICS, verbal memory, or working memory. Over the modest follow-up time, we observed no significant differences in cognitive decline between women with a history of breast cancer and cancer-free women. Conclusions: We observed no association of history of breast cancer or breast cancer treatment with cognitive function status or rate of decline, suggesting there is neither harm nor benefit of breast cancer diagnosis on long-term cognition. Research Sponsor: National Institute on Aging.

Blended survivorship and palliative care for patients with advanced lung cancer receiving targeted therapy: An open pilot.

Laura A. Petrillo, Roshni Sarathy, Heather Richard, Jill Libles Feldman, Lecia V. Sequist, Elyse Richelle Park, Dustin Rabideau, Vicki Jackson, Joseph Greer, Jennifer S. Temel; Massachusetts General Hospital, Boston, MA; University of Nebraska Medical Center, Omaha, NE; EGFR Resisters, Deerfield, IL; Massachusetts General Hospital, Harvard Medical School, Boston, MA; Department of Psychiatry, Mass General Brigham; Harvard Medical School, Boston, MA

Background: Targeted therapy improves survival and quality of life for patients with advanced non-small cell lung cancer (NSCLC) with driver alterations. However, advanced NSCLC remains incurable, and the timing of progression on targeted therapy is unpredictable. Thus, many patients live with an abiding, distressing sense of uncertainty. To better support patients with advanced NSCLC receiving targeted therapy, we 1) developed and refined a blended early palliative care and survivorship intervention and 2) conducted an open pilot to further refine the intervention. Methods: We conducted a review of evidence and prior palliative care and behavioral health interventions to inform the development of POISE, a structured, supportive care intervention for patients with advanced NSCLC receiving targeted therapy, in which trained palliative care clinicians aim to enhance patient coping with uncertainty, setting lifestyle goals, and prognostic awareness. To refine POISE, we first conducted qualitative interviews with 20 community partners, including patient/caregiver advocates, palliative care clinicians, psychologists, and oncologists. We elicited feedback on POISE intervention content and delivery. We used rapid analysis to analyze interview transcripts and identified themes, with which we finalized POISE (4 monthly one-hour palliative care visits). We then conducted an open pilot study of POISE among 10 patients diagnosed with advanced NSCLC with a targetable mutation (i.e., EGFR, ALK, ROS1 or RET) in the past 6 months who were receiving care at a single academic cancer center. All participants received POISE and completed selfreport surveys at baseline and at 12 and 20 weeks. Participants rated their satisfaction with POISE and completed exit interviews at 20 weeks. We used a framework approach to analyze exit interviews and identify themes for further intervention refinement. Results: Qualitative interviews highlighted a need to strengthen the POISE clinician training and supervision plan to increase palliative care clinicians' behavior modification therapy skills. We revised the POISE manual to be more flexible to accommodate patient choice in session focus and added a list of community organizations to support ongoing behavior change. With the revised intervention, we then initiated the POISE open pilot. We approached 13 eligible patients, of whom 10 (mean age = 67 years, 5 female, 5 male) consented to participate. Most (8/10) patients completed all 4 sessions and all surveys. All (8/8) patients reported that POISE was helpful and would recommend it to others. In exit interviews, patients suggested incorporating caregivers in sessions and adding a patient-facing workbook to assist with skill acquisition. Conclusions: POISE warrants further study in a feasibility pilot randomized controlled trial. Clinical trial information: NCT04900935. Research Sponsor: National Cancer Institute.

Experiences and preferences of cancer survivors across the immunotherapy journey.

Shelley Fuld Nasso, Elena Jeannotte, Karishma Shelley, Gabriela Burgos, Daniel Adamczyk, Kathryn Krupsky, Zander Pittman, Marc DeCongelio, Jay Grisolano, Jacob Matta, Saby George; National Coalition for Cancer Survivorship, Silver Spring, MD; National Coalition Cancer Survivorship, Silver Spring, MD; Bristol Myers Squibb, Princeton, NJ; Oracle Life Sciences, Austin, TX; Roswell Park Cancer Institute, Buffalo, NY

Background: Immuno-oncology (IO) drugs are recommended by guidelines for several tumor types and can significantly improve survival in patients with cancer. As patients experience long-term care due to extended survival, it is important to understand the challenges of survivorship and experiences receiving IO. Here, we present IO treatment experiences and preferences for IO based on modes of administration among cancer survivors. Methods: A webbased survey was administered to US cancer survivors in the fall of 2024. Patients were recruited via physician referral and were eligible to participate if they were \geq 18 years of age, diagnosed \geq 1 year prior with any solid tumor cancer (any stage), and received IO within the past 5 years. The survey included the Quality of Life-Cancer Survivor (QoL-CS) scale (range 0-10; higher scores indicate better QoL) and a direct preference exercise. The preference exercise asked patients to indicate whether they would prefer IO be administered via subcutaneous (SC) injection or intravenous (IV) infusion and asked patients to rank the influence of common characteristics of each administration on preferences. Study variables were analyzed descriptively. Results: The mean (standard deviation [SD]) age of patients (N = 100) was 57.8 (7.2) years; 46% were White and 51% were male. The most common tumor types reported were lung (26%), melanoma (14%), kidney (12%), and colon (10%). Mean (SD) time since cancer diagnosis was 4.1 (2.7) years and mean time since starting IO was 2.4 (1.5) years. Most (72%) patients reported that a typical visit for receiving an infusion lasted between 1-2 hours and most (56%) traveled 30-60 minutes to receive their infusion. Some patients experienced interrupted access to their most recent IO treatment due to transportation delays (24%) and not having someone to accompany them to treatment (24%). The average QoL-CS score was moderate (mean [SD], 5.1 [1.3]) and 57% of patients agreed that IO improved their QoL. Yet, 42% and 48% noted that daily activities and physical health, respectively, were negatively affected by their most recent IO treatment. Most patients (92%) preferred a hypothetical SC injection over IV infusion; the top SC injection characteristics influencing this preference were no need to access the vein with an IV catheter, the amount of time it takes to be administered (described as 5 vs 30 minutes), and the potential for more flexibility in scheduling/location of receiving IO treatment. Conclusions: Our study found that IO treatment improved the QoL of most cancer survivors. However, challenges to receiving IO, including the time required for travel and administration, were common. Most patients in our sample would prefer a SC administration of IO over an IV infusion, suggesting that less-invasive modes of administration requiring less time and greater flexibility may present opportunities to improve the patient treatment experience. Research Sponsor: Bristol Myers Squibb.

Health related social needs in an urban academic breast cancer survivorship program.

Mumtu Lalla, Alyson B. Moadel, Kevin P. Fiori, Samantha Levano, Janice Simpson, Della F. Makower; Montefiore Einstein Comprehensive Cancer Center, Bronx, NY; Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY

Background: Health-related social needs (HRSN) impact cancer care and are associated with late stage at diagnosis (dx), prolonged time to therapy initiation, and poor outcomes. Little data exists regarding long-term impact of cancer dx and therapy on HRSN in late survivorship. We evaluated associations of cancer therapies with HRSN in a diverse cohort of breast cancer (BC) survivors seen in an urban academic medical center. Methods: HRSN screening was completed by BC survivors seen in the cancer center survivorship program in 2023. Survivors were 4 or more years (yrs) from dx of Stage 0 to III BC, with all therapy complete (including endocrine therapy) and no evidence of metastasis. HRSN screens were compared with those completed by newly diagnosed (dxed) BC patients (pts) and adult general medical pts. Charts of survivors were reviewed for details of BC dx and treatment [stage, hormone receptor (HR) and HER2 status, type of surgery, and use of chemotherapy, radiation, and endocrine therapy]; as well as demographic data (age, race, ethnicity, insurance status, ZIP code). Neighborhood distress was categorized using Distressed Communities Index (DCI). Associations of clinical and demographic factors with HRSN in BC survivors were evaluated by Chi-Square and ANOVA tests. Results: 465 BC survivors [177 (38%) Black, 228 (49%) Hispanic] completed HRSN screening. Median age at assessment was 68 (range 43-98) and at dx was 57 (range 27-89); median time from dx was 11.25 yrs (range 4-35). 63.5% resided in distressed ZIP codes; 26.4% in at-risk ZIP codes. Most common HRSN in survivors completing their first HRSN screen (n = 395) were housing quality (5.3%) and food insecurity (4.8%). BC survivors were less likely to endorse HRSN than newly dxed BC pts (16.7% vs 24.0%, p = 0.03), but had similar HSRN as general medical pts (16.7% vs 14.6%, NS). Among survivors, younger age at BC dx (p = 0.006) and at HRSN screen (p = 0.004) was associated with greater risk of HRSN, with pts dxed prior to 57 almost twice as likely to endorse HRSN as those dxed after 57 (22.7% v 12.6%, p = 0.004). Younger survivors with HRSN were more likely to reside in distressed ZIP codes (p = 0.03). Hispanics seen in new survivorship visits were more likely to endorse HRSN than Hispanics seen in follow-up and than non-Hispanics seen in new or follow-up visits (p = 0.03). Race, insurance status, time from BC dx, stage, HR and HER2 status, extent of surgery, and use of chemotherapy, radiation, or endocrine therapy were not significantly associated with HRSN in survivors. Conclusions: In this diverse cohort, late BC survivors had similar HRSN prevalence as general medical pts. Younger age was associated with greater HRSN in survivors, while BC stage, receptor status, and extent of treatment were not. Hispanics presenting for first survivorship visit endorsed greatest HRSN. These findings have implications for interventions targeted to young survivors and for culturally sensitive survivorship care. Research Sponsor: None.

Feasibility trial of health coaching-based navigation after breast cancer treatment.

Ruvarashe Rumano, Akia Clark, Sherri Smith, Kyra Crook, Timiya Nolan, Maryam B. Lustberg, Electra D. Paskett, Bridget Oppong; The Ohio State University, Columbus, OH; Department of Surgery, The James Comprehensive Cancer Center, College of Medicine, The Ohio State University Wexner Medical Center, Columbus, OH; Center for Cancer Health Equity, The James Comprehensive Cancer Center, The Ohio State University Wexner Medical Center, Columbus, OH; The James Comprehensive Breast Center, College of Medicine, The Ohio State University Wexner Medical Center, Columbus, OH; The James Comprehensive Breast Center, Concer Center, Birmingham, AL; Department of Medical Oncology, Yale Cancer Center, Yale School of Medicine, New Haven, CT; Department of Internal Medicine, The James Comprehensive Cancer Center, The Ohio State University Wexner Medical Center, Columbus, OH

Background: Following breast cancer diagnosis, 25% of survivors experience psychosocial needs like depression, anxiety, and fear of recurrence. Integrative survivorship support services address these needs, but participation is lower among Black women, who report higher psychosocial distress. Patient navigation has emerged as a strategy to reduce these barriers. This study piloted a navigation-based intervention aimed at improving psychosocial symptom management over 6 months. Methods: A single-arm feasibility trial was conducted with Black breast cancer survivors from November 2022-June 2024. Women aged 18+ with non-metastatic breast cancer were recruited. A trained lay navigator provided personalized support and resource facilitation to address psychosocial and healthcare challenges. Interactions were analyzed qualitatively to assess preliminary impact. Surveys administered at baseline and postintervention included the Life and Longevity after Cancer, Patient Reported Outcomes Measurement Information System, and Breast Cancer Survivorship Experience Survey, with responses measured on a Likert scale. Quantitative data were analyzed descriptively. Results: Of 21 Black women who consented (mean age 64), 18 began the study while 3 did not proceed beyond consent. Of these, 44.4% completed all six months, while 61.1% completed three months. Eight participants completed post-surveys. All participants found the study easy to join, 5/8 found its length appropriate, and 6/8 were satisfied with session intervals. All would recommend the program, and 4 preferred in-person sessions. Participants reported confidence in accessing future support programs. Key benefits included managing stress, family stressors, and improving community support. Qualitative analysis of 108 transcripts from 17 participants identified six themes: managing health challenges, communication, emotional well-being, resilience in daily life, program support, and future planning. Survey results showed improvements in well-being and self-efficacy. LILAC scores increased from 52.7 to 63.9, PROMIS physical scores rose from 12.4 to 13.3, and mental scores improved from 13.3 to 15.6. Selfefficacy decreased slightly in BCSES scores from 53.6 to 52.5. Conclusions: Among Black breast cancer survivors, 61% completed biweekly sessions during the first 3 months, with a drop in participation after transitioning to monthly sessions. Participants reported benefits in addressing distress and accessing support programs. Future efforts should focus on tailored strategies to enhance engagement and retention. Research Sponsor: OSUCCC Intramural Research Program; Speilman Fund.

Predicting overall survival in adults with cancer in the US using machine learning approaches integrating comprehensive social risk factors.

Yiwang Zhou, Samira Deshpande, Ahmed Motiwala, Jaesung Choi, Gregory T. Armstrong, Madeline Horan, I-Chan Huang; St. Jude Children's Research Hospital, Memphis, TN; Wake Forest University School of Medicine, Winston-Salem, NC

Background: Adults with cancer in the U.S. face an elevated mortality risk compared to the general population, with social risk factors playing a critical role – particularly among those with comorbidities. However, traditional mortality risk prediction models often focus on treatment exposures and basic demographic factors, overlooking social risk factors. We aim to develop a machine learning (ML) model that integrates comprehensive social risk factors with traditional predictors to predict overall survival for adults with cancer in the U.S. Methods: We analyzed data from 6,181 nationally representative adults diagnosed with cancer from the National Health Interview Survey (NHIS; 2013-2014). A total of 74 risk factors, including basic demographics (e.g., age at the survey, sex, marital status, body mass index [BMI]), personal and household socioeconomic status (SES; e.g., education, food insecurity), lifestyle, social support, and health status (e.g., chronic health conditions [CHCs], disability), were included in modeling. The primary endpoint was 5-year overall survival from the survey completion date, with secondary endpoints of 1- and 2-year survival. Death from any cause after the survey was defined as an event, and subjects were censored 5 years post-survey. The sample was randomly split into 70% training and 30% testing. A random survival forest (RSF) model predicted survival. The time-dependent area under the receiver operating characteristic (AUROC) curve and the Brier score (BS) assessed the model performance. Both AUROC and BS range from 0 to 1, with higher AUROC for higher accuracy (discrimination) and lower BS for better alignment between predicted and observed risk (calibration). The Shapley additive explanations (SHAP) values were used to interpret variable importance in the established RSF model. Results: The mean age of subjects during the survey was 65.6±13.8 years, and 40.2% were male. For the established RSF model, the AUROC (mean \pm standard deviation) for predicting 1-, 2-, and 5year survival was 0.795 \pm 0.026, 0.810 \pm 0.018, and 0.831 \pm 0.011, respectively, reflecting high and improved predictive accuracy over time. The BS for 1-, 2-, and 5-year survival was 0.039 \pm 0.004, 0.065 \pm 0.005, and 0.119 \pm 0.005, respectively, indicating excellent calibration. The top five variables ranked by SHAP values include age at the survey (0.048), use of special equipment due to health problems (0.029), employment status (0.020), number of CHCs (0.016), and BMI (0.015). Conclusions: By integrating social risk factors with traditional risk predictors, we developed an ML model that predicts overall survival with high accuracy and excellent calibration for adults with cancer in the U.S. Identifying key risk social factors enables targeted interventions, potentially improving health outcomes and management for the adult cancer population. Research Sponsor: None.

Pioneering cancer survivorship care in Latin America: Early results from the OC sobre VIVER program in Brazil.

Luciana Landeiro, Thaiana Aragao Santana, Mônica de Azevedo Kalile Kalile, Carla Pavei, Elisa Mascarenhas, Maria Cecilia Borges Bittencourt, Fernanda Oliveira, Thais de Melo Passarini, Denise Strassburger Nunes, Cristiane Decat Bergerot, Flavia Santos Dumont Sorice, Bruno Favato Neto, Maria Helena Cruz Rangel Silva, Helaine Pantoja, Carolina Perini, Mariana Laloni, Rafael Brant Costa; Oncoclínicas&Co, Salvador, Brazil; Oncoclínicas&Co, Sao Paulo, Brazil; Oncoclínicas&Co, Salvador, Brazil; Oncoclínicas&Co, Sao Paulo, Brazil; Oncoclínicas&Co, Brasila, Brazil; Oncoclínicas&Co, Vitoria, Brazil; Oncoclínicas&Co, Minas Gerais, Brazil; Oncoclínicas&Co, Belo Horizonte, Brazil; Oncoclínicas&Co, Sao Paulo, Brazil; Oncoclínicas&Co, Rio de Janeiro, Brazil; Oncoclínicas&Co, Curitiba, Brazil; Oncoclínicas&Co, Sao Paulo, SP, Brazil

Background: Cancer survivorship poses a growing challenge, especially in low- and middleincome settings. The OC SobreVIVER program, launched in October, 2020 by the Oncoclínicas Group, addresses survivorship care gaps by providing structured, multidisciplinary care. Initially piloted for breast cancer survivors in two Brazilian units, the program expanded in 2023 to include colorectal and prostate cancer survivors across eight states. This study presents preliminary data. Methods: This descriptive, observational study assessed the OC SobreVIVER program's impact on survivorship care. Multidisciplinary consultations involving oncologists, nurses, psychologists, and nutritionists addressed late toxicities, recurrence risk, and quality of life, following international survivorship guidelines. Telehealth and digital tools improved accessibility. Data from July, 2023 to December, 2024 included clinical characteristics, program metrics, and patient-reported satisfaction via EORTC PATSAT 33 and Net Promoter Score (NPS). Descriptive statistics summarized key outcomes. Results: From July 2023 to December 2024, the program supported 577 survivors (518 breast, 47 colorectal, 12 prostate) across 11 practices in eight states, with 490 initial consultations, 91 follow-ups, and over 20 support groups conducted. Virtual consultations were available to all patients, enhancing accessibility for underserved regions. Patient-reported satisfaction was high, with 95% of respondents classified as Promoters (scores 9–10) in the NPS, demonstrating strong program loyalty. Based on EORTC PATSAT 33 evaluations, over 80% of respondents rated their medical care experience in the highest satisfaction range (41–50), and over 80% rated their nursing care experience in the highest category (29-35). Minimal dissatisfaction was reported, with less than 2% of responses falling into the lowest satisfaction ranges (< 20 for medical care and < 14 for nursing care). **Conclusions:** The OC SobreVIVER program demonstrates the feasibility of a structured, multidisciplinary survivorship model in a private network across Brazil. Preliminary data highlight its effectiveness in addressing complex survivorship needs, enhancing accessibility through telehealth, and maintaining high satisfaction. This integrated, patient-centric approach ensures continuity of care across physical, social, psychological, spiritual, and nutritional dimensions, fostering a more comprehensive and holistic survivorship experience. Research Sponsor: None.

Oncology primary care clinics for comprehensive care of high-risk adolescent and young adult (AYA) cancer survivors.

Alique Gabrielle Topalian, Melinda Butsch Kovacic, Elizabeth Ann Shaughnessy, Melissa Erickson; University of Cincinnati, CH; University of Cincinnati College of Medicine, Cincinnati, OH; University of Cincinnati Medical Center, Cincinnati, OH

Background: Adolescent and young adult (AYA) cancer survivors experience early development of chronic medical conditions compared to healthy peers. Due to their young age at diagnosis and living decades beyond treatment, they are also at higher risk for second primary malignancies (SPM) and late effects than older adult-onset cancer survivors. Primary care providers are responsible for most long-term care of survivors and many are unfamiliar with the effects of cancer treatment in younger populations. Oncology primary care providers are uniquely positioned to address increased needs of AYA patients because of their additional survivorship expertise. Methods: In 2020, the University of Cincinnati Cancer Center established an oncology primary care clinic. An accompanying clinical registry was developed to track patient outcomes longitudinally Electronic medical records of all patients seen between 1/2021 and 1/2025 (n = 901) were extracted and entered in REDCap. Records of AYA cancer survivors, defined as cancer diagnosis between the ages of 18-39, were queried and analyzed (9%, n = 85). Results: The patient population's mean age was 36 yrs (range 20-74; std dev = 11.3). Hematologic cancers (37%) were most common followed by breast (13%) and brain (9%). Additionally, 14% were diagnosed with a SPM. Comorbid conditions were prevalent with 60% of patients having cardiovascular disease such as hypertension. Neurologic (46%), endocrine (44%), and psychologic (71%) co-morbidities were also common. Over half of patients were overweight/obese (68%) and many patients were former (19%) or current (7%) smokers. Eligible patients received their recommended cancer screening including breast (82%), colon (60%), and cervical (40%). Due to treatment exposures, 53% of patients were eligible for cardiomyopathy screening and 73% received recommended echocardiograms. A reduced ejection fraction was found in 26% of patients screened. Conclusions: Comprehensive primary care services and longitudinal monitoring are imperative in this high-risk population. Oncology primary care provides necessary survivorship-informed care and longitudinal monitoring for early onset comorbidities and SPMs. Tailored education and outreach efforts for providers and patients should address preventative health services needed in this high-risk population. Research Sponsor: None.

Risk and predictors of late second primary malignancies in long-term breast, prostate, colon, and rectal cancer survivors.

Tendai Kwaramba, Sarah Westvold, Jessica B. Long, Terry Hyslop, Andrea Silber, Maryam B. Lustberg, Shi-Yi Wang, Michael Leapman, Ira L. Leeds, Michael Cecchini, Lisa P. Spees, Stephanie B. Wheeler, Cary Philip Gross, Michaela Ann Dinan; Department of Medical Oncology, Yale Cancer Center, Yale School of Medicine, New Haven, CT; Yale Cancer Outcomes, Public Policy and Effectiveness Research Center, New Haven, CT; Sidney Kimmel Cancer Center, Thomas Jefferson University, Philadelphia, PA; Yale School of Public Health, New Haven, CT; Department of Urology, Yale School of Medicine, New Haven, CT; Yale School of Medicine, Department of Surgery, Division of Colon and Rectal Surgery, New Haven, CT; Lineberger Comprehensive Cancer Center, Chapel Hill, NC

Background: In older, long-term (5-year) cancer survivors, mortality risks from aging and treatment-related effects may surpass those of their index cancer. Second primary malignancies (SPMs) occurring 5-10 years post-diagnosis are understudied in older patients. This study aims to quantify SPM risk, identify predictors, and describe prevalent SPM sites in older survivors of breast, prostate, colon, and rectal cancer to guide survivorship care. Methods: This retrospective cohort study analyzed patients aged 66+ with stage I-III cancer diagnosed between 2003-2011 using the SEER-Medicare database. Eligible patients survived ≥5 years post-diagnosis and had continuous Medicare Parts A & B enrollment from 1 year pre-diagnosis to 1 year post-diagnosis. The primary outcome was late SPMs occurring 5-10 years after index cancer diagnosis. Covariates included demographics, comorbidities, index cancer characteristics, treatment, and early SPMs (diagnosed within 5 years). Least absolute shrinkage and selection operator for variable selection and 5-year restricted mean survival time regression models were used. Cumulative late SPM incidence was calculated with mortality as a competing risk. The prevalence of specific SPMs was calculated as a proportion relative to the total number of SPMs within each cohort, and categorized as hematologic, predominantly screen-detected (breast, prostate, colorectal), or other solid tumors. Results: Of the 88,227 long-term survivors included with median age of 73.3 (IQR 69.5-78), 6.2% developed early SPMs and 8.2% (7,231) developed late SPMs. The 5-year cumulative incidence of late SPMs was 8.6%, highest in prostate (9.2%) and lowest in breast (6.7%) cancer survivors. Non-screenable cancers had the highest 5-year risk (6.2%), followed by screen-detected (1.3%) and hematologic malignancies (1.1%). Lung was the most common SPM overall (18.4% of SPMs), including in survivors of breast (21%), rectal (19.2%) and colon (16.5%) cancers, while prostate was most common in rectal cancer survivors (17.0%). Diagnosis of SPM in the early (< 5 years) survivorship cohort was associated with shorter time to a new late SPM, particularly in prostate cancer survivors (RMST Ratio 0.97, 95% CI 0.96-0.98). Treatments and high-risk disease features showed no significant associations with occurrence of late SPMs. Conclusions: Late SPMs were diagnosed in 8.6% of older, long-term cancer survivors. Lung cancer was the most common SPM overall. Some screen-detected SPMs, such as prostate were also common which is notable in a population aging out of screening guidelines. Prediction of SPMs was limited by the absence of modifiable risk factors, genetic data, and family history in SEER-Medicare data. Early SPMs were the sole predictor of late SPMs while treatment and index cancer features showed no effect, suggesting other drivers of late SPM development in older survivors. Research Sponsor: American Cancer Society.

Subtype-specific trends in lung cancer incidence and survival: A SEER analysis (2004–2021).

Shubhank Goyal, Anish Thomas, Parth Anil Desai; University of Texas Rio Grande Valley, Mcallen, TX; National Cancer Institute, Bethesda, MD; Fox Chase Cancer Center, Philadelphia, PA

Background: Lung cancer remains a leading cause of cancer mortality, with adenocarcinoma, squamous cell carcinoma (SCC), and small cell lung cancer (SCLC) as key subtypes. Advances in early detection (e.g., low-dose CT screening post-2013) and systemic therapies (e.g., targeted agents and immunotherapies [IO], approved 2015 for adenocarcinoma/SCC, 2018 for SCLC) have transformed care. However, links between incidence trends and survival outcomes remain unclear. This study leverages SEER data (2010–2021) to extend prior analyses (Howlader et al. 2000-2017, NEJM 2020) and evaluate subtype-specific trends, focusing on the post-2015 era of IO adoption and updated screening eligibility. Methods: Age-adjusted incidence and 3-year relative survival rates for adenocarcinoma, SCC, and SCLC were analyzed using SEER data (2004–2021), stratified by stage. Joinpoint regression identified significant trend changes. Survival shifts >2% annually were temporally linked to key milestones: low-dose CT screening (2013), EGFR/ALK inhibitors (2013), and IO (2015). Results: For adenocarcinoma, distant-stage survival rose from 12.8% (2011) to 23.0% (2018), with a sharp +3.1% annual increase in 2018 aligning with immunotherapy adoption. Localized and regional survival improved by 5.3% and 6.5%, respectively, over the study period. These trends probably reflect the combined impact of early detection and systemic therapies. In SCC, localized-stage survival increased from ~56% to ~66% after 2015, driven by earlier detection and reduced late-stage incidence. However, regional and distant-stage survival saw only modest gains (~7%), highlighting limited advancements for advanced disease. SCLC showed the least survival improvements despite declining incidence, largely attributed to reduced smoking. Distant-stage survival stagnated at ~4–6%, while localized-stage survival improved transiently by 17% from 2010 to 2012, likely reflecting temporary improvements in early-stage management. However, overall outcomes for SCLC remain poor, underscoring an urgent need for new therapies. Conclusions: Advancements in lung cancer treatment and cancer screening have led to significant survival gains. Adenocarcinoma's distant-stage survival improvements highlight the transformative impact of immunotherapy, while localized SCC gains emphasize the role of early detection and screening. SCLC remains a major challenge, with survival rates stagnating despite a steady decline in incidence. Further innovation in SCLC therapies, along with equitable access to both screening and novel treatments, is crucial to improving outcomes across all lung cancer subtypes. Survival data beyond 2018 for metastatic disease and post-2024 for localized disease (following IO approvals for respective indications) will provide deeper insights into the realworld impact of these therapeutic advancements. Research Sponsor: None.

Telehealth and cancer care delivery: An updated real-world analysis of the impact of telehealth on patient access and treatment utilization at a comprehensive cancer center.

Kelsey H. Natsuhara, Michelle Zhao, Jean Feng, Travis Zack, Jie Jane Chen, Nathan Magalit, Ryzen Benson, Ali Dorris, Anobel Y. Odisho, Hope S. Rugo, Sorbarikor Piawah, Alan P. Venook, Julian C. Hong; University of California, San Francisco Helen Diller Family Comprehensive Cancer Center, San Francisco, CA; University of California, San Francisco Bakar Computational Health Sciences Institute, San Francisco, CA; University of California, San Diego, La Jolla, CA; Research Advocate, University of California San Francisco, San Francisco, CA

Background: Telehealth in oncology (onc) has persisted due to its convenience and potential to improve equitable access to care. Data on telehealth's impact on treatment (tx) access are needed to guide long-term telehealth policies. Methods: We identified adult patients (pts) who completed \geq 1 medical, surgical, or radiation onc visit with an associated cancer diagnosis at our center from 2017-2019 (pre-telehealth) vs 2021-2023 (post-telehealth). Data from 2020 was excluded, given COVID irregularities. We selected 3 disease groups with varying telehealth use breast (low), GI (medium), and GU (high) – allowing us to better control for external factors (eg COVID). We compared changes in visit distribution, sociodemographic, and tx patterns within and between disease groups pre- vs post-telehealth using Chi-square and ANOVA tests. Logistic regression analyses identified post-telehealth predictors of receiving tx, including the percentage (%) of in-person (IP) visits per pt. Results: We analyzed 109,200 encounters and 26,907 pts pre-telehealth vs 143,159 encounters and 50,168 pts post-telehealth. Pt volume increased in all groups post-telehealth (+99% breast, +55% GI, +104% GU). Post-telehealth, the % of video visits (VVs) increased in breast (1.5% to 28.8%), GI (2.0% to 55.2%), and GU (3.0% to 80.9%). In all groups, the % of pts seen from outside the SF Bay Area decreased (-7.5 breast, -1.4 GI, -6.1 GU). In breast and GU, the % of pts receiving cancer tx decreased (-5.2, -16.0, p<0.01), while the % of pts receiving GI tx was stable (-0.9). For infusion tx, predictors of tx receipt included metastatic disease (OR 3.9, 95% CI 3.6-4.2) and higher % of IP medical onc visits (OR 3.6, 95% CI 3.3-3.9); while living outside the Bay Area was negatively associated with infusion tx (OR 0.5, 95% CI 0.4-0.5). For surgery, the % of IP surgical onc visits (OR 0.7, 95% CI 0.6-0.7) and living outside the Bay Area (OR 0.8, 95% CI 0.7-0.9) were negatively associated with tx receipt. For radiation tx, metastatic disease (OR 2.8, 95% CI 2.5-3.1), but not living outside the Bay Area (OR 0.6, 95% CI 0.5-0.7), was associated with tx receipt. The % of IP radiation onc visits was not significant (OR 1.1, 95% CI 1.0-1.4). Conclusions: Among 3 disease groups with varying telehealth use, pt volume increased in all groups, while the % of pts receiving tx at our center decreased. This suggests that providers may be providing collaborative care while pts receive care locally. In regression analyses, higher % of IP medical onc visits was positively associated with receiving infusions, highlighting the importance of IP visits during active medical onc tx. However, this was not seen for surgery and radiation tx. For these time-limited interventions, pts seen virtually are still likely to access tx at our center. Further analyses are needed to identify pts and visit types best suited for telehealth. Research Sponsor: Conquer Cancer Foundation Young Investigator Award.

Pilot study of an enhanced telehealth program for patients with prostate cancer.

Erin Mary Bange, Anne S. Reiner, Christine Liebertz, Susan Chimonas, Robert Michael Daly, Charlotte Malling, Shu Lei, Rosaline Campbell, Kristina Stevanovic, Jessie C. Holland, Rachel Ann Sanford, Sahil D. Doshi, Gilad Kuperman, Fernanda CG Polubriaginof, Peter D. Stetson, Deb Schrag, Katherine Panageas, Michael J. Morris; Memorial Sloan Kettering Cancer Center, New York, NY

Background: The time required for cancer treatment is considerable. Telehealth (TH) with home monitoring can minimize travel burden but patients' perceptions regarding tradeoffs of clinic visits versus enhanced telehealth (ET) are uncertain. We piloted an ET intervention offering patients on androgen deprivation therapy (ADT) for prostate cancer up to four components of care at home. Methods: Prostate cancer patients on ADT were offered participation in 4 at home services: 1) TH oncologist visits; 2) remote BP monitoring (BP); 3) home phlebotomy (HP); and 4) self-injection of ADT or denosumab at home with RN support via TH as needed. Clinicians referred eligible patients and specified frequency of each service. Completion rates were evaluated for each component. Patient perspectives, preferences for subsequent care, and assessments of the feasibility, acceptability, and appropriateness of each component were collected after participation in eligible services at least once over the course of the pilot. Feasibility, acceptability, and appropriateness were measured by validated measures (scores from 1-5). Patient satisfaction with ET was measured using a net promoter score. All results are based on the last completed patient survey. Results: Between 6/2023 and 6/2024, 39 patients enrolled in the pilot, the median age was 70 (IQR: 61.5-76.7), 62% were white, and 69% (N = 27) lived with family or a partner. Table 1 shows the %/(N) of patients who chose to participate in each at home component with completion rates at the patient and visit level. 73% (145/198) of remote monitoring failures were due to patient inability to execute the at home task. > 75% of patients reported that each service was convenient and saved time. Most patients reported no problems with completing the visit (TH 89%, BP 89%, HP 91%, injections 67%). Patients were either very likely or somewhat likely to participate again (TH 97%, BP 100%, HP 96%, injections 100%) and the majority preferred ET for future care (TH 79%, BP 79%, HP 87%, injections 100%). 62% (24/39) of patients found at-home visits to be equally or less stressful than in-person care. Patients found each service to be feasible, acceptable, and appropriate (mean score > 4.7 for all services) and gave ET a net promotor score of 79. **Conclusions:** Patients found ET for the management of prostate cancer on ADT to be feasible, acceptable, and appropriate, providing a more patient-centered and convenient alternative to traditional clinic-based care. Future studies will explore scalability and applicability across diverse patient populations and treatment regimens. Research Sponsor: National Cancer Institute/U.S. National Institutes of Health; P30 CA008748; National Cancer Institute/U.S. National Institutes of Health; P50 CA271357.

	% (N) Patients opting in for each component	% (N) Patients completing each component (at least once)	% (N) Total episodes completed
TH visits	100% (39)	59% (23)	90% (53/59)
Remote BP monitoring	92% (36)	94% (34)	60% (296/494)
Home phlebotomy	69% (27)	100% (27)	97% (143/148)
Home injections	28% (11)	73% (8)	90% (9/10)
All 4 components	18% (7)	29% (2)	70% (501/771)

Impact of telehealth utilization on adherence to endocrine therapies in privately insured breast cancer patients: A claims-based cohort study.

Shaimaa Elshafie, Lorenzo A. Villa Zapata; Clinical and Administrative Pharmacy, College of Pharmacy, University of Georgia, Athens, GA

Background: Adherence to endocrine therapies is essential for reducing recurrence and improving survival in breast cancer patients. However, nonadherence remains a significant challenge, particularly among young women. Telehealth has emerged as a promising tool to address barriers to care, yet its impact on long-term adherence to endocrine therapies is poorly understood. This study evaluated the association between telehealth utilization and adherence to endocrine therapies among privately insured women with nonmetastatic breast cancer. Methods: Using medical and pharmacy claims data from the Merative MarketScan database, we identified women under 65 years old who were newly diagnosed with nonmetastatic breast cancer in 2018 and were commercially insured for at least one year before diagnosis and five years after initiating endocrine therapy. Telehealth utilization was identified through billing codes, and adherence was measured by the proportion of days covered (PDC) with adherence defined as \geq 80% prescription coverage. Generalized linear mixed models were used to estimate odds ratios (ORs) and 95% confidence intervals (CIs) while adjusting for relevant patient-level covariates. Results: The study cohort included 1,141 patients with the majority (53%) aged 45-54 years and 92% exhibited moderate severity of comorbidities. All patients initiated endocrine therapy in 2018 with 34% receiving tamoxifen, 33% receiving an aromatase inhibitor, and 33% switching between agents during follow-up. Telehealth utilization increased sevenfold during the second year of treatment (coinciding with the COVID-19 pandemic) and peaked in the third year when 48% of patients used telehealth and 2,178 visits were recorded. Adherence rates declined steadily over time: from 75% in the first year to 36% by the fifth year. Patients who utilized telehealth were 58% more likely to be adherent compared to those who did not utilize telehealth (OR = 1.58; 95% CI: 1.31–1.91; p < 0.0001). Geographic region, insurance plan type, and endocrine therapy agent were also significant predictors of adherence. Conclusions: Telehealth utilization was significantly associated with improved adherence to endocrine therapies among privately insured breast cancer patients. These findings highlight the potential of telehealth to mitigate barriers to long-term treatment adherence. Future research should explore strategies to sustain adherence and evaluate the broader clinical and economic implications of telehealth in this population. Research Sponsor: None.
Comparative effectiveness of delivering early palliative care via video versus inperson on end-of-life outcomes in patients with advanced lung cancer.

Jessica R. Bauman, Areej El-Jawahri, Simone Rinaldi, Vicki Jackson, Emily R. Gallagher-Medeiros, Nora K. Horick, Dustin Rabideau, Jacob J. Strand, Finly Zachariah, Laura Kay Shoemaker, Marie Bakitas, Lori Ann Spoozak, Carl Grey, Kimberly A. Curseen, Eytan Szmuilowicz, Ramona Rhodes, Amelia M. Cullinan, Brianna Jewett, Jennifer S. Temel, Joseph Greer; Fox Chase Cancer Center, Philadelphia, PA; Division of Hematology and Oncology, Department of Medicine, Massachusetts General Hospital; Harvard Medical School, Boston, MA; Massachusetts General Hospital, Boston, MA; Massachusetts General Hospital, Harvard Medical School, Boston, MA; Massachusetts General Hospital, Boston, Clinic, Rochester, MN; City of Hope National Medical Center, Madras, OR; Cleveland Clinic, Cleveland, OH; University of Alabama at Birmingham, Birmingham, AL; University of Kansas Medical Center, Department of Internal Medicine, Kansas City, KS; Wake Forest Baptist Medical Center, Winston-Salem, NC; Emory School of Medicine, Morrow, GA; Northwestern University Feinberg School of Medicine, Chicago, IL; UT Southwestern Medical Center, Dallas, TX; Dartmouth-Hitchcock Medical Center, Lebanon, NH; Department of Psychiatry, Mass General Brigham; Harvard Medical School, Boston, MA

Background: Findings from our prior large-scale comparative effectiveness trial showed the equivalent effect of delivering early palliative care via video versus in-person on quality of life among patients with advanced non-small cell lung cancer (NSCLC). We now report on whether the two care delivery modalities were equivalent with respect to patient-reported communication with clinicians about their end-of-life (EOL) care preferences and hospice utilization. Methods: Between 6/14/2018 and 5/4/2023, we enrolled 1250 patients with newly diagnosed advanced NSCLC in a randomized trial of early palliative care across 22 US cancer centers. Patients were randomly assigned to meet with a palliative care clinician every 4 weeks from enrollment through the course of the disease, either via video or in the outpatient clinic. Participants completed self-report surveys at baseline and weeks 12, 24, 36, and 48, including an item asking if they had discussed with their clinicians the care they would want to receive if dving (ves/no); patients' final assessments prior to death or last follow up were analyzed. We reviewed patients' health records to collect data on hospice referral and length of stay. To test the equivalence in these outcomes, we used a binomial generalized linear model with the identity link function (pre-specified equivalence margin of $\pm 8\%$ for patient-reported communication about EOL care) and linear regression (pre-specified equivalence margin of ± 6 days for mean length of stay in hospice). P-values were adjusted for multiplicity using a Bonferroni correction. **Results:** Of the 1250 enrolled participants, 888 (71.0%) completed at least one survey post baseline regarding whether they communicated with clinicians about EOL care preferences. Among those, 29.1% of the video group and 26.0% of the in-person group reported "yes," indicating that they recalled such EOL care discussions (difference = 3.1%, 95% CI: -1.8%, 8.1%; p = 0.26 for equivalence). During the course of the trial, 733/1250 (58.6%) patients died, of whom 537/733 (73.3%) were referred to hospice. Mean lengths of hospice stay were 25.3 days for the video group versus 25.1 days for the in-person group (difference = 0.2, 95% CI: -7.0, 7.4; p = 0.46 for equivalence). When excluding outlying patients receiving hospice services > 180 days (n = 13), the mean lengths of hospice stay were 19.1 (video group) versus 19.7 (in-person group) days (difference = -0.6, 95% CI: -4.6, 3.3; p = 0.06 for equivalence). **Conclusions:** Although thresholds were not met to confirm equivalence statistically, the two modalities for delivering early palliative care demonstrate very similar outcomes with respect to patient-clinician communication about EOL care and hospice utilization. These findings provide further evidence of the utility of video visits for providing high quality palliative and EOL care. Clinical trial information: ClinicalTrials.gov Identifier (NCT03375489). Research Sponsor: Patient-Centered Outcomes Research Institute; PLC-1609-35995.

Assessing circadian rhythms and chemotherapy safety in remote patients with pancreatic ductal adenocarcinoma (PDAC) using a multidimensional digital plat-form (MultiDom, NCT04263948).

Francis Albert Lévi, Ayhan Ulusakarya, Sandrine Dulong, Rachel Bossevot, Dounya Boudriche, Xiaomei Li, Imène Hadj-Naceur, Elise Colle, Claudia Viaro, Tambo Bathily, Anne Thirot-Bidault, Pascal Agranat, Rodrigo Balp, Barbel Finkenstadt-Rand, Rene Adam, Mohamed Bouchahda, Pascal Hammel; UPR Chronotherapie, Cancers et Transplantation, Université Paris Saclay, Hôpital Paul Brousse ID Isco 13918, Villejuif, France; Paris-Saclay University, Digestive and Medical Oncology Department, Paul Brousse Hospital, APHP, Villejuif, France; Faculty of Medicine Paris Saclay, Villejuif, France; Digestive and Medical Oncology Unit, Paris-Saclay University, Paul Brousse Hospital, Assistance Publique-Hopitaux de Paris, Villejuif, France; Paris Saclay University Hospitals, Paul Brousse hospital, Villejuif, France; Cancers et Saclay University, Villejuif, France; Department of Digestive and Medical Oncology, Paul Brousse Hospital, Aphp, Villejuif, France; Clinique St Jean l'Ermitage, Melun, France; Oncology Unit, Private Hospital, Ramsay-Santé, Antony, France; Clinique du Mousseau, Évry, France; Cap Gemini, Issy-Les-Moulineaux, France; Department of Statistics, University of Warwick, Coventry, United Kingdom; Paul Brousse Hospital, Villejuif, France; Clinique du Mousseau, Ramsay Santé, Evry, France

Background: The disruption of circadian clocks is associated with reduced survival and treatment tolerability in cancer patients (pts). Here, real-time analyses of telemonitored circadian rhythms and electronic Pt-Reported Outcome (ePRO) are integrated within a multidimensional telemonitoring-telecare digital platform that triggers proactive telecare toward improved quality of life (QoL) and treatment safety. Methods: The multicentre, interventional, prospective, longitudinal, single-arm study recruited pts receiving mFOLFIRINOX chemotherapy (CT) q2-weeks for pancreatic ductal adenocarcinoma (PDAC). Early warning signals of circadian disruption, body weight loss, and ePROs severity are extracted from real time analysis and graphical displays of (i) continuously telemonitored rest-activity and chest surface temperature (chestemp) rhythms using a chest sensor, and (ii) daily body weight (e-balance), and (iii) daily self-rating of 23 symptoms using a GPRS tablet (MD Anderson Symptoms Inventory, MDASI). Pts participate for 1 week before (baseline) and 6 weeks after 1st CT course. Circadian disruption is defined by an (I < 0) value < 96%. (I < 0) is the % accelerations per min In-Bed that are below median accelerations per min Out-of-Bed for 3 days; (I < 0) range in controls, 97-100%). Automatic alerts are sent via internet for decision of proactive intervention by the oncology team, in case of circadian disruption, chestemp increase by 1.5°C, weight loss > 5%, or MDASI symptom \geq 7. **Results:** From 6/2021 to 7/2024, 58 pts with advanced PDAC were selected (male, 52%), median age, 58 y.o. (range, 33-82); WHO performance status (PS) 0/1/2, 36%/ 53%/10% of the pts; metastatic sites 0/1 > 2, 38%/24%/8%; liver metastases, 50%). Early PDAC-related complications prevented platform use in 5 pts. The platform was used by 53 pts during a median of 45.5 days (IQR, 38-50], with > 85% compliance. At baseline, large betweenpts differences in circadian rhythms were found for both rest-activity I < O (median [IQR]), 98.4 accelerations/min [95.8-99.6]); range, 75 to 100), and chestemp circadian amplitude (median, 1.1°C [IQR, 0.7-1.4], range, 0.3°C to 2.7°C). Baseline circadian disruption was larger in male pts (56% vs 31%; p = 0.07) and in those with PS 1-2 (47% vs 14%; p = 0.02). Consistently, median chestemp circadian amplitude was less in males compared to females (0.8°C vs 1.3°C, p < 0.01) and in pts with PS = 1-2 compared to PS = 0 (0.8°C vs 1.3°C; p < 0.01). Maximum toxicities of CT were circadian disruption (100% of the pts), body weight loss > 5% (59%), and MDASI symptom \geq 7 (46%), without any influence of baseline pt characteristics. **Conclusions:** The use of this multidimensional digital platform combining circadian and other physiology metrics with ePROs was feasible and accepted by the pts. Its implementation seemed to be clinically relevant toward improving the care of remote pts at risk of adverse events. Clinical trial information: 04263948. Research Sponsor: Education and Research Direction of Ramsay-Santé.

Remote physiologic and behavioral monitoring to predict early treatment response in metastatic cancer: High-Definition Oncology study (HDOs) preliminary results.

Leire Paz-Arbaizar, María Sauras, Sonia Pernas, David Vicente, Rosario Garcia-Campelo, Josefa Terrasa, Ramon Colomer Bosch, Ruth Vera, Desirée Jiménez, Santiago Gonzalez- Santiago, Begona Bermejo, Antonio López-Alonso, Berta Nasarre, Leonardo Garma, Pablo Martínez Olmos, Antonio Artés Rodríguez, Miguel Quintela-Fandino; Department of Signal Theory and Communications, University Carlos III, Leganés, Spain; Institut Català d'Oncologia, IDIBELL, L'Hospitalet, L'hospitalet, Barcelona, Spain; Virgen de Macarena University Hospital, Sevilla, Spain; University Hospital A Coruña, A Coruña, Spain; Hospital Universitario Son Espases, Palma De Mallorca, Spain; Hospital Universitario La Princesa, Madrid, Spain; Hospital de Navarra, Pamplona, Spain; CNIO - Spanish National Cancer Research Center, Madrid, Spain; Hospital Universitario San Pedro de Alcántara, Cáceres, Spain; Clinic University Hospital Valencia, Valencia, Spain; Hospital Universitario de Fuenlabrada, Fuenlabrada, Spain

Background: Emerging evidence suggests that behavioral, physiologic or emotional factors may act as real-time indicators of treatment response, with potential as modifiable factors. Advances in remote monitoring technologies provide passive (e.g., heart rate, sleep patterns) and active (e.g., self-reported emotions) data. HDOs collects such data and serial -omics from 300 women with metastatic cancer to identify novel markers, understand disease trajectories and develop a digital twin for individualized care. We present data from 25% accrual. Methods: Women receiving first-line treatment for metastatic colorectal, lung, or hormone-positive breast cancer were eligible. Patients continuously wore a smartwatch and used the EB2 App to capture step count (SC), sleep duration (SL), phone usage (PU), time at home (TH), location clusters (LC), mean (MHR) and minimum (mHR) heart rate, mean (MSHR) and minimum (mSHR) sleeping heart rate and sleeping oxygen saturation (SOS). Emotional valence was selfreported from a list of 20 emotions and classified as negative (-1), neutral (0) or positive (+1). Aim 1: to explore the relationship between the variables and response (CB: CR+PR+SD vs. PD) at the first CT scan at day +90 analyzing data from days 1-15 and 75-90 (Mann-Whitney U). Aim 2: to find Response-Associated Behavioral Patterns (RABPs) associated with CB or PD. First, Daily Behavioral Profiles (DBPs) are obtained using unsupervised learning models from > 2 million days of smartwatch and App data (external set). After identifying 256 DBPs with the VQ-VAE model, Latent Dirichlet Allocation defined RABPS based on the frequency and abundance of DBPs per patient. RABPs were compared among classes (response type, age group) using X^2 . Bilateral P values < 0.01 were deemed significant. Results: from May 2023 to April 2024, 77 female patients (median age 61; 28-80) were accrued (46 Breast, 23 Lung, 8 Colorectal). At first CT, 72 (93.5%) achieved CB while 5 (6.5%) had PD. During days 1–15, CB patients showed lower PU (2.4 vs. 3.9 hours; P = 0.002), TH (18.5 vs. 22 hours; $P = 2*10^{-7}$), MHR (78 vs. 88 bpm), mHR (59 vs 70 bpm), MSHR (75 vs 88 bpm) mSHR (66 vs 78 bpm) (all Ps $< 10^{-10}$) and reported more negative EV. The trends persisted in days 76-90 in addition to SC (7235 vs 4038 steps/day; P =0.00001) and decreased SOS (90.1% vs. 92.6%; $P = 1.5*10^{-8}$). Six RABPS were identified. Patients < 60 yo displayed more often RABPs 1, 2 and 5 (84% vs. 16%; P = 0.02). RABP1 breast cancer and RABP5 lung cancer patients were more likely to experience PD vs. CB (75% vs. 24%; P = 0.08; and 69% vs.19%, P = 0.07, respectively). **Conclusions:** Behavioral and physiologic data in days 1-15 and 76-90 were strongly associated with treatment response, independent of tumor type, age or treatment. RABPS identifying patients at high risk of PD can be detected, highlighting their value as markers for early intervention. Research Sponsor: None.

Administration of tarlatamab in an outpatient setting utilizing remote patient monitoring: Mayo Clinic experience.

Ashley Potter, Syeda A. Mina, Abdullah Al-Ajmi, Dhauna Karam, Yi Lin, Jonas Paludo, Tyler B. Sandahl, Adrienne Nedved, Lucy M. Holmes, Antonious Ziad Hazim, Julian R. Molina, Aaron Scott Mansfield, Anastasios Dimou, Kaushal Parikh, Katherine Emilie Rhoades Smith, Ailsa Luce, Anna J. Schwecke, Konstantinos Leventakos; Mayo Clinic Rochester, Rochester, MN; Mayo Clinic, Rochester, MN; Division of Hematology, Mayo Clinic, Rochester, MN

Background: Tarlatamab is a bispecific T-cell engager targeting DLL3 that has shown promise as a therapy in small cell lung cancer. Administering tarlatamab requires careful consideration of immune-related adverse events (AE), including cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). Prescribing information recommends patients to be monitored for 22-24 hours in an appropriate healthcare setting for cycle 1 (C1), days 1 and 8. At Mayo Clinic in Rochester MN (MCR), tarlatamab is initially administered in a hospital-based outpatient (HBO) setting utilizing an innovative remote patient monitoring system (RPM). In this study, we describe our RPM process and patient outcomes thus far. Methods: We retrospectively reviewed records of patients treated with tarlatamab from August through December 2024. All patients received tarlatamab in the HBO setting and were enrolled into RPM for C1, days 1–10. Patients attended daily HBO visits on days 1-3 and 8-10 of C1 and were required to stay within 30 minutes of the hospital with a 24-hour caregiver for 48 hours following infusion days in C1-2. Data on patient characteristics, frequency of RPM alerts, escalations, rate of CRS & ICANS, and need for hospitalizations were reported using descriptive metrics. Results: As part of RPM, patients are provided with a kit containing preconnected Bluetooth-enabled devices to measure vital signs (VS), including blood pressure (BP), heart rate (HR), temperature (T), and pulse oximetry (SpO2). The kit also includes a cellular-enabled tablet for electronic ICANS questionnaires, which upload directly into our electronic medical record system. Patients are required to log VS four times daily, monitored in real-time by a centralized virtual RPM nursing (RN) team. Embedded decision trees trigger alerts, prompting the RN team to contact patients and follow care pathways for escalations as needed. Among the 16 patients treated, the median age was 68 years, and the median ECOG PS was 1. During the 10-day RPM period, a total of 2,233 VS entries were recorded. Of these, 88% (14/16) of patients had alerts triggered, with a median of 2 alerts per patient. Alerts were mostly for out-of-range systolic BP (56%), HR (56%), and T (25%), with none for SpO2. The RN team escalated alerts in 50% (8/16) of the patients. Overall, 38% (6/16) of patients were managed entirely in the HBO setting. Among the 63% hospitalized, 56% had CRS limited to grade (G) 2, and 31% had ICANS limited to G3. Two patients were hospitalized for other indications. The mean length of stay was 2.6 days, with no ICU admissions. Conclusions: Our experience shows that frequent monitoring required with tarlatamab can be safely and effectively executed in an outpatient setting with the utilization of an RPM system. It can potentially minimize the burden of hospitalizations for patients and the healthcare system. Research Sponsor: None.

Teledermatology-dermoscopy: Expanding access to skin cancer screening to reduce healthcare disparities.

Brenda Santellano, Gabriela Duchesne, Mitchell Hanson, Michael Arnold, Jorge E. Cortes, Kendall Buchanan; Georgia Cancer Center, Augusta University, Augusta, GA; Medical College of Georgia Augusta University, Augusta, GA

Background: Skin cancer, the most common malignancy in the United States, continues to rise in incidence. Underserved populations face significant barriers to care, including lack of insurance, language differences, and limited access to specialists. The Augusta Free Dermatology Clinic, a student-run clinic, collaborates with the Teledermatology in Rural Georgia program to address these challenges through store-and-forward (SAF) teledermatology-dermoscopy. This approach involves transmitting dermoscopic images to a dermatologist for remote analysis. Implemented during Community Health Fairs (CHFs), this initiative aims to enhance access to skin cancer screening in underserved communities. Methods: Volunteer medical students (MS) from the Medical College of Georgia (MCG) and general physicians underwent training to use a dermatoscope effectively. Trained MS collected brief medical histories and dermoscopic images for SAF referrals during CHFs serving individuals with incomes below 200% of the federal poverty line. Polarized dermoscopic images were captured using iPhones equipped with magnetic dermatoscope attachments and were securely transmitted to a boardcertified dermatologist via a teledermatology platform. Dermatological recommendations were provided within one hour and communicated to patients, with Spanish translators facilitating communication. Results: Across two CHFs (~8 hours each), 10 MS volunteered in shifts under the supervision of a general physician (n = 1) or dermatology resident (n = 1). A total of 141 patients presented with dermatological concerns, of whom 24 (17.02%) were referred for SAF consultations due to suspicious skin lesions. Among these, 17 (70.83%) had benign lesions, while 7 (29.17%) were identified as potentially malignant and referred for in-person follow-up at the Augusta Free Dermatology Clinic for further evaluation or biopsy. Comprehensive data were available for 112 patients (79.43%), most of whom were female (58.04%, n = 65) and Latino/Hispanic (98.21%, n = 110). The majority were uninsured (73.21%, n = 82), Spanishspeaking (98.21%, n = 110), and required translation services (98.21%, n = 110). Nearly all participants worked in skilled agricultural roles (98.21%, n = 110) and reported a median of two household dependents (range: 0-9). Common diagnoses among follow-up patients included healthy skin (45.54%, n = 51), acne (5.36%, n = 6), melasma (5.36%, n = 6), benign nevi (5.36%, n = 6), dermatitis (4.46%, n = 5), and folliculitis (3.57%, n = 4). Other less common conditions were diagnosed in 30.36% (n = 34) of patients. Conclusions: The implementation of teledermatology-dermoscopy at CHFs effectively addressed barriers to dermatological care in underserved populations. This approach demonstrated the potential to improve early detection of skin cancer, facilitate timely care, and reduce healthcare disparities. Research Sponsor: United States Department of Agriculture Rural Utilities Service (USDA).

Patient-reported experience with an immunotherapy telehealth platform.

Robert Michael Daly, Charlotte Malling, Andrea DAgostino, Erin Mary Bange, Isabel Ruth Preeshagul, David H. Aggen, Marie Carlo, Monica F. Chen, Juliana Eng, Kenneth K. Ng, Martin H. Voss, Michael A. Postow, Adam Jacob Schoenfeld, Neil J. Shah, James William Smithy, Raymond E. Baser, Peter D. Stetson, Deb Schrag, Katherine Panageas, Michael J. Morris; Memorial Sloan Kettering Cancer Center, New York, NY; Memorial Sloan Kettering, New York, NY; Memorial Sloan-Kettering Cancer Center - Fellowship (GME Office), New York, NY; Genitourinary Oncology, Memorial Sloan Kettering Cancer Center; Weill Cornell Medical College, New York, NY; Memorial Sloan Kettering Cancer Center, Rockville Centre, NY; Memorial Sloan Kettering Cancer Center and Weill Medical College, New York, NY; Memorial Sloan Kettering Cancer Center, New York, NY; Weill Cornell Medical College, New York, NY; Thoracic Oncology Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY; Weill Cornell Medical College, New York, NY; Thoracic Oncology Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY; Weill Cornell Medical College, New York, NY; Thoracic Oncology Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY; Weill Cornell Medical College, New York, NY; Thoracic Oncology Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY; Weill Cornell Medical College, New York, NY; Thoracic Oncology Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY; Weill Cornell Medical College, New York, NY; Thoracic Oncology Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY

Background: The Making Teleheath Delivery of Cancer Care at Home Effective and Safe for Immunotherapy (MATCHES-IO) intervention seeks to improve the efficiency and patient experience for those treated with single agent pembrolizumab. Because pembrolizumab is administered as an outpatient infusion every 3-weeks, patients require up to 18 clinic visits per year to receive treatment, which is arduous. During the COVID-19 pandemic, the FDA granted accelerated approval for an extended interval dosing administered every 6 weeks, but despite this approval every 3-week dosing remains the standard (65% of prescriptions) as clinicians perceive this schedule enables them to identify and manage toxicity early. Telehealth may be the impetus to change the standard to the more convenient 6-week in person schedule, but evidence is needed. Methods: We conducted a single arm pragmatic trial to evaluate the efficiency and patient experience of a telehealth immunotherapy platform (MATCHES-IO) in patients with non-small cell lung, genitourinary, or melanoma cancers receiving single agent pembrolizumab. MATCHES-IO evaluates whether in-person visits for pembrolizumab therapy q6wk (rather than q3wk) with interim telehealth toxicity checks between in-person treatments for the first six months of therapy is more efficient and enhances patient experience relative to the standard q3wk infusion visits. The components of the platform include clinicianpatient virtual visits, labs at home, biometric devices at home for vital sign monitoring, and electronic patient-reported outcomes to monitor for common IO-related toxicities. Patient experience was assessed after each MATCHES-IO televisit for up to two televisits. We measured experience with a patient experience survey that included how likely are they to recommend this intervention to similar patients (scale 0-10). **Results:** Between July 2023 and January 2025, 59 patients were enrolled, median age 69 (range 25–85), 81.5% White, 11.1% Black, 7.4% Asian, and 61.1% male. Cancer types included thoracic (50.9% of patients), genitourinary (30.5%), and melanoma (18.6%). 45 patients (76.3%) have completed a MATCHES-IO televisit and completed a patient experience survey. The median score for likelihood to recommend was 10 (range 4-10). 97.8% patients perceived a benefit to the MATCH-IO televisit including saved time (82.2% of respondents), patient convenience (71.1%), convenience for caregiver/family (44.4%), saved money (44.4%), and better monitoring of cancer and treatment (24.4%). 57.8% of patients found the at home visit less stressful than the in-person visit. Conclusions: Patients endorsed an enhanced experience with an immunotherapy telehealth platform for extended dosing of pembrolizumab. Further follow-up is needed to confirm these experience findings and determine whether this platform improved efficiency through fewer in-person visits. Research Sponsor: National Cancer Institute; Emerson Collective Digital Oncology Care.

Outcomes of germline expedited point of care (POC) genetic testing through telehealth in the Veterans Health Administration (VA).

Akiko Chiba, Andrea Stoddard, Wendy Kohlmann, Micaela R. Scobie, Daniel McSkimming, Alyssa Gardner, Cathryn Koptiuch, Vida Almario Passero, Michael J. Kelley, Carolyn S. Menendez; Department of Surgery, Duke University Medical Center, DUMC, Durham, NC; Department of Veterans Affairs, Washington, DC; Hunstman Cancer Institute at the University of Utah, Salt Lake City, UT; National Oncology Program Office, Department of Veterans Affairs, Washington, DC; VA National TeleOncology, VA National Oncology Program Office, Durham, NC; Department of Veterans Affairs, National Oncology Program Office, Durham, NC; VA Pittsburgh Healthcare System and University of Pittsburgh, Pittsburgh, PA; Durham VA Medical Center and Duke University School of Medicine, Durham, NC; Durham VA Medical Center and Duke University Durham, NC

Background: Germline genetic testing is standard of care for treatment planning for several malignancies. To increase access to genetic testing for Veterans, VA developed and disseminated educational materials, laboratory portal access, and templates for ordering and documenting consent and testing in the electronic health record to facilitate POC testing by oncology providers. Here, we describe the outcomes of POC testing. Methods: POC tests ordered between 2/24/23-11/18/24 by oncology providers at VA sites or with National TeleOncology (NTO) were identified through the VHA's Corporate Data Warehouse and the VINCI (VA Informatics and Computing Infrastructure) research environment. Pathogenicity of variants was determined by the classification provided by the laboratory. Providers are recommended to use the POC testing for patients actively being treated for the following cancers: metastatic/ high risk prostate, breast, ovarian, exocrine pancreatic/ampullary, colon < 50 years of age, medullary thyroid, and pheochromocytoma/paraganglioma. Results: POC tests were ordered at 45 different VAs for 1293 patients. Total of 1364 tests were ordered, and 1195 (87.5%) tests were . The tests ordered included 854 (62.6%) curated multigene panel and 510 (37.4%) targeted cancer panels. Demographics are summarized in Table. Among 1382 diagnoses listed as the indication for testing (some patients had multiple), the most common cancer diagnoses were prostate (831, 60.1%), breast (206, 14.9%), and pancreatic (94, 6.8%). Most tests were ordered for patients who met POC indications, but 13.6% of orders were for other indications. A total of 77 (6.4%) patients were found to have pathogenic/likely pathogenic variants (PV) in dominantly inherited cancer predisposition genes. Seventy-one (5.9%) patients had PVs in high/ moderate penetrance cancer predisposition genes. Conclusions: POC testing is feasible and being widely adopted across the VA. Further work is needed to determine if patients found to have actionable PVs through the POC mechanism have changes in treatment or are referred for follow-up genetic counseling. A significant, minority of tests were ordered for patients with diagnoses not eligible for POC testing. Continued education and support is planned to increase utilization of POC testing in oncology across the VA. Research Sponsor: None.

Demographics of veterans with a point of care genetic testing order (n=1293).	
White/Other races	701 (54.2%)/ (45.8%)
Non-Hispanic/Hispanic Male/Female	1225 (94.7%)/29 (2.2%) 1034 (80%)/259 (20%)
Rural/Urban POC test orders	369 (29.5%)/915(70.8%)
Testing completed (n=1364) Comprehensive panel/targeted panel (n=1364)	1195 (87.6%) 854 (62.6%)/510(37.4%)
POC eligible cancer diagnosis (n=1382) Pathogenic/likely pathogenic variant in a dominant high/moderate risk gene (n=1195)	1194 (86.4%) 71 (6.4%)

DIPCAN, a multidimensional approach to precision oncology: Harnessing genomic, clinical, pathological and radiographic data to advance personalized cancer treatment.

Enrique Grande, Cristina Aguado, Elena Báez, Xana Da Silva, Mónica Díez-Fairen, Fabio Franco, Victor Gonzalez-Rumayor, Roberto López, Álvaro Santos, Marta Martin, Esther Martin-Illana, Anna Nogué Infante, Alberto Orta, David G Pisano, Carmen Prieto-de-la-Lastra, Ruth Román, Raquel Sáiz-Martínez, Carlos Tarin, Teresa Valdés-Sánchez, Carlota Costa, DIPCAN Consortium; Department of Medical Oncology, MD Anderson Cancer Center Madrid, Madrid, Spain; Hospital Universitário Quiron Dexeus, Barcelona, Spain; Eurofins, Madrid, Spain; Genomcore, Barcelona, Spain; Fundación MD Anderson International España, Madrid, Spain; Research & Data Intelligence, ATRYS Health, Madrid, Spain; Artelnics, Salamanca, Spain; Radiology Department, MD Anderson Cancer Center Madrid, Madrid, Spain; Quibim SL, Valencia, Spain; Quantitative Imaging Biomarkers in Medicine, Quibim, Madrid, Spain; Pangaea Oncology, Barcelona, Spain; Eurofins, Barcelona, Spain

Background: Advances in big data analytics and artificial intelligence (AI) are enabling novel approaches to patient classification in oncology. While existing studies often correlate only a few data types, the DIPCAN Study (Digitalisation and Integral Management of Personalised Medicine in CANcer) seeks a comprehensive, integrated analysis combining phenotypic, clinical, pathological, radiomic, and genomic data from patients with metastatic cancer in Spain. DIPCAN aims to deepen insights into cancer's multifactorial nature, driving personalized care and more precise therapeutic strategies. Methods: DIPCAN was initiated through a consortium comprising five technology and healthcare SMEs—Genomcore, Quibim, Pangaea Oncology, Artelnics, and Atrys Health—alongside Eurofins Megalab and the non-profit MD Anderson International Foundation Spain. Funding was secured via the Spanish Ministry of Economic Affairs and Digital Transformation under the EU-funded Recovery, Transformation, and Resilience Plan (R&D Missions Program in Artificial Intelligence, File No. MIA.2021.M02.0006). DIPCAN's primary objective is to characterize and map clinical, phenotypic, genomic, and radiomic profiles of metastatic cancer patients across Spain. Secondary goals involve developing Big Data, AI, and machine learning tools to enable multidimensional analysis of these patients. Eligible patients are 18 years or older, have histologically confirmed metastatic solid tumors, a life expectancy exceeding three months, and available tumor material for histological and molecular analyses. Participants consent to undergo a comprehensive set of diagnostic and imaging procedures outlined in the study protocol. If recent tumor tissue (<3 years) is unavailable, patients may opt for a current biopsy or liquid biopsy. At no cost, participants receive consultations with oncology and drug development specialists, who document baseline characteristics and compile structured medical histories. Additional diagnostics include bloodwork emphasizing lipid metabolism, digital pathology, extensive NGS sequencing on tissue or blood, and a full-body MRI. All participants receive digital access to their data and a clinical report with tailored recommendations for their physicians. With ethics approval in place, DIPCAN has enrolled 1,500 patients since June 14, 2022. Data collection is ongoing, with anticipated advancements in AI-driven analysis aimed at refining precision oncology approaches for metastatic cancer in Spain. Clinical trial information: 2021.M02.0006. Research Sponsor: European Union; MIA.2021.M02.0006.

A pilot single-arm, pragmatic trial in progress of in-home versus in-clinic subcutaneous nivolumab administration through Cancer Care (connected access and remote expertise) Beyond Walls (CCBW) program.

Dina Elantably, Jeremy Clifton Jones, Yanyan Lou, Gina L. Mazza, Chanice Howard, Sunnie Confiado, Amber Baskin, Alexis Jackson, Angela Hazel Fritsche, Kaila Lopez, Jade Brown, Luci Nolan, Dustin Chapin, Gregory Beliles, Nathan Smith, Winston Tan, Mohamed Kharfan-Dabaja, Grzegorz S. Nowakowski, Cheryl Willman, Roxana Stefania Dronca; Mayo Clinic, Jacksonville, FL; Mayo Clinic, Rochester, MN; Division of Hematology, Mayo Clinic, Rochester, MN; Mayo Clinic Comprehensive Cancer Center, Rochester, MN

Background: Cancer treatments are traditionally administered in clinical settings, which can isolate patients from their familiar environments and exacerbate physical, psychosocial, and financial burdens. Travel requirements further amplify these challenges, particularly for underserved populations. Studies indicate that patients prefer receiving care at home, and international models have demonstrated the safety of home-delivered chemotherapy since the 1990s; however, no U.S. clinical trial data exists. In response, Mayo Clinic has developed the Cancer CARE (Connected Access and Remote Expertise) Beyond Walls (CCBW) program, a distributed cancer care delivery model that expands access to quality cancer care by bringing it to the home environment, providing in-home cancer treatment, lab testing, telemedicine, and community paramedic support. This trial evaluates the safety, acceptability, and impact of home-based subcutaneous (SC) nivolumab (Nivo) administration compared to in-clinic treatment within the CCBW initiative. Methods: This open-label, single-arm trial evaluates the impact of SC Nivo administration location—home versus infusion center—on patient reported cancer care experience, patient-preferred treatment location, acceptability, safety, and patient-reported outcomes. Eligible adult patients (ECOG 0-1) receiving IV Nivo for an FDA-approved indication and residing within 75 miles of Mayo Clinic Florida will transition to SC Nivo, receiving two initial in-clinic cycles. If tolerated without injection reactions, four cycles will be administered at home before resuming in-clinic treatment. Exclusion criteria include concurrent investigational/standard treatments or contraindications to immunotherapy. Fifty patients will be enrolled, with an estimated 75% (n=38) providing cancer care ratings after 8 weeks inclinic and 8 weeks at-home, offering 85% power to detect a mean difference in ratings of 0.50 standard deviations. The primary endpoint is within-patient change in cancer care rating (0-10 scale, CAHPS Cancer Care Survey) comparing 8 weeks of in-clinic vs. at-home care. Secondary endpoints include patient-preferred treatment location, comfort with home injections, safety (grade 3+ adverse events), function (EORTC QLQ-F17), symptoms (PRO-CTCAE), side effect impact (GP5), and healthcare utilization (ER visits, hospitalizations). Cost will be assessed as a tertiary endpoint. The trial has FDA approval (IND #170079), Mayo Clinic IRB approval (#23009663), and ClinicalTrials.gov registration (NCT06265285). Enrollment began in April 2024, with an expected accrual period of 24 months. To date, 10 patients have been enrolled, and final analysis is expected 2.5 years after trial activation. Clinical trial information: NCT06265285. Research Sponsor: BMS; Mayo Clinic.

Trial in progress: Evaluating the effectiveness of Blue-button—A tool for institutionagnostic, EHR-integrated regional automated clinical trial prescreening and matching.

Waddah Arafat, Richard Tuli, Charles-Michael E. Uzuegbunam, Jennifer Burgess, Sarah Bittle, Melanie Hullings, Mujeeb Basit, Muhammad Shaalan Beg, Sharon Shriver, Salim Semy, Zach Lister, Joseph M. Unger, Mark Fleury; Simmons Comprehensive Cancer Center, University of Texas Southwestern Medical Center, Dallas, TX; USF Health Morsani College of Medicine, Tampa, FL; Harold C. Simmons Comprehensive Cancer Center, The University of Texas Southwestern Medical Center, Dallas, TX; Tampa General Hospital, Tampa, FL; UT Southwestern Medical Center, Dallas, TX; Science 37, Culver City, CA; American Cancer Society Cancer Action Network, Washington, DC; MITRE, Bedford, MA; Fred Hutchinson Cancer Center, Seattle, WA

Background: Clinical trial enrollment is essential for advancing cancer treatment and improving patient outcomes. Despite the benefits, only 7% of adult cancer patients in the US enroll in clinical trials due to barriers such as limited awareness, the time-intensive nature of manual prescreening and lack of relevant on-site clinical trials. This contributes to insufficient enrollment, causing approximately 20% of trials to fail. Automated prescreening using electronic health records (EHRs) offers a promising solution to streamline trial identification and improve access. This study builds on our published feasibility study (Cancer 2023; doi: 10.1002/ cncr.35022) that demonstrated the potential of an open-source clinical trial matching tool, developed in collaboration with ACS CAN and MITRE Corporation, to improve locoregional trial identification for patients. Methods: Trial Design: This prospective, randomized, two-arm pilot study is being conducted at two sites: University of Texas Southwestern Medical Center (UTSW), an academic center, and Tampa General Hospital (TGH), a community hospital. Patients are randomized to usual care or an intervention arm utilizing Blue-button, an automated prescreening tool. This SMART-on-FHIR tool automatically extracts deidentified patient data (e.g., cancer type, stage, biomarkers) from the site EHR system and uses them to query external matching services via the FHIR mCODE standard. Using the standard FHIR ResearchStudy resource format, research coordinators review potential trial matches returned within a specified radius of the practice for eligibility and discuss them with patients. At UTSW, this includes prostate, bladder, breast cancer and colon cancer cohorts. At TGH, the trial includes breast, prostate, and colorectal cancers, as well as glioblastoma and multiple myeloma. Statistical Methods: The primary endpoint is the proportion of patients enrolling in trials, comparing intervention and usual care arms. Secondary objectives include evaluating usability, barriers to enrollment, and participant diversity. A total of 1200 patients (600 per arm) will be enrolled, with 81% power to detect a 75% relative increase in enrollment from 9.0% (control) to 15.8% (intervention) at a one-sided alpha of 0.05. Trial Progress: The first phase of the trial addressed institutional approvals, security compliance, and complex server and EHR integrations. The later phase addressed integration of the automated tool into diverse clinical workflows, engagement with site staff and participating patients. Both sites have enrolled approximately 200 patients to date, half on the intervention arm. The final phase will address primary and secondary outcomes as per trial design. Clinical trial information: NCT05885880. Research Sponsor: American Cancer Society Cancer Action Network.

DISCO App: A patient intervention to reduce the financial burden of cancer in a diverse patient population.

Lauren M. Hamel, David W. Dougherty, Seongho Kim, Elisabeth I. Heath, Lorna Mabunda, Teneisha Austin, Hadeel Assad, Hirva Mamdani, Eyouab Tadesse, Roman Grossi, Nouran Jarbo, Susan Eggly; Karmanos Cancer Center, Wayne State University, Detroit, MI; Penn Medicine Abramson Cancer Center, Philadelphia, PA; Biostatistics Core, Karmanos Cancer Institute, Wayne State University School of Medicine, Detroit, MI; Mayo Clinic, Rochester, MN; Barbara Ann Karmanos Cancer Institute, Detroit, MI; Department of Hematology and Oncology, Barbara Ann Karmanos Cancer Institute, Wayne State University School of Medicine, Detroit, MI; Karmanos Cancer Institute, Detroit, MI; Karmanos Cancer Institute, Detroit, MI; Wayne State University, Detroit, MI; Karmanos Cancer Institute, Detroit, MI

Background: Financial toxicity, the material and psychological burden of treatment cost, affects up to half of people with cancer and can affect adherence and survival. Financial toxicity is a health equity issue, disproportionately affecting Black patients. Patient education about cost and patient-provider cost discussions are recommended to mitigate financial toxicity but occur infrequently. Our goal is to mitigate financial toxicity through a tailorable education and communication intervention, the DISCO App. The DISCO App was shown to be feasible, acceptable, and preliminarily effective at prompting cost discussions and improving related outcomes in a pilot trial. The aim of the ongoing trial is to test the effectiveness of the DISCO App on shortand longer-term outcomes for Black and White patients with cancer. Methods: This study is a longitudinal RCT. Oncologists are eligible if they treat patients with solid tumors at the trial site. Patients of participating oncologists are eligible if they are \geq 18 years of age; identify as Black or White; can read and write in English; have an email address; and were diagnosed with a solid tumor for which systemic therapy is a likely recommended treatment. Strata were created to balance arms by patient race, income, age, and sex. Upon consent, patients are randomized to one usual care arm (1) or one of two intervention arms (2 and 3). All patients are asked to allow one treatment discussion with their oncologist to be video recorded for analysis. Prior to the recording, intervention patients utilize the DISCO App on an iPad. The DISCO App includes a video about treatment costs, ways to manage costs, and the importance of discussing costs with oncologists. Once patients enter their socio-demographic information (e.g., employment, insurance) and any financial concerns, they receive a tailored list of questions to ask their oncologist. Arm 3 patients receive an intervention booster via email two months after the recording. Patients complete measures at baseline, right after the recording, and at 1, 3, 6 and 12 months after the recording. Measures assess outcomes including cost discussions, communication quality, cost knowledge, self-efficacy for cost management, referrals for support, short- and longer-term financial toxicity, and treatment adherence. The patient-oncologist interaction is the unit of analysis and we will use multi-linear models to compare outcomes by arm. We anticipate recruiting up to 15 oncologists and 240 patients. Data collection began in March 2021 and will continue until July 2025. Participants to date include 13 oncologists and 192 patients (116 Black, 76 White). Most patients completed the baseline assessment (n=164), the post-interaction assessment (n=137), and at least 1 follow-up assessment (n=132); 125 treatment discussions have been recorded. The IRB reviewed the trial in December 2024 and approved continuation. Clinical trial information: NCT04766190. Research Sponsor: American Cancer Society; ACS RSG-20-026-01-CPHPS.

RACED (Reduction of Cervical Cancer Disparities): The impact of navigators and racial literacy training.

Abna Faustina Sousa Vieira, Janaína Santos Paulista, Mateus Fonseca de Gouvea Franco, Camila M. Venchiarutti Moniz, Maria Del Pilar Estevez-Diz, Júlio Oliveira, de, Ana Cláudia Camargo Gonçalves Germani; Instituto do Câncer do Estado de São Paulo, Faculdade Medicina da USP, São Paulo, Brazil; Faculdade de Medicina da Universidade de São Paulo, São Paulo, Brazil; Instituto do Câncer do Estado de São Paulo, Universidade de São Paulo, São Paulo, Brazil; Instituto do Câncer do Estado de São Paulo, Faculdade de Medicina da Universidade de São Paulo, São Paulo, Brazil; Instituto do Câncer do Estado de São Paulo, Faculdade de Medicina da Universidade de São Paulo, São Paulo, Brazil; Instituto do Câncer do Estado de São Paulo, University of São Paulo, São Paulo, Brazil; Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brazil

Background: Cervical cancer is the third most prevalent cancer in Brazilian women. Approximately 17,000 new cases are expected for Brazil's 2023-2025 triennium. The complex multimodality treatment of locally advanced cervical cancer (LACC), which relies on platinum-based chemoradiotherapy (CRT) and brachytherapy (BT), in addition due to the significant healthcare demands of patients with cervical cancer, creates challenges for a public-funded health system. The Black population experiences the highest cancer mortality rates compared to the general population, partly due to inequalities in social, economic, political, and health areas spheres. Data showed that, compared to White women, the mean age-adjusted mortality rates according to race/skin color were 27% higher in Black women. Around 60% of Black patients have a cervical cancer diagnosis in locally advanced or advanced stages. The incidence rate among Black women was found to be significantly higher than that of their White counterparts, with a relative risk of incidence nearly 50% higher. This disparity cannot be ignored. Methods: Our study is based on Critical Racial Praxis for Public Health. It is inspired by the ACCURE (Accountability for Cancer Care Through Undoing Racism and Equity) initiative trial, composed of 3 anti-racist actions: 1- oncology navigation with racial literacy, 2- real-time medical record alert system, and 3- race-specific feedback. Our intervention, in turn, consists of oncology navigation with racial inequities training and improving interprofessional team knowledge about race and diversity through race-specific feedback. This prospective, single-center, nonrandomized clinical trial of anti-racist actions and treatment support will compare prospective patients with a historical control from the same hospital. The primary endpoint is to increase the completion rate of definitive treatment with CRT+BT for 100 patients with IB2 to IVA cervical cancer (convenience sample). The secondary endpoints are to analyze the implementation policy of this strategy and to make an economic assessment of the use of this implementation (we hypothesize that such measures reduce both visits to the emergency room due to toxicity, as well as admissions to wards and ICU). Patient inclusion is expected to begin in March 2025. Nurses are receiving training in oncology navigation and racial literacy in healthcare. As this is a race-conscious trial, the researchers plan to prospectively compare outcomes between the intervention group's Black/Brown and non-Black/Brown populations. In addition, given critical race theory, the research team comprises Black women in creation, design, and throughout the entire study continuum. Clinical trial information: 85819325.0.0000.0068. Research Sponsor: Bristol Myers Squibb Foundation.

Practical geriatric assessment (PGA) implementation strategies and correlative evaluations (PACE-70): A hybrid implementation-effectiveness study in 3 community practices.

Gabriel Aleixo, Julianne Ani, William J. Ferrell, Ravi Bharat Parikh, Peter Gabriel, Efrat Dotan, Simone Fernandes dos Santos Hughes, Ramy Sedhom, Samuel U. Takvorian; University of Pennsylvania, Philadelphia, PA; Penn Medicine, Philadelphia, PA; Emory University, Atlanta, GA; University of Pennsylvania, Ann B. Barshinger Cancer Institute, Lancaster, PA; The Ann B. Barshinger Cancer Institute, Penn Medicine Lancaster General Health, Lancaster, PA; Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA

Background: The use of a geriatric assessment to inform oncologic care for older persons with cancer is an evidence-based practice that improves patient-clinician communication, reduces treatment-related toxicity, and is recommended by national guidelines. However, the implementation of a geriatric assessment can be time-consuming and burdensome, leading to suboptimal use in clinical practice. Developed and endorsed by the American Society for Clinical Oncology (ASCO), the Practical Geriatric Assessment (PGA) is designed to improve clinical usability and adoption, but its implementation in real-world settings has not been evaluated. The PACE-70 study aims to evaluate PGA implementation and resultant chemotherapy dose modification among older adults with advanced cancer treated in a community setting. An exploratory aim will evaluate how the PGA, body composition and step count monitoring correlate with chemotherapy toxicity and other clinical outcomes. Methods: The PACE-70 study is a Type III hybrid implementation-effectiveness study enrolling at three community sites within a large academic health system. Eligible participants will be 70 years or older, have a diagnosis of advanced or metastatic solid malignancy, and be starting a new line of palliativeintent systemic therapy, where the expected prevalence of grade 3 toxicity exceeds 50 percent. The PGA will be administered via the electronic health record (EHR), available for patients to complete independently prior to an initial medical oncology visit, or during the visit with staff assistance. Results from the PGA will be shared automatically with clinical teams via the EHR, including a Best Practice Alert highlighting any identified geriatric impairment(s) and ASCO's recommendation for PGA-adapted care. The primary outcome will be the PGA completion rate. The secondary outcome will be the rate of chemotherapy dose modification among those with any identified geriatric impairment. Clinician perspectives on PGA implementation will be assessed via structured interviews among a sub-sample of participating clinicians. In a subsample of patients consenting to additional data collection, exploratory analyses will examine correlations between the PGA, step counts (measured via FitBit) and body composition (measured via standard abdominal CT scans) with clinical outcomes, including toxicity, hospitalization, and death. PACE-70 will be the first study to report on real-world implementation of the PGA in a multisite community oncology setting. It will provide insights on the facilitators and barriers of the PGA to inform chemotherapy dose modification, as well as its potential predictive value for clinical outcomes. It will lay the foundation for larger trials of effectiveness seeking to encourage PGA implementation and PGA-adapted care. Clinical trial information: pending. Research Sponsor: None.

Patient Priorities Care for older breast cancer survivors: A patient-centered approach to improve quality of breast cancer survivorship.

Dana Elena Giza, Anneliese Gonzalez, Meghan Sri Karuturi, Samiran Ghosh, Holly Michelle Holmes, Aanand Naik; The University of Texas Health Science Center at Houston, Houston, TX; University of Texas Medical School at Houston, Houston, TX; The University of Texas MD Anderson Cancer Center, Houston, TX; The University of Texas Health Science Center at Houston (UTHealth Houston) McGovern Medical School, Houston, TX; Department of Management, Policy and Community Health, UT School of Public Health; and UTHealth Consortium on Aging; The University of Texas Health Science Center, Houston, TX

Background: Older adult breast cancer survivors have higher rates of chronic conditions compared with other cancer survivors and may have a higher treatment burden. High treatment burden is associated with poor quality of life and increased healthcare utilization. Aligning care with patient priorities can reduce the treatment burden during survivorship care. Patient Priorities Care (PPC) is an approach designed to align care around each patient's goals to help decrease treatment burden. Although the PPC approach was previously designed for patients with multiple chronic conditions, we sought feedback from stakeholders, including older patients with a history of breast cancer, to adapt the PPC approach to breast cancer survivorship context. This quality improvement project aims to use PPC and patient's self-defined goals to improve the quality of survivorship care for older adults breast cancer survivors. Methods: We are conducting a multicenter, randomized quality improvement project with a hybrid implementation-effectiveness design to evaluate the impact of the adapted PPC approach compared to standard survivorship care on treatment burden and quality of life (NCT06478589). We are recruiting 120 older adult breast cancer survivors from outpatient oncology and primary care clinics. Eligible patients are: (1) \geq 65 years of age; (2) stage I-III breast cancer, who had finished active breast cancer treatment and are in the first year of survivorship care; (3) have evidence of burdensome care; (4) English-speaking; and (5) able to provide informed consent. Enrollment started in December 2024. Patients are stratified based on treatment burden at baseline; patients with a score of > 15 on the treatment burden questionnaire (TBQ) undergo simple randomization with a 2:1 ratio to either the PPC or standard survivorship care group. The PPC for Breast Cancer Survivorship intervention consists of: (1) a 30-minute priorities identification visit with a facilitator, 2) delivery of a structured patient priorities report to the survivorship care team, 3) survivorship care alignment using the patient's priorities. The primary outcome measures are differences in treatment burden (TBQ) and quality of life (FACT-B) from baseline at 3 to 6 months. Secondary outcomes include goal attainment achievement at 3,6 months for patients in the intervention group and adherence to standard and priorities-based breast cancer survivorship recommendations at 12 months for both groups. Descriptive statistics will be used to report patients' baseline and clinical characteristics. All analysis will be intention to treat. The effect of the intervention on changes (baseline to 3, 6 months) in the TBQ and FAST-B scores using Bayesian analysis. For the goal attainment differences, we will compare the differences in goal ratings from baseline at 3, 6 months within the Patient Priorities Group. Clinical trial information: NCT04513977. Research Sponsor: NIA.

Impacting quality of life and pancreatic cancer survivorship through a telehealth intervention.

Vincent Chung, Pashtoon Murtaza Kasi, Sarah Ali, Suzanne Patricia Graf, Evelyn Leyva, Jacqueline Carranza, Virginia Sun; City of Hope, Duarte, CA; City of Hope, Irvine, CA; City of Hope Mission Hills, Mission Hills, CA; City of Hope National Medical Center, Duarte, CA

Background: Pancreatic cancer patients experience significant debilitating symptoms as a direct or indirect result of disease, treatment, and co-morbidities resulting in higher symptom burden compared to other cancer types. The presence of comorbidities, declines in organ function, and increased need for assistance with daily function complicates the care of older adults with pancreatic cancer. Cancer not only affects the patient but also the entire family, especially the one that assumes the role of the family caregiver (FCG). Robust evidence suggests that survivors with pancreatic cancer and their FCGs experience high symptom burden and reduced quality-of-life (QOL). Despite robust evidence pointing to potential benefits of palliative care, many pancreatic cancer patients never receive any due to the workforce shortage. A scalable method of providing palliative care is needed. Methods: We are conducting a randomized pilot study to determine the feasibility, acceptability, and preliminary efficacy of a centrally administered telehealth, self-management survivorship care intervention in patients with pancreatic cancer and their FCGs. Patients within 8 weeks of initiating first line treatment for metastatic disease are eligible. Prior to initiating the intervention sessions, an advanced practice nurse (APRN) will complete separate comprehensive survivor/FCG QOL assessments using baseline surveys. The assessments will focus on QOL needs for survivors/FCGs and will include geriatric assessment for all regardless of age (activities of daily living, physical mobility, falls, social activity limitations, social support). Based on the QOL and geriatric screenings, the Intervention APRN will complete a personalized care plan for the patient, and a personalized self-care plan for the FCG. This provides for tailoring of the care plan to the participant's needs and preferences and will be shared with each participant's oncology care team after session completion. Both care plans will be organized around the four QOL aspects of care (physical, psychological, social, spiritual). Cultural aspects of care are taken into account and integrated appropriately within the four QOL aspects of care. A fully developed intervention resource manual with support reference materials and intervention content are provided to each patient and FCG. The patient and FCG coaching sessions are bi-weekly, centrally administered and separate but parallel to allow participants to freely discuss their QOL needs. Clinical trial information: NCT06524973. Research Sponsor: U.S. Department of Defense.