2000 **Oral Abstract Session, Fri, 8:00 AM-11:00 AM**

Intervention combining nurse navigators (NNs) and a mobile application versus standard of care (SOC) in cancer patients (pts) treated with oral anticancer agents (OAA): Results of CapRI, a single-center, randomized phase III trial.

Olivier Mir, Marie Ferrua, Aude Fourcade, Delphine Mathivon, Adeline Duflot-Boukobza, Sarah Naomie Dumont, Eric Baudin, Suzette Delaloge, David Malka, Laurence Albiges, Patricia Pautier, Caroline Robert, David Planchard, Stéphane de Botton, François Lemare, Marilene Guillet, Vanessa Puglisi, May Abbas, Mario Di Palma, Etienne Minvielle; Gustave Roussy Cancer Institute, Villejuif, France; Gustave Roussy, Villejuif, France; Gustave Roussy Cancer Campus, Villejuif, France; Department of Nuclear Medicine and Endocrine Oncology, Gustave Roussy Cancer Campus, Villejuif, France; Breast Cancer Unit, Department of Medical Oncology, Gustave Roussy, Villejuif, France; Gustave Roussy, Université Paris-Saclay, Département de Médecine Oncologique, Villejuif, France; Medical Oncology Department, Institut Gustave Roussy, Villejuif, France; Gustave Roussy Comprehensive Cancer Center, Villejuif, France; Institut Gustave Roussy, Thoracic Team, Villejuif, France; Institut Gustave Roussy, Villejuif, France; AstraZeneca, Courbevoie, France; Gustave Roussy, Polytechnique School, Palaiseau, France

Background: Various interventions aiming to improve a safe use of oral anti-cancer agents have previously been reported. These retrospective studies involved nurse-led follow-up and use of health technologies. However, the potential impact of these combined strategies is limited by a lack of rigorous methodology. **Methods:** We performed a randomized phase 3 trial comparing an intervention combining NNs and a mobile application vs. SOC in cancer pts treated with OAA (excluding hormonal therapy) in our tertiary cancer center. Pts initiating OAA (all types of cancer, PS < 3, life expectancy > 6 months), were randomized in a 1:1 basis. The intervention combined a nursing-led follow-up and a mobile application for patients. NNs provided regular phone follow-ups to manage symptoms and assess toxicities, adherence and supportive care needs. Pts had access to a mobile application to record tracking data, contact NNs via secure messaging or a dedicated phone line. The intervention lasted 6 months. The primary endpoint was the Relative Dose Intensity (RDI). Secondary endpoints included adherence, toxicity, response and survival, quality of life, pts experience (PACIC Score), end-of-life support, and economic estimation of the use of healthcare resources. **Results:** From October 2016 to May 2019, 609 pts (median age: 62 years, 20-92; PS2: 11.8%) were included. 39% were receiving oral chemotherapy, and 61% other OAA. The RDI was significantly higher in the CAPRI arm (93.4% $\pm$0.26 vs. 89.4% $\pm$0.19, p = 0.04). The CAPRI intervention also improved PACIC scores (mean: 2.94$\pm$0.83 vs. 2.67$\pm$0.89, p = 0.01), the number of unplanned hospitalizations (15.1% vs. 22.0%, p = 0.04), hospitalization duration (mean: 2.82$\pm$6.96 days vs. 4.44$\pm$9.60, p = 0.02), and treatment-related grade$\geq$3 toxicities (27.6% vs. 36.9%, p = 0.02). **Conclusions:** Compared to SOC, the CAPRI intervention improved RDI, pts experience, hospitalizations and their duration, as well as the rate of treatment-related grade$\geq$3 toxicities. This type of intervention should represent a new standard in pts receiving OAA. Clinical trial information: NCT02828462. Research Sponsor: Fondation Philanthropia Lombard Odier, Other Government Agency, Pharmaceutical/Biotech Company.

2001 **Oral Abstract Session, Fri, 8:00 AM-11:00 AM**

Chemotherapy remote care monitoring program (CRCMP): Integration of an SMS text patient-reported outcome (PRO) in the electronic health record (EHR) to identify patients needing pharmacist intervention for chemotherapy-induced nausea and vomiting (CINV).

Shannon Hough, Rachel McDevitt, Victoria Nachar, Shawna Kraft, Anna Brown, Catherine Christen, Barbara Walters, Jeffrey B. Smerage; University of Michigan, Ann Arbor, MI; University of Michigan Rogel Cancer Center, Ann Arbor, MI; University of Michigain Health System, Ann Arbor, MI

Background: CINV is a feared side effect of cancer therapy. Despite advances in management, CINV is a common cause for emergency department (ED) evaluation and other unplanned health care utilization. The University of Michigan Rogel Cancer Center initiated the CRCMP to proactively identify patients (pts) experiencing CINV and intervene prior to the need for urgent evaluation. **Methods:** Pts receiving highly emetogenic chemotherapy are identified by administration of a NK1 antagonist. Once enrolled in the CRCMP, pts receive a daily text message survey for 7 days after treatment. The survey is based on the validated MASCC anti-emesis tool (MAT). Responses are stored within a flowsheet in the EHR. Responses above a set threshold trigger a message to the team pharmacist for intervention. Data presented was reviewed from EHR and claims data. **Results:** In 8 mo, 652 pts received a NK-1 antagonist (2244 total cycles) and 387 pts enrolled in the CRCMP (59%). Each pt enrolled for an average of 1.8 cycles of chemo (range 1-8). Of patients enrolled, 61.4% were female and 86.2% were Caucasian. Chemotherapy intent was curative for 51.7% and palliative for 48.3% of pts. Pts enrolled most commonly received cisplatin-based (29.7%) followed by carboplatin-based (22.5%), and 5-fluoruracil-based (20.9%) therapy. Text message response rate was 94% (N=18,143 responses of 19,256 total messages sent). During 861 cycles of therapy, 7% of responses noted vomiting and 33% of responses noted nausea. Since implementation of CRCMP, total hospitalization, ED, and urgent care use has decreased (p=0.029) compared to historical data. When utilization for nausea-related diagnoses was considered, the reduction was more notable (Table). **Conclusions:** Pts engaged in the CRCMP for CINV, allowing for rapid assessment of PROs by a pharmacist. Health care utilization related to nausea was reduced following implementation of CRCMP. While these changes were numerically small, reduction in unnecessary care utilizing PROs can contribute to high value care for cancer patients. Research Sponsor: None.

Claims-based review of health care utilization before and after CRCMP.

	BEFORE CRCMP (n=3504 doses)	AFTER CRCMP (n=2244 doses)	p value
Admissions (ED/IP/OBS)	124	80	0.958
Nausea-Related Admissions	22	7	0.1
Urgent Care	110	38	0.001
Nausea-Related Urgent Care	23	7	0.077
Total visits	234	118	0.029
Total Visits: Nausea-Related	45	14	0.015

IP: inpatient;OBS:observation

2002 **Oral Abstract Session, Fri, 8:00 AM-11:00 AM**

Home-based management of cancer patients (CPs) experiencing toxicities while on anticancer treatment: The impact of a nurse-led telephone triage (NTT).

Lorenzo Calvetti, Marta Tealdo, Roberta Cimenton, Angela Gentile, Rachele Pretto, Monica Pavan, Barbara Gasparin, Gaetana Pagiusco, Rocco De Vivo, Laura Merlini, Giuseppe Aprile; Department of Oncology, San Bortolo General Hospital, Vicenza, Italy

Background: Novel organization models are needed to ensure early management of new treatment-related toxicity of anticancer treatments. Aim of this prospective observational study was to evaluate the impact of the introduction of NTT in reducing hospitalization of CPs. **Methods:** CPs on active medical treatment at the Department of Oncology of San Bortolo Hospital (Vicenza, Italy) were given instructions to refer to NTT in case of treatment-related adverse events (TRAEs). The service was opened Mon to Fri from 8am to 8pm. Assessment of TRAEs was performed by trained oncology nurses according to the CTCAE scale and subsequent actions were taken according to the severity of the events. The assessment was made under supervision of a medical oncologist in charge of the service while on duty. Primary endpoint of the study was to compare the rate of hospitalization of CPs on anticancer treatment after the introduction of NTT compared to 2017-2018 period. **Results:** From September 2018 to September 2019 1,075 patients received systemic anticancer treatment (versus 936 patients in the equivalent 2017 – 2018 period). Total consultations at NTT were 429; 581 TRAEs were reported. 117 patients reported more than one TRAE. CTCAE were graded as G1 237 (40.8%), G2 231 (39.8%) or G3-G4 113 (19.4%). The most common grade $\geq$ 3 TRAE was fever (38 events (33.6%) that resulted a febrile neutropenia in 7 cases) followed by cancer pain (15 (13.3%)) and fatigue (9 (8%)). In the observation period, 109 CPs on treatment were hospitalized versus 138 in the 2017-2018 period with a normalized hospitalization rate of 10.1% versus 14.7 % ($p = 0.002$, chi-square) with a reduction of normalized number of hospitalizations of 44 (estimated cost savings of 380.160 euros). **Conclusions:** Our results provided evidence of successful implementation of the NTT system in reducing rates of hospitalization through emergency room in cancer patients receiving modern medical treatments. Research Sponsor: None.

2003 **Oral Abstract Session, Fri, 8:00 AM-11:00 AM**

Changes in cancer mortality rates after the adoption of the Affordable Care Act.

Anna Lee, Kanan Shah, Junzo P. Chino, Fumiko Chino; Memorial Sloan Kettering Cancer Center, New York, NY; NYU Grossman School of Medicine, New York, NY; Department of Radiation Oncology, Duke University Medical Center, Durham, NC

Background: The Affordable Care Act (ACA) was designed to improve health status in the US primarily through improving access to health insurance. As adoption of Medicaid expansion varied at the state level, this study aims to compare cancer mortality rates over time between states who did (EXP) and did not adopt (NonEXP) Medicaid expansion. **Methods:** Age-adjusted mortality rates per 100,000 were gathered from the National Center for Health Statistics from 1999-2017 to establish trends. Only deaths due to cancer in patients less than 65 were included. Absolute change in cancer mortality was calculated from 2011-2013 and then from 2015-2017 with 2014 as washout year. Changes within subpopulations (gender, race, ethnicity) were also assessed. Mortality changes between EXP and NonEXP groups were via "difference in differences" analysis. **Results:** Overall age-adjusted cancer mortality in the US fell from 1999-2017 from 66.9 to 48.8 per 100,000. EXP states had higher population (157 vs 118 million) with less black/African Americans (19.2 vs 21.8 million) and more Hispanics (33.0 vs 21.7 million) than NonEXP states (all examples from 2017). The overall age-adjusted cancer mortality was consistently worse in NonEXP states, cancer mortality fell from 64.7 to 46.0 per 100,000 in EXP states and from 69.0 to 51.9 per 100,000 in NonEXP states from 1999-2017 (both trends $p < 0.001$, comparison $p < 0.001$). Comparing the mortality changes in the peri-ACA years (2011-2013 vs 2015-2017) between the 2 cohorts, the difference in differences between EXP and NonEXP states was -1.1 and -0.6 per 100,000 respectively ($p = 0.006$ EXP, $p = 0.14$ NonEXP). The estimated overall cancer mortality benefit gained in EXP states after Medicaid expansion ($\Delta\Delta\Delta$) is -0.5 per 100,000 (p = NS). In EXP states, this translates to an estimated 785 less cancer deaths in 2017. Age-adjusted cancer mortality per 100,000 was worse in NonEXP states for black patients (58.5 EXP vs 63.4 NonEXP in 2017) however there was no differential mortality benefit after ACA expansion when comparing between the peri-ACA years. Of the subpopulations assessed, Hispanics in EXP states had the highest differential cancer mortality benefit at -2.1 per 100,000 ($p = 0.07$). **Conclusions:** This is the first study to show a directly measured cancer survival benefit from the ACA on a national scale using a comprehensive database. Hispanic populations appear to have the highest differential cancer mortality benefit after Medicaid expansion. Further study is needed to elucidate why other populations like black patients did not appear to reap the same mortality decrease.
Research Sponsor: None.

2004 Oral Abstract Session, Fri, 8:00 AM-11:00 AM

Survival impact of multidisciplinary thoracic oncology care in a regional healthcare system.

Raymond U. Osarogiagbon, Nicholas Ryan Faris, Matthew Smeltzer, Anna Derrick, Philip Edward Lammers, Shailesh R. Satpute, William Walsh, Rameses Sroufe, Todd Robbins, Keith Tokin, Rob Optican, Angela Fulford, Laura McHugh, Jeffrey Wright, Anurag Mehrotra, Thomas Callihan, Meredith Ray; Multidisciplinary Thoracic Oncology Program, Memphis, TN; Baptist Cancer Center, Memphis, TN; University of Memphis, School of Public Health, Memphis, TN; Baptist Memorial Health Care Corporation, Memphis, TN; Meharry Medical College, Nashville, TN; Midsouth Imaging and Therapeutics, Memphis, TN; Memphis Lung Physician Foundation, Memphis, TN; Trumbull Laboratories, LLC, Memphis, TN

Background: Much-advocated, the value and impact of multidisciplinary care and planning (MDC) needs greater evidence. We compared non-small cell lung cancer (NSCLC) patient characteristics, treatment patterns and survival in a large community healthcare system spanning 3 US states with some of the highest lung cancer incidence and mortality rates. **Methods:** We identified MDC patients in the Tumor Registry NSCLC data from 2011-2017. Because the MDC program was located in metropolitan Memphis, we separated non-MDC patients by location of care resulting in 3 cohorts: MDC, non-MDC metropolitan care and non-MDC regional care. Using National Comprehensive Cancer Network guidelines, we categorized treatment by stage as 'preferred', 'appropriate' (allowable under certain circumstances). We compared demographic and clinical characteristics across cohorts using chi-squared tests and compared survival using Cox regression with Bonferroni adjustment. We repeated survival analysis with propensity matched cohorts. **Results:** Of 6259 patients, 14% received MDC, 56% metro care and 30% regional care; MDC had the highest rates of African Americans (34% v 28% v 22%), stage I-IIIB (63 v 40 v 50), urban residents (81 v 78 v 20), stage-preferred treatment rates (66 v 57 v 48), stage-appropriate treatment rates (78 v 70 v 63;), and lowest non-treatment rates (6 v 21 v 28). All $p<0.001$. Compared to MDC, the hazard for death was higher in metro (1.4, 95% confidence interval 1.3-1.6) and regional (1.7, 1.5-1.9); hazards were higher in regional care v metro (1.2, 1.1-1.3); all $p<0.001$ after adjustment. Results were similar for MDC comparisons after propensity matching with and without adjusting for preferred treatment. No differences in regional and metro cohorts. **Conclusions:** In this large community-based healthcare system, receipt of MDC for NSCLC was associated with significantly higher rates of guideline-concordant care and survival, providing strong evidence for recommending rigorous implementation of MDC. Research Sponsor: PCORI.

Care Setting Cohorts*	Hazard Ratio (95% Confidence Interval)	Pvalue	Bonferroni Adjusted Pvalue
Propensity matched†			
Metro v MDC	1.5 (1.2, 1.8)	0.001	0.003
Regional v MDC	1.7 (1.4, 2.2)	<.001	<.001
Regional v Metro	1.2 (1.0, 1.4)	0.058	0.139
Propensity matched adjusting for preferred treatment			
Metro v MDC	1.4 (1.1, 1.8)	0.006	0.018
Regional v MDC	1.5 (1.15, 1.9)	0.003	0.007
Regional v Metro	1.1 (0.9, 1.3)	0.525	0.800

*MDC-multidisciplinary care, Metro-non-MDC metropolitan care, Regional- non-MDC regional care; †matched on age, race, sex, insurance, rurality, and clinical stage.

2005 **Oral Abstract Session, Fri, 8:00 AM-11:00 AM**

Barriers to prescribing targeted therapies for NSCLC patients with highly actionable gene variants in the VA National Precision Oncology Program.

Vishal Vashistha, Jenna Armstrong, David Winski, Meghan Price, Bradley J. Hintze, Pradeep Poonnen, Jane Snowdon, Gretchen Purcell Jackson, Dilhan Weeraratne, David Brotman, Neil L. Spector, Michael J. Kelley; Duke University Health System/Durham VA Health Care System, Durham, NC; Duke University School of Medicine, Durham, NC; Durham VA Medical Center, Durham, NC; Duke University Health System, Durham, NC; Duke University Health System/Durham VA Medical Center, Durham, NC; IBM Watson Health, Cambridge, MA; Duke University Medical Center, Durham, NC

Background: Next-Generation Sequencing (NGS) gene panels are often completed to guide therapeutic decisions for patients with advanced stage non-small cell lung cancer (NSCLC). Patients with highly-actionable gene variants may experience improved therapeutic treatments and reduced toxicities with use of targeted agents. Ensuring appropriate prescription of targeted therapies is therefore of high importance. We sought to identify barriers to targeted agent use within the Veterans Health Affairs' (VHA) National Precision Oncology Program (NPOP). **Methods:** A retrospective evaluation examined the cohort of NSCLC patients who underwent NGS multi-gene panels through NPOP between July 2015 and February 2019. A level of evidence for drug actionability was assigned to each observed oncogenic gene variant using an artificial intelligence offering (IBM Watson for Genomics: WfG). WfG level 1 and 2A evidence was reviewed by NPOP staff to exclude gene variants that did not conform to NPOP level 1 and 2A definitions. Anti-neoplastic drug prescriptions and oncology provider notes were obtained for all included patients from the VHA Corporate Data Warehouse. Review of clinical notes of patients who did not receive targeted agents was performed to categorize the reason(s). **Results:** Of 1764 NSCLC patients who successfully underwent NGS gene panel testing, 156 (8.9%) received therapeutic level 1 (7.3%) or 2A (1.6%) options for targeted agents based on WfG evidence analysis. In total, 117 (6.6%) patients had NPOP level 1 and 2A gene variants, all within *ALK*, *BRAF*, *EGFR*, *ERBB2*, *MET*, and *RET*. Of these, 49 (41.2%) patients were not prescribed available targeted agents. The three most common reasons were: (1) treating provider did not comment on NGS results (30.7%), (2) patient did not carry a diagnosis of advanced stage disease (18.4%), and (3) patient had begun an alternative systemic therapy prior to completion of sequencing (16.3%). No patient was denied access to a level 1 or 2A targeted drug due to utilization-management review. **Conclusions:** A substantial minority of patients with advanced NSCLC bearing highly-actionable gene variants are not prescribed available targeted agents. Further provider- and pathologist-directed educational effort are needed, as well as implementation of health informatics systems to provide near real-time decision support for test ordering and interpretation. Research Sponsor: None.

2006 **Oral Abstract Session, Fri, 8:00 AM-11:00 AM**

Launch prices and price developments of cancer drugs in the United States and Europe.

Kerstin Noëlle Vokinger, Paola Daniore, ChangWon C Lee, Aaron S Kesselheim, Thomas J Hwang; Harvard Medical School, Program on Regulation, Therapeutics, and Law/University of Zurich, Boston, MA; University of Zurich, Zurich, Switzerland; Harvard Medical School, Program on Regualtion, Therapeutics, and Law, Boston, MA; Harvard Medical School/Program on Therapeutics, Regulation, and Law, Boston, MA; Harvard Medical School, Boston, MA

Background: Cancer drug costs are rising in the US and Europe. While drug manufacturers set prices without restriction in the US, European countries have regulations that allow national authorities to directly negotiate drug prices at launch and over time. We analyzed and compared the launch prices and price developments of cancer drugs in the US, Germany, Switzerland and England. **Methods:** We identified new drugs indicated to treat solid tumors in adults that were FDA-approved between 2009 and 2019 and had also been approved by the EMA and Swissmedic by 31 December 2019. Launch prices and post-launch price changes as of 1 January 2020 were extracted and adjusted to average sales prices for monthly treatment costs in the US and compared to comparable currency-adjusted ex-factory monthly treatment costs in Germany, Switzerland, and England. A cross-sectional analysis was conducted to infer yearly trends in launch prices and post-launch price changes across the countries. **Results:** The study cohort included 42 drugs for solid tumors, of which 40 (95%) drugs were first approved in the US compared to Germany and England, and 41 (98%) to Switzerland. Average launch prices for monthly treatment costs per patient were $15,178 in the US vs $7,049 in Germany, $7,421 in Switzerland and $8,176 in England, i.e., 215% (interquartile range [IQR] 263%-187%), 205% (IQR 202%-185%) and 186% (IQR 166%-189%) higher in the US compared to Germany, Switzerland and England respectively. Post-launch prices of 36 (86%), 40 (95%), and 38 (90%) drugs decreased over time with total savings of monthly treatment costs for all drugs in the study cohort of $86,744, $44,936, and $1744 in Germany, Switzerland, and England respectively. By contrast, prices of 8 (19%) drugs decreased, while 34 (81%) increased post-launch in the US with total additional expenses of $128,192 for monthly treatment costs. **Conclusions:** Launch prices for cancer drugs are far higher in the US than in Germany, Switzerland, or England. These price disparities continue to increase substantially after market entry since cancer drug prices, in general, decrease over time in Europe and increase in the US. Spending on cancer drugs could be reduced in the US if it adopted the principles used to more effectively negotiate drug prices in Europe. Research Sponsor: Swiss Cancer Research Foundation.

2007 **Oral Abstract Session, Fri, 8:00 AM-11:00 AM**

The BRCA founder outreach study: Initial results of a digital health model.

Kelly Morgan, Heather Symecko, Daniella Kamara, Colby Jenkins, Jeffrey Levin, Jenny Lester, Kelsey Spielman, Lydia E. Pace, Vanessa Marcell, Temima Wildman, Yuri Anthony Fesko, Jacob Heitler, Mark E. Robson, Katherine Nathanson, Nadine M. Tung, Beth Y. Karlan, Susan M. Domchek, Judy Ellen Garber, Jada G. Hamilton, Kenneth Offit; Memorial Sloan Kettering Cancer Center, New York, NY; Basser Center for BRCA, University of Pennsylvania, Philadelphia, PA; David Geffen School of Medicine at UCLA, Los Angeles, CA; Dana-Farber Cancer Institute, Boston, MA; Basser Center/HUP Cancer Center, Philadelphia, PA; Brigham And Women's Hospital, Boston, MA; Quest Diagnostics, Secaucus, NJ; LifeLink, Oakland, CA; University of Pennsylvania, Philadelphia, PA; Beth Israel Deaconess Medical Center and Dana-Farber Cancer Institute, Boston, MA; Cancer Genetics and Prevention, Dana-Farber Cancer Institute, Boston, MA

Background: NCCN now endorses BRCA founder mutation genetic testing (GT) via longitudinal studies in all Ashkenazi Jewish (AJ) individuals. The BRCA Founder OutReach (BFOR) study offers pre-GT online education with posttest engagement of primary care providers (PCPs). **Methods:** The study in 4 US cities enrolls those age $>$ 25 with $>$ 1 AJ grandparent. Participants enroll online with chatbot and video education, have GT at local centers, receive results from their PCP or BFOR staff, and are surveyed 12 weeks post disclosure and annually for 5 years. Univariate analyses and multivariable (MV) logistic regression models were used to evaluate characteristics associated with not completing GT, selecting PCP to disclose GT, and positive GT. **Results:** As of January 2020, 4754 participants consented (77.5% female, median age 51); 37.7% never previously considered GT. Cancer family histories (FHx) were 56.4% low risk (LR), 36.4% high risk (HR), and 7.2% had a familial mutation (FM). To date, 3658 participants (76.9%) completed and 677 (14.2%) did not complete GT; the remainder are pending. Only 34.8% of participants selected PCP to disclose GT, and 42.6% of PCPs agreed. Of the 124 mutation carriers (3.4%) identified, 60.5% had a FM. At the 12-week survey, 65.4% of mutation carriers planned to proceed with recommended screening or scheduled risk reducing surgery; 3.5% of those with negative GT and HR FHx reported further GT. Satisfaction was high (mean 9.58/10, SD 1.12) and unrelated to result (p$>$.05). **Conclusions:** A digital model for founder mutation testing engaged those with LR FHx and no prior experience with GT. Older participants were more likely to complete the study. Males were less likely to enroll but more likely to carry mutations. The majority of those who tested positive had a FM. A minority of results were disclosed by PCPs. Continued follow up is needed to determine long term outcomes. Research Sponsor: The Sharon Levine Corzine Foundation, Breast Cancer Research Foundation, Basser Center for BRCA, Nancy Ann Mellen Fund for Hereditary Cancer Research, Robin and Ken Isaacs, Brooke and Eric Meltzer, Jerold O. and Abbe Beth Young, Anonymous Donors.

Select variables included in MV analysis.

	Fail to complete GT	MV p value	Select PCP to disclose GT	MV p value	Positive GT	MV p value
Age ≥51/<51	6.5%/ 13.8%	<.001	39.6%/ 29.7%	<.001	2.8%/ 4.1%	NS
Male/Female	7.1%/ 8.9%	NS	33.9%/ 34.8%	NS	8.1%/ 2.0%	<.001
Has children (yes/no)	7.4%/ 11.4%	NS	36.1%/ 30.1%	NS	2.9%/ 5.1%	0.044
FHx LR	9.0%	ref	34.7%	ref	1.0%	ref
FM	4.8%	<0.006	26.5%	0.015	27.1%	<0.001
HR	8.1%	NS	36.1%	NS	2.2%	0.003
Baseline cancer specific distress ≤/>5.0 (median)	7.7%/ 8.5%	NS	34.8%/ 35.5%	NS	2.7%/ 4.0%	0.013
Provider previously recommended GT (yes/no)	8.1%/ 8.5%	NS	46.0%/ 33.8%	0.004	4.2%/ 3.3%	NS
Has PCP (yes/no)	9.5%/ 12.8%	NS	37.9%/ 4.6%	<0.001	3.1%/ 6.1%	NS

NS= not significant by MV analysis ref= reference for FHx comparisons

2008 **Oral Abstract Session, Fri, 8:00 AM-11:00 AM**

Randomized trial of web-based genetic education versus usual care in advanced cancer patients undergoing tumor genetic testing: Results from the ECOG-ACRIN NCI Community Oncology Research Program (NCORP; EAQ152) COMET trial.

Angela R. Bradbury, Ju-Whei Lee, Jill B Gaieski, Shuli Li, Ilana F Gareen, Keith Flaherty, Benjamin A. Herman, Angela DeMichele, Susan M. Domchek, Kara Noelle Maxwell, Adedayo A. Onitilo, Shamsuddin Virani, Sujung Park, Bryan A. Faller, Stefan C. Grant, Ryan C. Ramaekers, Robert J. Behrens, Gopakumar S. Nambudiri, Ruth Carlos, Lynne I. Wagner; University of Pennsylvania, Philadelphia, PA; Dana-Farber Cancer Institute, ECOG-ACRIN Biostatistics Center, Boston, MA; Dana Farber Cancer Institute – ECOG-ACRIN Biostatistics Center, Boston, MA; Brown University–ECOG-ACRIN Biostatistics Center, Providence, RI; Dana-Farber Cancer Institute/Harvard Medical School/Massachusetts General Hospital, Boston, MA; Abramson Cancer Center, University of Pennsylvania, Philadelphia, PA; Marshfield Clinic-Weston Center, Marshfield, WI; Aurora Cancer Care-Southern Lakes VLCC, Burlington, WI; Medical Oncology Hematology Consultants PA, Newark, DE; Missouri Baptist Medical Center, Saint Loius, MO; Wake Forest University Health Sciences, Winston Salem, NC; CHI Health St. Francis Cancer Treatment Center, Grand Island, NE; Medical Oncology and Hematology Assoc-Des Moines, Des Moines, IA; Saint John's Hospital-Healtheast, Maplewood, MN; University of Michigan Comprehensive Cancer Center, Ann Arbor, MI; Wake Forest University Health Sciences, Winston-Salem, NC

Background: Enthusiasm for precision oncology may obscure the complex psychosocial and ethical considerations for tumor genetic testing. Low patient genetic knowledge has been documented and heightens the risk for adverse experiences. We developed a web-based intervention to increase genetic knowledge and decrease distress among advanced cancer patients undergoing tumor genetic testing. **Methods:** 594 patients (80% from NCORP Community Sites) were recruited and randomized to web-intervention (n = 293) or usual care (n = 301), prior to receipt of tumor genetic test results. Primary outcomes were genetic knowledge, anxiety, depression, and cancer-specific distress measured at T0 (prior to intervention), T1 (post-intervention), T2 (after receipt of tumor results) and T3 (3 months post receipt of tumor results). Secondary outcomes included satisfaction, regret and disappointment. The effect of web-intervention was evaluated using t-test, multiple linear regression and logistic regression, with an intent-to-treat approach. **Results:** Patients randomized to web-intervention had better knowledge improvement than those randomized to usual care (T1-T0, $p < 0.0001$; T2-T0, $p = 0.003$). No difference was observed in change scores for anxiety, depression or cancer-specific distress. To find the moderators of intervention effect (including sex, age, education, and literacy) two 2-way interactions were noted with statistical significance: higher depression among those in the intervention arm versus the control arm for patients with lower literacy ($p = 0.03$); and lower cancer-specific distress among women in the intervention arm than with usual care but no such effect noted in men ($p = 0.01$). 71% of patients reported receiving tumor test results and this did not differ by arm. Only 20% of patients reported regret and disappointment at T2, which was more likely for those without a mutation of interest (MOI) detected vs those with a MOI detected (OR = 2.08, 95% CI, 1.13 to 3.83, $p = 0.02$). **Conclusions:** Web-based education prior to receipt of tumor genetic test results increases patient understanding of tumor genetic testing. While the intervention did not significantly reduce distress, results suggest that women who received the intervention had lower cancer-specific distress than those with usual care. Future refinements to the web-intervention are needed to address low literacy groups, men and patients with no actionable results. Clinical trial information: NCT02823652. Research Sponsor: U.S. National Institutes of Health.

2009 Poster Discussion Session; Displayed in Poster Session (Board #1), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Prospective validation of a machine learning algorithm to predict short-term mortality among outpatients with cancer.

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Background: Oncologists accurately identify only 35% of patients with cancer who will die in six months. There is an urgent need for automated, accurate prognostic systems to inform treatment and advance care planning in oncology. We assessed the prospective performance of a previously described ML algorithm (Parikh et al, JAMA Netw Open, 2019) to predict short-term mortality in a cohort of general oncology outpatients. **Methods:** Our prospective cohort consisted of patients aged ≥18 years who had a medical or gynecologic oncology encounter between March 1 and April 30, 2019 in either a tertiary academic practice or one of twelve community practices within a large academic cancer system. We used a retrospectively validated gradient-boosting ML algorithm, based on 559 structured electronic health record (EHR) variables, to predict 180-day mortality prior to each oncology encounter. For patients with multiple encounters, we selected the last encounter to assess performance. We assessed several performance metrics, including area under the receiver operating curve (AUC), area under the precision-recall curve (AUPRC), scaled Brier score (sBrier; a measure of calibration ranging from 0 [random] to 1 [perfect]), and positive predictive value (PPV). **Results:** Of 25,537 unique patients, median age was 64.4 (interquartile range 53.3 – 73.0), 76.8% were White, 56.5% were treated at a community center, and 4.1% died within 180 days. The ML algorithm had an AUC of 0.89 (95% confidence interval [CI] 0.88-0.90), AUPRC 0.34, and sBrier 0.29. At a prespecified threshold of 40%, observed 180-day mortality was 44.5% (95% CI 40.7 – 48.4%) in the high-risk group vs. 3.0% (95% CI 2.8% – 3.3%) in the low-risk group. There was an 85-fold difference in mortality (13.6% vs. 0.16%) in the top vs. bottom risk quartiles. The model was well-calibrated for mortality risks ≤40% and slightly under-calibrated for mortality risks > 40%. Performance varied across cancer types in the tertiary hospital but did not vary by race or practice type (Table). **Conclusions:** In this prospective cohort study among outpatients with cancer, a ML prognostic algorithm based on EHR data had better discrimination and calibration that published cancer-specific models. This is one of the first ML prognostic models to be prospectively validated in oncology. Research Sponsor: University of Pennsylvania Center for Precision Medicine.

	AUC	PPV
OVERALL	0.89	0.45
Tertiary center	0.89	0.45
· **Breast**	0.96	0.56
· **Myeloma**	0.91	0.59
· **Lymphoma**	0.91	0.46
· **Genitourinary**	0.88	0.38
· **Gastrointestinal**	0.85	0.40
· **Thoracic**	0.82	0.40
Community practices	0.89	0.44
Black	0.91	0.46
White	0.89	0.45

2010 Poster Discussion Session; Displayed in Poster Session (Board #2), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Multi-institutional comparative effectiveness of advanced cancer longitudinal imaging response evaluation methods: Current practice versus artificial intelligence-assisted.

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Background: Current-practice methods to evaluate advanced cancer longitudinal tumor response include manual measurements on digital medical images and dictation of text-based reports that are prone to errors, inefficient, and associated with low inter-observer agreement. The purpose of this study is to compare the effectiveness of advanced cancer longitudinal imaging response evaluation using current practice versus artificial intelligence (AI)-assisted methods. **Methods:** For this multi-institutional longitudinal retrospective study, body CT images from 120 consecutive patients with multiple serial imaging exams and advanced cancer treated with systemic therapy were independently evaluated by 24 radiologists using current-practice versus AI-assisted methods. For the current practice method, radiologists dictated text-based reports and separately categorized response (CR, PR, SD, and PD). For the AI-assisted method, custom software included AI algorithms for tumor measurement, target and non-target location labelling, and tumor localization at follow up. The AI-assisted software automatically categorized tumor response per RECIST 1.1 calculations and displayed longitudinal data in the form of a graph, table, and key images. All studies were read independently in triplicate for assessment of inter-observer agreement. Comparative effectiveness metrics included: major errors, time of image interpretation, and inter-observer agreement for final response category. **Results:** Major errors were found in 27.5% (99/360) for current-practice versus 0.3% (1/360) for AI-assisted methods ($p < 0.001$), corresponding to a 99% reduction in major errors. Average time of interpretation by radiologists was 18.7 min for current-practice versus 9.8 min for AI-assisted method ($p < 0.001$), with the AI-assisted method being nearly twice as fast. Total inter-observer agreement on final response categorization for radiologists was 52% (62/120) for current-practice versus 75% (90/120) for AI-assisted method ($p < 0.001$), corresponding to a 45% increase in total inter-observer agreement. **Conclusion:** In a large multi-institutional study, AI-assisted advanced cancer longitudinal imaging response evaluation significantly reduced major errors, was nearly twice as fast, and increased inter-observer agreement relative to the current-practice method, thereby establishing a new and improved standard of care. Research Sponsor: None.

2011 Poster Discussion Session; Displayed in Poster Session (Board #3), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Prospective study of an AI enabled online intervention to increase delivery of guideline compliant cancer care, on the ground.

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Background: Despite survival benefits of guideline compliant cancer care, under treatment and over treatment are prevalent. Navya is an AI enabled online intervention that matches a patient's medical record with NCCN and NCG guidelines (National Cancer Grid, India) and layers live multidisciplinary expert review to recommend actionable treatment plans. It was developed to standardize care and mitigate morbidity and mortality, by delivering on-t ime, guideline based expert treatment plans. **Methods:** From July 2019 to January 2020, all patients who received a Navya treatment plan based on guidelines and live expert review were included. Intended treatment plans were prospectively collected from the patient. Compliance of intended plans with NCCN (including Resource Stratified Framework) or NCG was measured. Noncompliant intended plans were categorized as overtreatment or undertreatment. After delivery of Navya plan, prospective phone follow up assessed whether noncompliant intended plans were changed to guideline compliant care. **Results:** Of 1707 consecutive patients who received a Navya plan, 1549 intended plans were available. Patients were diverse with respect to geographic, socioeconomic, and primary tumor distribution: West of India: 28%, North: 26%, East: 21%, South: 15%, Central: 7%, International: 3%; 35% of patients with income $<$ \$300/month; GI: 23%, Breast: 14%, Head & Neck: 11%, Thoracic: 10%. Of the 1549 intended plans, 441 (28.47% (95% CI $\pm$ 0.26%)) were not compliant with NCCN or NCG. Undertreatment was 35%, overtreatment 26%, incomplete staging workup 28% and 11% could not be categorized. Of 441 patients with noncompliant intended plans, 80.19% ($\pm$ 0.97%) shared the Navya plan with their treating oncologists and 50.40% ($\pm$ 0.88%) changed their intended plan to receive the Navya treatment plan. Intervention with Navya increased on-the -ground guideline compliance by ~15% (from 71.53% $\pm$0.42% to 85.87% $\pm$ 1.73%). **Conclusions:** Guideline compliant care ensures best achievable clinical outcomes with existing therapies. A technological earthshot that significantly increases adoption of guideline based care is the first step towards cancer moonshots. Research Sponsor: None.

2012 Poster Discussion Session; Displayed in Poster Session (Board #4), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Four distinct patient-reported outcome (PRO) trajectories in longitudinal responses collected before, during, and after chemotherapy.

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Background: Cancer chemotherapy, whether given with curative or palliative intent, is toxic. Toxicity is routinely captured in clinical trials by investigator observation and increasingly by PRO. The ability to capture PRO in the routine treatment workflow has been standard at Stanford since 2015 (Roy et al ASCO 2020). Analysis of longitudinally captured, real world PRO and prospectively identifying patients (pts) whose quality of life (QOL) is at risk of deteriorating either permanently or temporarily is needed. Routine serial PRO measurement should enhance precision care delivery, precision toxicity detection and management. **Methods:** We identified patients undergoing chemotherapy at Stanford and analyzed PROMIS (PRO Measurement Information System) responses. Pts with PROMIS survey information at three intervals—pre-treatment, during chemotherapy and post chemotherapy—were identified. We evaluated global physical health (GPH) and global mental health (GMH). Pts with a clinically significant decrease (CSD) in GPH or GMH scores were identified. A k-median cluster analysis was used to identify patient trajectory clusters and a machine-learning model was applied to identify risk factors for CSD and predict CSD. **Results:** We identified 670 adult oncology patients undergoing chemotherapy who completed at least one PROMIS survey in each interval. GPH scores were 48.4 $\pm$ 9.1 before, 47.1 $\pm$ 8.5 during, and 48.5 $\pm$ 8.9 after chemotherapy and GMH scores were 50.5 $\pm$ 8.2, 49.1 $\pm$ 8.5, and 50.7 $\pm$ 9.0, respectively. The majority of patients did not have a CSD in GPH or GMH post treatment compared to pretreatment scores. Pretreatment scores were the strongest predictor of a CSD in GPH and GMH. Trajectory clustering identified four distinct trajectories: Temporary Improver, Temporary Deteriorator, Improver, Inexorable Deteriorators. We were not able to predict any cluster based on pre-treatment features. **Conclusions:** Using routinely collected PROMIS surveys in a real-world setting, we are able to predict patients with post-treatment decreases in their physical and mental well-being. We further defined four novel patient trajectories during chemotherapy, which could guide personalized supportive interventions to improve patient's chemotherapy experience. Identification of patients at risk for deterioration and the patterns of deterioration could help guide efficient deployment of toxicity mitigating and supportive care interventions to patients most in need. Research Sponsor: U.S. National Institutes of Health.

2013 Poster Discussion Session; Displayed in Poster Session (Board #5), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Patient-reported care satisfaction and symptom burden in hospitalized patients with cancer.

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Background: Hospitalized patients with cancer often experience high symptom burden, which may impact their care satisfaction and use of health care services. Yet, studies describing these patients' care satisfaction, symptom burden, and health care utilization are lacking. **Methods:** We prospectively enrolled patients with cancer and unplanned hospitalizations from 9/2014-4/2017. Upon admission, patients self-reported their care satisfaction (FAMCARE items asking about satisfaction regarding speed with which symptoms are treated and coordination of care) and physical (Edmonton Symptom Assessment System [ESAS]) and psychological (Patient Health Questionnaire 4 [PHQ4]) symptom burden. We used regression models to identify patient factors associated with care satisfaction. We also explored associations between patients' care satisfaction, symptom burden, and hospital length of stay (LOS) in models adjusted for age, sex, marital status, comorbidity score, cancer type, cancer documented as curable/incurable, time since cancer diagnosis, and admission to a dedicated oncology service. **Results:** We enrolled 1,576 of 1,749 (90.1%) consecutive patients (mean age = 63.19±13.39 years, 46.3% female). Most reported being very satisfied/satisfied with the speed with which symptoms are treated (89.0%) and coordination of care (90.1%). Older age (B = 0.01, $P < .02$ for both) and admission to a dedicated oncology service (B = 0.20, $P < .01$ for both) were each independently associated with higher satisfaction with the speed with which symptoms are treated and coordination of care. Higher satisfaction with the speed with which symptoms are treated was associated with lower PHQ4 depression (B = -0.14, P = .01), PHQ4 anxiety (B = -0.11, $P < .01$), ESAS physical (B = -1.30, $P < .01$), and ESAS total (B = -2.44, $P < .01$) symptoms. Higher satisfaction with coordination of care was associated with lower PHQ4 depression (B = -0.14, P = .02), PHQ4 anxiety (B = -0.16, $P < .01$), ESAS physical (B = -1.30, $P < .01$), and ESAS total (B = -2.75, $P < .01$) symptoms. Satisfaction with the speed with which symptoms are treated (B = -0.47, P = .03) and coordination of care (B = -0.50, P = .03) were both associated with shorter hospital LOS. **Conclusions:** Most hospitalized patients with cancer reported high care satisfaction, which was associated with older age and admission to a dedicated oncology service. We found relationships among higher care satisfaction, lower symptom burden, and shorter hospital LOS, underscoring the importance of efforts to enhance symptom management and care coordination in this population. Research Sponsor: Massachusetts General Hospital Cancer Center.

2014 Poster Discussion Session; Displayed in Poster Session (Board #6), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Mapping PRO-CTCAE responses to clinician-graded adverse events, dose reductions, interruptions, and discontinuations in phase I cancer trials.

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Background: Typically symptomatic adverse events (sy-AEs) on clinical trials are reported by clinicians using the CTCAE. To complement clinician collected sy-AEs and understand tolerability better, the patient report outcome version of the CTCAE (PRO-CTCAE) has been developed to provide the patient (pt) perspective on severity of AEs (graded scale 0-4) and their interference in daily life (scale 0-4). The aim of this study was to correlate PRO responses with the grade (G) of AEs, dose interruptions/ reductions and dose limiting toxicities (DLTs). **Methods:** Pts enrolled on phase 1 clinical trials at Princess Margaret were surveyed electronically on tablet using the full library of items for PRO-CTCAE. The PRO-CTCAE was administered at baseline (prior to therapy), mid-cycle 1, and mid-cycle 2. AEs on study were recorded by physicians using the CTCAE. The electronic medical records were analyzed for an association between reported sy-AEs and PRO score. Summary statistics were used to describe patient and disease characteristics, as well as the outcomes. Spearman's method was used to correlate PRO severity and interference responses. Logistic regression was used to assess which factors were associated with CTCAE G 3-4 vs G 2 AEs. **Results:** We analyzed 158 pts: median age 60yrs, 77 (49%) were male; all were ECOG $\leq$1 and 22, 55 and 81 pts completed 1, 2 and 3 surveys, respectively. Clinician reported G2, 3 and 4 sy-AEs occurred in 81, 47 and 3 pts, respectively and all of these were related to a PRO item except 5% (4/81), 9% (4/47) and 33% (1/3), respectively because either the AE occurred after 3rd time point or patient not able to complete the PRO (encephalitis). Sy-AEs causing dose interruptions, reductions, DLTs and discontinuations occurred in 45 (28%), 12 (7.5%), 5 (3%) and 12 (7.5%) pts, respectively; with a corresponding PRO item in 40 (89%), 12 (100%), 4 (80%) and 11(92%) pts, respectively. For patients who had CTCAE G2, G3/4 AEs, interruptions and discontinuations, their severity and inference levels were positively correlated (coefficient 0.49, $p < 0.001$; 0.45, $p < 0.001$ 0.59, $p < 0.001$, 0.86, $p < 0.001$). Dose interruptions ($p = 0.0027$) and reductions ($p = 0.0061$) were significantly associated with G3-4 compared to G2 AEs. **Conclusions:** This is the first time an association between PRO-CTCAE severity and interference; and CTCAE G2, 3, 4 AEs, dose interruptions and discontinuations has been demonstrated. Additional modelling and more patient data are being analyzed to explore the relationship. Research Sponsor: None.

2015 Poster Discussion Session; Displayed in Poster Session (Board #7), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Cancer diagnoses and survival rise as 65-year-olds become Medicare eligible.

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Background: A "Medicare effect" has been described to account for increased health care utilization occurring at the age of 65, when individuals become eligible for government-sponsored health care. The existence of such an effect in cancer care, where it would be most likely to reduce mortality, has been unclear. **Methods:** Patients aged 61-69 diagnosed with lung, breast, colon, or prostate cancer from 2004-2016 were identified using the Surveillance, Epidemiology, and End Results database and dichotomized based on eligibility for Medicare (age 61-64 vs 65-69). Using age-over-age percent change calculations, trends in cancer diagnosis, AJCC staging, and survival were characterized. **Results:** 134,991 patients were identified with lung cancer; 175,558 with breast; 62,721 with colon; and 238,823 with prostate. The age-over-age growth in the number of cancer diagnoses was highest at age 65 when compared to all other ages within the decade, for all four cancers (Table: $p<0.01$, $p<0.001$, $p<0.01$, $p<0.001$ respectively). Comparing age 65 diagnoses to the 61-64 year old cohort, the greatest difference for all four cancers was seen in stage I (lung $p<0.001$; breast $p<0.002$; colon $p<0.001$; prostate $p<0.02$). The older (65-69), Medicare-eligible cohort had higher cancer specific 5-year survival than the 61-64 aged cohort for lung (22.0% vs 21.0%, $p<0.01$) and colon cancer (66.2% vs 63.2%, $p<0.01$). **Conclusions:** The 65 age threshold for Medicare eligibility is associated with more cancer diagnoses, particularly in stage I, resulting in improved cancer-specific survival for some cancers. Near-elderly individuals may be delaying care until the age of 65. A Medicare-for-all system would thus be likely to reduce cancer mortality. Research Sponsor: None.

Age-over-age percent change in number of cancer diagnoses.

		61	62	63	64	65	66	67	68	69
Lung Cancer	Incidence	13,000	13,438	13,869	14,433	15,835	15,728	16,059	16,408	16,221
	Δ	N/A	3.4%	3.2%	4.1%	**9.7%***	-0.7%	2.1%	2.2%	-1.1%
Breast Cancer	Incidence	20,996	20,832	20,464	19,469	21,312	19,624	18,538	17,620	16,739
	Δ	N/A	-0.8%	-1.8%	-4.9%	**9.5%***	-7.9%	-5.5%	-5.0%	-5.0%
Colon Cancer	Incidence	6,526	6,604	6,749	6,861	7,893	7,154	7,144	7,068	6,732
	Δ	N/A	1.2%	2.2%	1.7%	**15.0%***	-9.4%	-0.1%	-1.1%	-4.8%
Prostate Cancer	Incidence	23,772	25,112	26,019	25,888	30,183	28,392	27,794	26,667	24,996
	Δ	N/A	5.6%	3.6%	-0.5%	**16.6%***	-5.9%	-2.1%	-4.1%	-6.3%

Δ denotes age-over-age (AoA) percent change – comparing incidence for a specific age with the previous age year
*P-values of T-tests comparing AoA percent change at age 65 vs all other ages: lung: < 0.01, breast: < 0.001, colon: < 0.01, prostate: < 0.001

2016 Poster Discussion Session; Displayed in Poster Session (Board #8), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Association between a national insurer's pay-for-performance program for oncology and changes in prescribing of evidence-based cancer drugs and spending.

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Background: Efforts to standardize quality and control cost growth for cancer care have focused heavily on promoting evidence-based cancer drug prescribing. We evaluated the association between a national commercial insurer's ongoing pay-for-performance (P4P) program for oncology and changes in prescribing of evidence-based cancer drugs and spending. **Methods:** Retrospective difference-in-differences quasi-experimental study utilizing administrative claims data from the insurer's commercial health plans in 14 states covering 6.7% of US adults. We included patients 18 years of age or older with breast, colon, or lung cancer who were prescribed cancer drug regimens by 1,867 participating oncology physicians between 2013 and 2017. We leveraged the geographically staggered, time-varying rollout of the P4P program to simulate a stepped-wedge study design. Specifically, we estimated a patient-level model clustered by physician and used physician fixed-effects to examine pre- to post-intervention changes in evidence-based prescribing and spending for patients of participating physicians eligible earlier versus later in the period of P4P program rollout. We evaluated four categories of spending over a 6-month episode period: cancer drug spending; other (non-cancer drug) health care spending; total episode spending; and patient out-of-pocket spending. **Results:** The P4P program was associated with an increase in evidence-based regimen prescribing from 57.1% of patients in the pre-intervention periods to 62.2% in the post-intervention periods for a difference of +5.1 percentage points (pp) (95% CI 3.0 pp to 7.2 pp, $P < 0.001$). The P4P program was also associated with a differential $3,235 (95% CI $1,004 to $5,466, $P = 0.005$) increase in cancer drug spending, a differential $253 (95% CI $101 to $406, $P = 0.001$) increase in patient out-of-pocket spending, but no significant changes in other health care spending or total health care spending over the 6-month episode period. **Conclusions:** A national insurer's oncology P4P program was associated with a 5.1 percentage point increase in prescribing of evidence-based cancer drug regimens. Our findings suggest that P4P programs may be effective in increasing evidence-based cancer drug prescribing at national scale -- enhancing cancer care quality. However, they may also increase out-of-pocket expenses and may not lead to savings in total health care spending during the 6-month episode. Research Sponsor: None.

2017 Poster Discussion Session; Displayed in Poster Session (Board #9), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Out-of-pocket cost of screening with breast MRI for women at high risk for breast cancer.

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Background: The prevention provision of Affordable Care Act (ACA) mandates private insurance to waive cost sharing for preventive services with grade A or B recommendations from the US Preventive Services Task Force. Although several professional societies have recommended augmenting screening mammography with MRI for women at high risk for breast cancer, the ACA prevention provision does not apply to screening MRI. This study examined the proportion of high-risk women having zero cost sharing associated with breast MRI for screening purposes and estimated out of pocket (OOP) costs as well as sources of variations. **Methods:** We identified women who underwent MRI and mammography for breast cancer screening from Marketscan database, 2009-2017. We quantified OOP costs as the sum of copayment, coinsurance, and deductible and defined zero cost sharing as having no OOP cost. We calculated the proportion of zero cost sharing for mammography and that for MRI and compared the time trend of each before and after ACA (enacted in 2010). We used multivariable logistic regression to examine factors associated with zero cost sharing for MRI use. We estimated OOP costs of MRI and examined cost variations by geographic regions or whether a woman had high deductible plans. **Results:** 25,232 women were included in the analysis. For screening mammography, the rate of zero cost sharing increased from 81% in 2009 to 91% in 2011 (post ACA) then 97% in 2017. For MRI, the rate was 41%, 37%, and 25%, respectively. The odds ratio (OR) of zero cost sharing for MRI screening was significantly lower for women with high deductible plans (OR = 0.65, 95% CI: 0.59-0.72) and for those resided in South (vs. Northeast) region (OR = 0.50, 95% CI: 0.46-0.53), after controlling for age, MSA, family breast cancer history, and year. OOP costs of MRI varied by region and insurance plan (Table); the mean OOP cost for women with high deductible plan were more than twice the mean cost for those in other plan types. **Conclusions:** With the financial protection under the ACA prevention provision applying to only screening mammography, many women at high risk for breast cancer are subject to high OOP costs for MRI screening. Those enrolled in high deductible plans and resided in the South are especially vulnerable financially. Research Sponsor: U.S. National Institutes of Health.

OOP costs (USD) for screening MRI, by insurance plan and region.

Subgroup	Category	No. of Cases	Mean	STD	P25	Median	P75
Total		25232	271	449	0	88	359
High Deductible	No	22602	240	403	0	76	323
	Yes	2630	537	682	3	246	843
Region	Northeast	7159	189	411	0	20	172
	Midwest	5183	295	459	0	123	393
	South	7994	331	486	0	162	462
	West	4896	265	412	0	113	362

2018 Poster Discussion Session; Displayed in Poster Session (Board #10), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Post-hoc power of clinical trials supporting anticancer drug approval by FDA.

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Background: Regulatory approval of drugs is based typically on randomized control trials (RCTs) observing statistically significant superiority of an experimental agent over a prior standard. Statistical significance can result from large effect size and/or over-sampling (as a result of large sample size or long follow-up). Here we explore the source(s) of statistically significant results in trials supporting anti-cancer drug approval by the FDA. **Methods:** We searched Drugs@FDA to identify anti-cancer drug approvals for solid tumors (excluding lymphoma) from 2015-2019. We retrieved corresponding manuscripts and associated appendices and extracted data on study characteristics, statistical plan, primary outcomes and accrual and follow-up times. Post-hoc power was calculated based on observed results and was compared to expected effect size and power in the statistical plan. We explored associations with higher than expected power resulting from over-sampling using binary logistic regression. **Results:** We identified 75 unique drug-approvals reporting 94 endpoints. The most common tumour types were lung, breast, melanoma, and renal cell carcinoma. The most common endpoints were progression free survival and overall survival (OS). In 74 endpoints (79%), observed power was greater than expected power. The magnitude of higher than expected power ranged from 0.1 to $>$ 20%. Of these, 59 (80%) had an effect size greater than predicted in the statistical plan. In 44/74 over-powered endpoints (60%), post-trial power was 100%. When post-hoc power was calculated based on expected effect size rather than observed effect size, 50 endpoints (85%) remained over-powered. Higher than expected power resulting from over-sampling was associated with OS compared to other endpoints (OR 3.03), with targeted agents compared to immunotherapy (OR 1.63) and inversely associated with year of approval (OR 0.57). **Conclusions:** Most cancer drug approvals result from statistically significant studies which are over-powered due to greater than anticipated effect size. Approximately 1 in 5 studies are over-powered likely due to over-sampling. In this setting, benefit observed in RCTs may not translate to the real-world setting. Research Sponsor: None.

2019 Poster Discussion Session; Displayed in Poster Session (Board #11), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Methodology, results, and publication of oncology clinical trials: Insights from all the world's randomized controlled trials (RCTs) 2014-2017.

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Background: Clinical cancer research is now a global effort. Most published overviews of oncology trials are restricted to a specific disease site or cohort of high-profile journals. Here we describe authorship, trial characteristics, design, and results of all oncology RCTs published globally during 2014-2017. **Methods:** A structured literature search was designed using PUBMED to identify all RCTs evaluating anti-cancer therapies published during 2014-2017. Data were captured regarding authorship, participants, study characteristics, design, and results. Among superiority RCTs that met the primary endpoint (i.e. statistically "positive"), we calculated the ESMO-MCBS to identify trials with substantial clinical benefit (MCBS scores 4/5 or A/B). Outcomes were compared with Chi Square or Fisher's Exact tests. **Results:** The study cohort included 694 RCTs. The most common cancers evaluated were breast (17%, 121/694), lung (15%, 104/694) and colorectal (8%, 58/694). Treatment intent was curative, adjuvant/neoadjuvant, and palliative in 10% (68/694), 25% (176/694), and 65% (448/694) of trials respectively. Median sample size was 443 (IQR 246-718). Seventy percent (488/694) of RCTs were supported by industry; 87% (601/694) of experimental arms tested systemic therapy. Ninety-two percent (636/694) of RCTs were led by investigators in 28 high-income countries; the most common countries leading these trials were US (27%, 174/636), France (10%, 64/636), Germany (10%, 62/636), Japan (9%, 59/636), and UK (9%, 57/636). The most common primary endpoints were PFS (32%, 220/694), OS (31%, 215/694), and DFS (11%, 79/694); Forty-six percent of all trials (318/694) met their primary endpoint. Among superiority trials with "positive" results, 33% met ESMO-MCBS threshold for substantial clinical benefit. The median impact factor (IF) of journals which published the overall study cohort of trials was 21 (IQR 7-27); trials meeting their primary endpoint were published in higher profile journals (median IF 25 vs 18, $p < 0.001$). **Conclusions:** At the global level, oncology clinical trials are dominated by high-income countries and study diseases which do not necessarily reflect the global burden of cancer. The vast majority of trials are funded by industry and only one third of "positive" trials meet ESMO-MCBS threshold for substantial clinical benefit. Research Sponsor: None.

2020 Poster Discussion Session; Displayed in Poster Session (Board #12), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Absence of optimism bias in industry-sponsored cancer trials.

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Background: Randomized controlled trials (RCTs) in oncology power their studies to detect expected effect sizes. Prior studies have shown that there is optimism bias, the *a priori* overestimation of treatment effect size among cooperative-group-supported RCTs. However, it is unknown whether such bias is present among industry-supported trials. **Methods:** All published phase 3 clinical oncology RCTs were identified through ClinicalTrials.gov. Only superiority-design RCTs assessing a therapeutic intervention to improve disease-related outcomes were included. We compared the ratio of observed to expected hazard ratio (OEHRR) between trial subgroups using the Mann-Whitney U-test; comparisons of median OEHRR to a hypothetical median of 1 was performed using the Wilcoxon Signed Rank test. **Results:** We identified 140 phase 3 trials with available hazard ratio (HR) data. Of these, 123 trials (88%) were industry-sponsored, and 38 trials (27%) were cooperative-group-supported. For all trials, the median OEHRR was 1.099 (IQR = 0.855-1.291), demonstrating evidence of optimism bias when compared to a hypothetical median OEHRR of 1 ($p = 0.018$). In the subgroup analysis, compared to non-industry-sponsored trials (median OEHRR 1.253, IQR 1.061-1.334), industry-supported trials (median OEHRR 1.061, IQR 0.829-1.274) had a significantly lower OEHRR ($p = 0.022$) and did not demonstrate optimism bias ($p = 0.15$). Similarly non-cooperative group trials (median OEHRR 1.208, IQR 1.019-1.317) had a significantly lower OEHRR ($p = 0.005$) and did not demonstrate optimism bias ($p = 0.562$) compared to cooperative group trials (median OEHRR 1.208, IQR 1.019-1.317), which did demonstrate optimism bias ($p < 0.001$). **Conclusions:** Cooperative group trials, which represent a minority of trials, suffer from optimism bias. In contrast, industry-funded trials, which account for the majority of trials, do not demonstrate evidence of optimism bias, and have very close concordance between observed and expected effect size. These findings suggest that the powering and design of industry-funded trials better models the outcomes eventually observed. The reasons for this are likely complex and multifactorial, but may include financial constraint considerations, as industry-supported trials may not be as financially-limited as cooperative group studies. Therefore, industry-supported studies may be able to power trials with sufficient participants to reflect the estimated effect size. Research Sponsor: None.

2021 **Poster Session (Board #13), Fri, 8:00 AM-11:00 AM**

Distress screening through PROMIS at an academic cancer center and network site: Implementation of a hybrid model.

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Background: The NCCN guidelines recommend routine distress screening of patients with cancer, but the implementation of such programs is inconsistent. Up to one in three such patients experience distress, however fewer than half of them are identified and referred for supportive services. **Methods:** We implemented a hybrid (electronic and paper) distress screening tool, using a modified version of the PROMIS-Global Health questionnaire. Patients received either an electronic or in-clinic paper questionnaire to assess overall health and distress at the Stanford Cancer Center and its associated integrated network site. Iterative changes were made including integration with the electronic health record (EHR) to trigger questionnaires for appointments every 60 days. A consensus "positive screen" threshold was defined, with data collected on responses and subsequent referrals placed to a supportive care services platform. **Results:** Between June 2015 and December 2017, 53,954 unique questionnaires representing 12,744 distinct patients were collected, with an average completion rate of 58%. Approximately 30% of the questionnaires were completed prior to the visit electronically through a patient portal. The number of patients meeting the positive screen threshold remained ~ 40% throughout this period. Following assessment by the clinical team, there were 3763 referrals to cancer supportive services. Among the six most common referral categories, those with a positive screen were more likely to have a referral placed (OR 6.4, 95% CI 5.8-6.9 p- $<$ 0.0001), with a sensitivity of 80% and a specificity of 61%. However, 89% of responses with a positive screen did not have a referral to supportive care services. **Conclusions:** The hybrid electronic and paper use of a commonly available patient reported outcome tool, as a high throughput distress screening tool, is feasible at a multi-site academic cancer center. Our positive screen rate for referrals was sensitive and consistent, but with a low positive predictive value. This screening also resulted in variable clinical response and overall increased clinical burden. Future directions for our group have included refining the threshold for a positive screen and implementation of a real-time response system, especially to address acute concerns. Research Sponsor: None.

2022 Poster Session (Board #14), Fri, 8:00 AM-11:00 AM

Association of hospital type and patient volume growth with timely cancer treatment.

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Background: Studies have suggested superior outcomes for patients with cancer treated at National Cancer Institute (NCI) and academic hospitals, leading some to advocate for complex cancer care to be delivered at regional referral centers. However, growing demand at such centers may exceed their capacity to provide timely treatment, which could be detrimental to patient outcomes. We evaluated the relationship between hospital type, the average annual growth rate in patient volume (PV), and time to treatment initiation (TTI) trends. **Methods:** We used the National Cancer Database to identify patients undergoing initial treatment for a new diagnosis of cancer (breast, lung, prostate, colorectal, melanoma, bladder, non-Hodgkin lymphoma, renal, uterine or pancreatic) in 2007-2016. The exposure was hospital type (NCI, academic, community or integrated network). The primary outcome was TTI over time. We estimated both the average annual growth rate for PV and adjusted TTI trends by hospital type using linear mixed effects models, including a hospital type-by-time interaction and, when modeling TTI, a patient volume-by-time interaction. **Results:** We identified 4,218,577 patients treated at 1351 hospitals (49% at 897 community, 23% at 177 academic, 14% at 50 NCI and 14% at 227 integrated network hospitals). Over the study period, PV grew by 40% at NCI and 25% at academic hospitals, compared to 8% at community hospitals (p-value for trend both < 0.001). Meanwhile, mean TTI increased by 3.2 days at community, remained stable at academic (+0.3 days) and decreased by 4.3 days at NCI hospitals (p-value for trend both < 0.001 vs community). A higher annual PV growth rate was associated with a statistically but not clinically significant TTI increase (0.05 days for each 100 patient/year increase in the growth rate, $p = 0.001$). **Conclusions:** Patients with newly diagnosed cancer are increasingly receiving treatment at NCI and academic hospitals. While TTI at NCI and academic hospitals is longer than in the community, PV growth has been possible without delaying cancer treatment. Further study is needed to determine whether continued growth at this rate is sustainable. Research Sponsor: None.

	Community (ref)	Academic	NCI
Patient Volume			
Mean no. patients treated (95% CI), 2007	232 (217, 248)	505 (470, 540)*	1027 (960, 1093)*
Average annual growth rate, 2007-16 - patients/year (95% CI)	2 (0.4, 4)	14 (10, 18)*	45 (38, 52)*
Time to Treatment			
Mean no. days (95% CI), 2007	34 (34, 35)*	43 (42, 45)*	52 (49, 54)*
Average annual growth rate, 2007-16 - days/year (95% CI)	0.4 (0.3, 0.4)	0.04 (-0.1, 0.2)*	-0.5 (-0.8, -0.2)*

*$p < 0.001$ compared to ref

2023 **Poster Session (Board #15), Fri, 8:00 AM-11:00 AM**

Are ED visits in cancer patients preventable? Care patterns before an ED visit.

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Background: Medicare's Oncology Care Model alternative payment program participation requires 24-hr patient access to clinician phone advice. Many participating practices have established oncology urgent care clinics to reduce the frequent ED visits in the early phase after cancer diagnosis. However, little is known about patients' use of pre-ED visit clinical advice via phone. We combined EHR data on phone/secure messaging encounters, outpatient visits, and regional ED visits, to assess how often patients visit the ED without prior clinical advice, and to compare ED visit severity between those with and without preceding clinical advice. **Methods:** We linked adults ages 18+ from Parkland Health and Hospital System (PHHS), the Dallas County public safety net system, and UT Southwestern (UTSW) NACR Gold-certified cancer registry (2012-2018), to their respective EHR, and identifiably linked patients to a regional health information exchange of ED and hospital encounters. Exchange data included hospital name, ED disposition, diagnoses, and ED Severity Of Illness. We tallied ED visits within 6 months (180 days) after cancer diagnosis and EHR clinical contacts for 24 hours prior to ED visit (telephone/secure messaging, outpatient visits). After descriptive statistics, we used mixed-effects multivariate logistic regression clustering at patient level to model ED disposition after a pre-ED clinical contact. **Results:** We matched 8,289 Parkland (54% female, 78% Medicaid/charity assistance) and 10,817 UTSW patients (50% female, 12% Medicaid), who generated 21,009 and 22,696 ED visits, respectively. Two-thirds of all ED visits occurred without preceding clinical contact (70.2% PHHS, 66.7% UTSW); large shares of ED visits were to 67 other regional hospitals (22.2% PHHS, 69.5% UTSW). Telephone encounters and outpatient visits to any specialty were the most common contact before ED visit (UTSW: 28.2 and 12.4%; PHHS: 8.7 and 16.1%), but while nearly all UTSW clinic visits were to oncology, only 30% of PHHS clinic visits were to oncology. Though ED visit severity was slightly higher for ED visits without preceding clinical contact (46% vs. 43% $\geq$Major severity, $p < 0.01$), patients were discharged home more often if clinical contact preceded ED visits (aOR of hospitalization 0.82, 95% CI: 0.74 – 0.90). **Conclusions:** Two-thirds of ED visits occurred without prior clinical contact, and though these no-contact ED visits had higher severity of illness, they were more often discharged home from the ED. Future work should identify patient-oriented options to optimize the use of clinical care and the ED. Research Sponsor: Texas Health Resources Clinical Scholars Program, U.S. National Institutes of Health.

2024 Poster Session (Board #16), Fri, 8:00 AM-11:00 AM

The impact of early integrated supportive care on length of stay at an NCI-designated cancer center.

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Background: With movement towards value-based care, institutions seek ways to reduce costs by decreasing inpatient stays. A multidisciplinary approach to supportive care, especially when provided early, is one way to realize value-based care. We assess the impact of pre-admission versus post-admission involvement of an Integrated Supportive Care Model (ICSM) on inpatient length of stay (LOS) at a NCI-designated cancer center. **Methods:** Data was collected from 2014 to 2016 at City of Hope. The Integrated Supportive Care Model at City of Hope includes: palliative care, psychiatry, psychology, interventional pain, social work, child-life, distress screening, and couples program. "Pre-admission" was defined as seeing at least one service prior to hospital admission; "Post-admission" defined as seeing at least one service during admission. "Short LOS" for hematology patients was categorized as $\leq$ 14 days and for oncology patients as $\leq$ 3 days. Continuous LOS between patients receiving an ISCM intervention pre- and post-admission was compared using Kruskal-Wallis test. Univariate and multivariable logistic regression was done to examine association between involvement of ISCM pre- and post-admission and categorical LOS. P-values < 0.05 were considered statistically significant. **Results:** 1,627 (809 with hematologic malignancy, 818 with oncologic malignancy) patients with only one hospitalization during the study time were included. For hematology patients, involvement with the ISCM pre-admission was associated with shorter LOS ($\leq$ 14 days) compared with involvement post-admission (29.3 vs 11.1%, multivariable OR = 4.08, $P < 0.001$). Median LOS for hematology patients who participated in the ISCM pre-admission was shorter than those who received ISCM services post-admission (21 vs. 22 days, $p = 0.049$). Similarly, for oncology patients, ISCM involvement pre-admission was associated with shorter LOS ($\leq$ 3 days) compared to involvement post-admission (91.4% vs 8.6%, multivariable OR = 3.74, $P < 0.001$). Median LOS for oncology patients who received an ISCM intervention pre-admission was shorter than those who received an ISCM intervention post-admission (2 vs. 6 days, $p < 0.001$). **Conclusions:** In hematologic and oncologic malignancies, use of an ISCM prior to patient's first hospitalization is associated with significantly shorter LOS compared with those who received ISCM services during the hospital stay. This suggests efforts should be made to include an ISCM early in the trajectory of illness, prior to first hospitalization. Research Sponsor: City of Hope.

2025 Poster Session (Board #17), Fri, 8:00 AM-11:00 AM

Integrating breast cancer screening into a cervical cancer screening program in three rural districts in Rwanda.

Lydia E. Pace, Jean Marie Vianney Dusengimana, Jean Paul Balinda, Origene Benewe, Vestine Rugema, Cyprien Shyirambere, Jean Bosco Bigirimana, Chuan-Chin Huang, Tharcisse Mpunga, Nancy Lynn Keating, Lawrence N. Shulman, Francois Uwinkindi; Brigham And Women's Hospital, Boston, MA; Partners In Health-Rwanda/Inshuti Mu Buzima, Butaro, Rwanda; Rwanda Biomedical Centre, Kigali, Rwanda; Partners In Health/Inshuti Mu Buzima, Kigali, Rwanda; Ministry of Health/ Butaro Hospital, Butaro, Rwanda; Partners in Health/Inshuti Mu Buzima, Butaro, Rwanda; Partners In Health/Inshuti Mu Buzima, Butaro, Rwanda; Harvard Medical School, Boston, MA; Ministry of Health, Butaro, Rwanda; Abramson Cancer Center, University of Pennsylvania, Philadelphia, PA

Background: In low-income countries where mammography is not widely available, optimal strategies to facilitate earlier breast cancer detection are not known. We previously conducted a cluster randomized clinical trial of clinician trainings in Burera District in rural Rwanda to facilitate earlier diagnosis among symptomatic women; 1.3% of women evaluated at intervention health centers (HCs) were diagnosed with cancer. Early stage breast cancer incidence was higher in intervention areas. Subsequently, Rwanda Biomedical Centre, Rwanda's national health implementation agency, adapted the program in 3 other districts, offering screening clinical breast exams (CBE) to all women aged 30-50 years receiving cervical cancer screening and any other woman requesting CBE. A navigator facilitated patient tracking. We sought to examine patient volume, service provision and cancer detection rate in the adapted program. **Methods:** We abstracted data from weekly HC reports, facility registries, and the referral hospital's electronic medical record to determine numbers of patients seen, referrals made, biopsies, and cancer diagnoses from July 2018-December 2019. **Results:** CBE was performed at 17,239 visits in Rwamagana, Rubavu and Kirehe Districts (total population 1.34 million) over 18, 17 and 7 months of program implementation respectively. At 722 visits (4.2%), CBE was abnormal. 571 patients were referred to district hospitals (DH); their average age was 35 years. Of those referred, 388 (68.0%) were seen at DH; 32% were not. Of those seen, 142 (36.6%) were referred to a referral facility; 121 of those referred (85.2%) actually went to the referral facility. Eighty-eight were recommended to have biopsies, 83 (94.3%) had biopsies, and 29 (34.9% of those biopsied; 0.17% of HC visits) were diagnosed with breast cancer. **Conclusions:** Integrating CBE screening into organized cervical cancer screening in rural Rwandan HCs led to a large number of patients receiving CBE. As expected, patients were young and the cancer detection rate was much lower than in a trial focused on symptomatic women. Even with navigation efforts, loss-to-follow-up was high. Analyses of stage, outcomes, patient and provider experience and cost are planned to characterize CBE screening's benefits and harms in Rwanda. However, these findings suggest building health system capacity to facilitate referrals and retain patients in care are needed prior to further screening scaleup. In the interim, early diagnosis programs targeting symptomatic women may be more efficient and feasible. Research Sponsor: Breast Cancer Research Foundation.

2027 **Poster Session (Board #19), Fri, 8:00 AM-11:00 AM**

Pilot program of remote monitoring for high-risk patients on antineoplastic treatment.

Robert Michael Daly, Gilad Kuperman, Alice Zervoudakis, Alice Ro, Ankita Roy, Abigail Baldwin, Rori Salvaggio, Jessie C. Holland, Kimberly Chow, Tara Lauria, Margarita Rozenshteyn, Melissa Zablocki, Yeneat Ophelia Chiu, Nicholas Silva, Claire Perry, Stefania Sokolowski, Isaac Wagner, Brett A Simon, Diane Lauren Reidy, Wendy Perchick; Memorial Sloan Kettering Cancer Center, New York, NY; Winthrop Oncology Hematology Associates, Mineola, NY

Background: Early detection and management of symptoms in patients with cancer improves outcomes, however, the optimal approach to symptom monitoring and management is unknown. This pilot program uses a mobile health intervention to capture and make accessible symptom data for high-risk patients to mitigate symptom escalation. **Methods:** Patients initiating antineoplastic treatment at a Memorial Sloan Kettering regional location were eligible. A dedicated staff of RNs and nurse practitioners managed the patients remotely. The technology supporting the program included: 1) a predictive model that identified patients at high risk for a potentially preventable acute care visit; 2) a patient portal enabling daily ecological momentary assessments (EMA); 3) alerts for concerning symptoms; 4) an application that allowed staff to review and trend symptom data; and 5) a secure messaging platform to support communications and televisits between staff and patients. Feasibility and acceptability were evaluated through enrollment (goal $\geq$25% of new treatment starts) and response rates (completion of $>$ 50% of daily symptom assessments); symptom alerts; perceived value based on qualitative interviews with patients and providers; and acute care usage. **Results:** Between October 15, 2018 and July 10, 2019, the pilot enrolled 100 high-risk patients with solid tumors and lymphoma initiating antineoplastic treatment (median age: 66 years, 45% female). This represented 29% of patients starting antineoplastics. Over six months of follow-up, the response rate to the daily assessments was 56% and 93% of patients generated a severe symptom alert (Table). Both patients and providers perceived value in the program and 5,010 symptom-related secure messages were shared between staff and enrolled patients during the follow-up period. There was a preliminary signal in acute care usage with a 17% decrease in ED visits compared to a cohort of high-risk unenrolled patients. **Conclusions:** This pilot program of intensive monitoring of high-risk patients is feasible and holds significant potential to improve patient care and decrease hospital resources. Future work should focus on the optimal cadence of EMAs, the workforce to support remote symptom management, and how best to return symptom data to patients and clinical teams. Research Sponsor: None.

Prevalence of symptoms reported at moderate and severe levels on one or more days % (n = 100).

Symptom	Moderate	Severe
Pain	73%	74%
Anxiety	73%	21%
Depression	70%	14%
Functional status	66%	53%
Diarrhea	62%	12%
Decreased Oral Intake	61%	18%
Nausea	58%	25%
Dyspnea	38%	22%
Emesis	24%	9%

2028 **Poster Session (Board #20), Fri, 8:00 AM-11:00 AM**

Interest in cessation treatment and survival among smokers in a community-based multidisciplinary thoracic oncology program.

Meghan Meadows, Kenneth Daniel Ward, Nicholas Ryan Faris, Matthew Smeltzer, Carrie Fehnel, Folabi Ariganjoye, Jessica Smith, Laura McHugh, Angela Fulford, Raymond U. Osarogiagbon; University of Memphis, School of Public Health, Memphis, TN; Baptist Cancer Center, Memphis, TN

Background: Tobacco cessation is essential to high quality oncology care. Many patients smoke when diagnosed and continue to smoke during treatment, which adversely affects treatment response and survival. Although most patients are motivated to quit, few receive effective cessation therapy. The multidisciplinary clinic (MDC), where patients, their caregivers, and key specialists coordinate care, is an ideal setting to integrate a cessation program. To assess the need for cessation services within a MDC setting, we surveyed incoming patients about their smoking status, interest in quitting, and willingness to participate in a clinic-based cessation program. **Methods:** The study was conducted in the Multidisciplinary Thoracic Oncology Program at Baptist Cancer Center, Memphis TN. We evaluated sociodemographic/clinical characteristics, smoking status, and tobacco dependence of consecutive new patients diagnosed with lung cancer from 2014-2019, who completed a social history questionnaire. Current smokers reported their interest in quitting and their willingness to participate in a cessation program. Chi square tests and logistic regression models were used to compare characteristics of those who would participate vs. those who would not/were unsure. Kaplan-Meier curves and multivariable Cox regression were used to evaluate the association between willingness to participate in a cessation program and overall survival, adjusted for age, sex, race, and total pack-years of smoking. **Results:** Of 641 patients, the average age was 69 years (range: 32-95), 47% were men, 64% white/34% black, and 17% college graduates; 90% had ever smoked, 34% currently smoked, and 24% quit smoking within the past year. Among current smokers, 60% were very interested in quitting and 37% would participate in a clinic-based cessation program. Willingness to participate was associated with greater interest in quitting ($p = 0.0010$) and greater overall survival (log rank $p = 0.01$;HR: 0.48, 95% CI: 0.24-0.95) but was not associated with any sociodemographic, clinical, or smoking-related characteristics. **Conclusions:** Over half (58%) of patients in a community-based MDC program were current smokers/recent quitters. Willingness to participate in a cessation program was associated with improved survival, suggesting patients with favorable prognoses are especially interested in receiving cessation support. There is considerable need for cessation services and relapse-prevention support within a coordinated, MDC lung cancer care setting. Research Sponsor: Patient-Centered Outcomes Research Institute (PCORI).

2029 **Poster Session (Board #21), Fri, 8:00 AM-11:00 AM**

Nickel and dimed: Parking fees at NCI-designated cancer centers.

Anna Lee, Kanan Shah, John Byun, Fumiko Chino; Memorial Sloan Kettering Cancer Center, New York, NY; NYU Grossman School of Medicine, New York, NY; Massachusetts General Hospital, Boston, MA

Background: Nonmedical costs from cancer treatment can be a significant out-of-pocket expense. As treatment may span over months, parking costs can become a significant burden on patients and caregivers. This cross-sectional study aims to report parking fees at National Cancer Institute (NCI)-designated cancer centers and to project parking costs for the treatment duration of certain cancers. **Methods:** Parking fees from NCI treatment centers were obtained via online search or phone call in Fall of 2019. City cost of living, median city household income, and discount availability were documented. Pearson correlation was used between parking costs and city variables. Parking costs were estimated for treatment of node positive breast cancer (12 daily rates plus 20 1-hr rates), definitive head and neck cancer (35 1-hr rates) and acute myeloid leukemia (AML) (42 daily rates). RStudio Version 1.2.5033 was used for analyses. **Results:** Parking costs were obtained for 100% of the 63 NCI centers included. Median city cost of living relative to New York City was 75.0 (out of 100); median city household income was $55,295 (range $28,974-$120,573). Twenty-five (40%) of NCI centers did not have detailed parking cost information online. Average parking costs were $3.55/hr (median $2, range 0-$15) and $7.79/day (median $5, range 0-$40). Twenty centers (32%) offered completely free parking for patients. Free parking was available at 43 (68%) centers for radiation appointments and 34 (54%) centers for chemotherapy appointments. Averaged estimated parking costs including discounts for a course of treatment for breast cancer was $122.03 (range 0-$800); head and neck cancer, $85.56 (range 0-$665); and AML hospitalization, $327.33 (range 0-$1470). City cost of living was positively correlated with daily parking costs ($R = 0.7$, $p < 0.01$) and negatively correlated with both free daily parking ($R = -0.33$, $p = 0.02$) and free parking during radiation ($R = -0.34$, $p = 0.02$) or chemotherapy ($R = -0.37$, $p < 0.01$). The median city household income was correlated with the daily parking costs ($R = 0.30$ $p = 0.02$) but not with free daily parking ($R = -0.19$, $p = 0.16$), free parking for patients on radiation ($R = -0.23$, $p = 0.09$) or on chemotherapy ($R = -0.21$, $p = 0.14$). **Conclusions:** Patients may face significant nonmedical costs through parking fees, even at centers that reflect the highest standard of care. There was high variability in costs with the potential for patients to pay hundreds of dollars in parking in order to receive their care. Efforts to minimize financial toxicity should focus on this potentially under-reported patient concern. Research Sponsor: None.

2030 **Poster Session (Board #22), Fri, 8:00 AM-11:00 AM**

Implementation of Symptom Care Clinic (SCC) for acute symptoms management at outpatient oncology ambulatory centers.

Han Xiao, Rosanna Fahy, Rori Salvaggio, Maryellen OSullivan, Desiree Sokoli, Cheryl Murray, Jibran Majeed, Jun J. Mao, Jeffrey S. Groeger; Memorial Sloan Kettering Cancer Center, Basking Ridge, NJ; Memorial Sloan Kettering Cancer Center, New York, NY

Background: With improved overall cancer survival, increasing number of cancer patients are undergoing active treatment. This, in return, add burden in acute symptom management related to disease and treatment. This has resulted in increasing unplanned emergency room (ER) visits and negatively impacted patients experience and health cost. We establish Symptom Care Clinic (SCC) embedded in suburban ambulatory oncology centers to reduce unplanned ER lists and to improve patient experience. **Methods:** Together with all stakeholders, we developed six SCCs at regional ambulatory centers in NY and NJ. Clearly defined work flow and algorithm were developed to ensure appropriate patient referral. On-site radiology and laboratory services are available. The SCCs are staffed with combination of Advanced Practice Provided (APP) and physicians or APP alone supported by on site medical oncologist or remote central Urgent Care Center Attendings. We evaluated clinic volumes, reduction ins unplanned ER visits and patient experience. **Results:** From October 2017 to December 2019, total of 17,542 SCC visits were documented. Total of 17,479 lab and 5,355 radiology tests as well as 3,915 infusions were performed. The top five most common laboratory tests are CBC, blood cultures, CMP, respiratory panel and urine culture. The most common symptoms are fever, nausea/vomiting/dehydration, rash and pain. Among all SCC visits during this period, 83% were discharged home and 17% were transferred to ER or hospitals. During 2019, total 10,736 SCC visits were recored, APP evaluated 73.7% of visits and physicians 16.3% with comaprable recidivism rate, 2.52% and 2.75%, respectively. Conservatively, we estimated that approximately 40% of visits would have been Er visits based on numbers of CBC and other testes performed. Qualitative feedbacks from patients indicated positive experience in convenient access, cohesive care coordination and time saving from traveling to and waiting in ER. **Conclusions:** We successfully implemented an effective acute symptom management system in busy ambulatory oncology centers that is patient centric. Out data showed that SCC reduced unplanned ER visits and that APP/physician model has low recidivism rate. Research Sponsor: None.

2032 **Poster Session (Board #24), Fri, 8:00 AM-11:00 AM**

Impact of an immuno-oncology (IO) education/monitoring program on patient's self-efficacy and adverse event reporting from immune checkpoint inhibitors (ICIs).

Parneet Kaur Cheema, Massey Nematollahi, FeRevelyn Berco, Janet Papadakos, Deepanjali Kaushik, Priscilla Matthews, Marco Iafolla, Kirstin Perdrizet, Margaret Balcewicz, William Raskin, Stephen Reingold, Juhi Husain, Philip Kuruvilla, Henry Jacob Conter; William Osler Health System, University of Toronto, Brampton, ON, Canada; William Osler Health System, Brampton, ON, Canada; Princess Margaret Cancer Centre, Toronto, ON, Canada

Background: ICIs have unique side effects of immune related adverse events (irAEs). For early detection and management of irAEs, at a large community hospital we implemented a standard IO nursing baseline assessment, education and monitoring program. We studied it's impact on a patient's irAE reporting and self-efficacy (confidence to manage symptoms) of ICIs. **Methods:** Prospective study conducted at William Osler Health System, Brampton, Canada from May 2018-December 2019. Patients aged $>$ = 18, English speaking that received an ICI for cancer were included. Patients underwent a standardized baseline nursing assessment and education class. Patients identified at the assessment as high risk (risk of grade 3/4 irAE $>$20%) had weekly nurse proactive calls. Cancer Behaviour Inventory – Brief Version (CBI-B) (Heitzmann et al, 2011) was used to evaluate patient's self-efficacy. **Results:** Eighty patients were enrolled. Median follow up of 4.1 months. Baseline demographics: median age 69, 70% males, 77% Caucasian, 81% ECOG 0/1, 66% had English as their first language and 19% highest education was elementary, 30% high school, 26% trade diploma and 21% post-secondary. Fourty-one percent had limited cancer health literacy (measured by CHLT6 (Dumenci et al, 2014)). ICIs prescribed were 70% monotherapy anti-PD1/PDL1, 13% combination nivolumab/ipilimumab, 17% anti-PD1/PDL1 + chemotherapy/other therapies. Majority had a diagnosis of non-small cell lung cancer (55%), melanoma (19%) and renal cell carcinoma (9%). A statistically significant improvement in the average CBI-B scores were found pre and post baseline assessment/education ($p < 0.001$) and this improvement was maintained over time at follow-up visits (non-significant change in scores from post education results). Fourty-three percent of patient's experienced $>$ 1 irAE. Most were grade 1/2 at time of detection (65%). Method of detection was mainly by patient self-reporting (62%), followed by proactive calls (27%). Only 3 patients had detection of an irAE with an ER visit. Rate of discontinuation of ICIs due to toxicity was 8.8%. **Conclusions:** In this diverse patient population with almost half of patients having limited cancer health literacy, a standardized IO baseline assessment, education and monitoring program resulted in improved patient self-efficacy with most irAEs detected by self-reporting and proactive calls. Our IO program can be a model for other oncology programs. Research Sponsor: None.

2033 **Poster Session (Board #25), Fri, 8:00 AM-11:00 AM**

Evaluating barriers to uptake of comprehensive genomic profiling (CGP) in advanced cancer patients (pts).

Kortnye Maureen Smith, Sophie O Haire, Dong Anh Khuong-Quang, Ben Markman, Hui Kong Gan, Paul G Ekert, Kenneth John O'Byrne, Michael Millward, Benjamin J. Solomon, Ben Tran, Clare L. Scott, Damien Kee, Grant A. McArthur, Andrew Fellowes, Rona Weerasuriya, Elly Lynch, Melissa Martyn, Clara Gaff, Stephen B. Fox, Jayesh Desai; Peter MacCallum Cancer Centre, Melbourne, VIC, Australia; Peter MacCallum Cancer Centre, Melbourne, Australia; Monash Health and Monash University, Melbourne, Australia; Olivia Newton-John Cancer Research Institute, Victoria, NSW, Australia; Royal Children's Hospital, Parkville, VIC, Australia; Princess Alexandra Hospital, Brisbane, Australia; School of Medicine and Pharmacology, Nedlands, WA, Australia; Walter and Eliza Hall Institute of Medical Research, Melbourne, Australia; Melbourne Genomics Health Alliance, Melbourne, VIC, Australia

Background: Despite increasing evidence of benefit supporting CGP in personalizing cancer therapy, its widespread uptake remains limited. Barriers include low patient understanding, unmet patient expectations related to low utility, clinician concerns over cost-effectiveness, perceived value, and discomfort in management of complex genomic results. **Methods:** This prospective cross-institutional demonstration study was designed to evaluate implementation of CGP in the care of adult and paediatric advanced cancer pts, incorporating pt reported outcomes (PROMs), discrete choice experiment (DCE), ongoing process optimization and clinician evaluations. DNA sequencing of FFPE tumor and matched blood was completed with CGP (PMCC Comprehensive Cancer Panel; 391 genes) via central laboratory. A tumor board reported results weekly with emphasis on therapeutic relevance. Oncologists performed consent and results delivery. Pts completed pre-and post-test surveys, including validated and study-specific questions, DCE and if eligible, semi-structured interviews. Qualitative interviews were undertaken with study clinicians and laboratory staff to evaluate processes. **Results:** 86% (315) of 365 enrolled pts had successful CGP; of these 63% (199) had relevant therapeutic, diagnostic or germline results. 50 (16%) had treatment change at 6m, 49 (16%) had germline mutations. 293 (88% of adult pts) completed PROMs. 17 of 19 clinicians/laboratory staff approached consented to an interview. At consent pts cited multifaceted value in testing, showed good understanding of basic concepts, but most (69%) overestimated the likelihood of result-led change. Post-test pts remained consistently satisfied with accessing CGP; valuing research contribution, taking opportunities and information for family. 21% struggled with understanding results but there were low levels of decisional regret following participation (89% had nil/mild regret). Pt-elicited preferences (via DCE) indicated priority for high rates of clinical utility and timeliness. Clinicians sited collaboration and communication as critical to delivery of CGP. **Conclusions:** Pts undergoing CGP are generally satisfied, and derive value on its use beyond potential therapeutic benefit. Our results suggest that to improve test utility and delivery of CGP with value to pts and investing institution, focus must be placed on addressing the additional barriers to its wider implications including efforts to improve process efficiencies, clinician genomic literacy and decision-making support. Research Sponsor: Melbourne Genomic Health Alliance, Other Foundation.

2034 **Poster Session (Board #26), Fri, 8:00 AM-11:00 AM**

Effect of a supportive medicine program for cancer patients on patient connectivity to care and health care utilization.

Brooke Worster, Gregory D. Garber, Rebecca Cammy, Liana Yocavitch, Ayako Shimada, Valerie Pracilio Csik, Andrew E. Chapman, Amy Leader; Sidney Kimmel Cancer Center, Philadelphia, PA; Sidney Kimmel Cancer Center at Jefferson, Philadelphia, PA; Sidney Kimmel Cancer Center, Thomas Jefferson University Hospital, Philadelphia, PA; Sidney Kimmel Medical College of Thomas Jefferson University, Philadelphia, PA; Thomas Jefferson University, Philadelphia, PA

Background: The benefits of supportive medicine (SM) for cancer patients include improved quality of life, increased patient satisfaction, improved symptom management, increased cost savings and improved survival rates. At one NCI-designated cancer center, all patients were screened for distress; those who screened positive or were directly referred by a provider were enrolled into our multi-disciplinary SM program. Here, we document the impact of the supportive medicine program on outcomes of emergency department (ED) visits, hospital readmission, and non-billable touchpoints associated with patient navigation and resource referrals. **Methods:** The program systematically screened for biopsychosocial distress utilizing the National Comprehensive Cancer Center Distress Thermometer (DT) and the Problem Checklist (PC) to identify practical, emotional, spiritual and physical issues. Patients were categorized into three types: screened and enrolled in the SM program, and screened and not enrolled in the SM program, or provider referral into the SM program. Data included patient's age, number of hospital admissions, emergency department visits, and non-billable touchpoints at 90 and 180 days after the distress screening or referral. Descriptive data were analyzed with counts and percentages for categorical variables and summarized with mean and standard deviation for numerical variables. For investigation of the effects of time and patient type on the change in utilization rate, generalized estimation equations for Poisson regression were conducted for each outcome. **Results:** In all, 2,738 patients were included in the analysis. Patients who were referred from a provider tended to be younger ($p < .01$) and more likely to die within 90 days ($p < .001$). At 180 days, ED visits decreased 18% for patients referred to the SM program and 42% for patients screened into the SM program, compared to a 3% decrease in ED visits among those not enrolled in the SM program ($p < .01$). Similarly, hospital admissions decreased 34% for patients referred to and 39% screened into the SM program, compared to a 4% increase for patients not enrolled in the SM program ($p < .01$). Non-billable touchpoints increased among all types of patients. **Conclusions:** An SM program reduces hospital admissions and ED visits, therefore improving outcomes and potentially reducing the cost of care for cancer patients. Future research should link this data to claims data to definitely evaluate the impact of SM programs on cost. Research Sponsor: None.

2037 **Poster Session (Board #29), Fri, 8:00 AM-11:00 AM**

Disparities in the treatment of brain metastases from breast cancer: Insights from the National Cancer Database.

Zena Chahine, Muhammad Salman Faisal, Thejus Thayyil Jayakrishnan, Stephen Abel, Rodney E. Wegner; Allegheny General Hospital, Pittsburgh, PA; Allegheny Health Network, Pittsburgh, PA; Department of Radiation Oncology, Allegheny Health Network Cancer Institute, Bradenton, FL; Division of Radiation Oncology, Allegheny Health Network Cancer Institute, Pittsburgh, PA

Background: Breast cancer is the most common malignancy in women accounting for over 300,000 cases per year. Unfortunately, brain metastases are found in a sub-group of patients with breast cancer even at presentation. Management of brain metastases typically includes radiotherapy with conventional whole brain radiation therapy (WBRT) or more focused stereotactic radiosurgery (SRS). We queried the National Cancer Database (NCDB) to analyze the incidence of brain metastases at diagnosis in breast cancer patients, as well as trends in radiation use/technique. **Methods:** The NCDB was queried for patients who were diagnosed with breast cancer between 2004-2015 and had brain metastasis at presentation (N = 4,491). We excluded patients without brain radiation and inadequate follow up. Odds ratios were calculated to identify factors associated with treatment. Multivariable cox regression was used to determine predictors of survival. **Results:** Using the eligibility criteria above 1,505 patients were identified in the NCDB. The cohort had a median age of 58 years. A small portion were uninsured (7%) population uninsured and 81% of radiation treatments were delivered in metropolitan areas. Two hundred sixty-one (17.3%) patients received SRS while 1,244 (82.7%) received WBRT. Those patients with private insurance, higher income, metro location, and having care delivered at an academic center were more likely to receive SRS. Conversely, the likelihood of receiving WBRT was significantly higher in those with luminal type cancer, African Americans, the uninsured, and those located in urban areas or treated at a community cancer center. On Cox regression, predictors of worse survival were age $>$ 60 with Hazard Ratio (HR) 1.3 (95% CI 1.17-1.49), a comorbidity score $>$ 2 with HR 1.45 (95% CI 1.1-1.9), and extra cranial metastatic disease with HR 1.33 (95% CI 1.15-1.54). **Conclusions:** This analysis of the NCDB demonstrates socioeconomic and demographic disparities in the treatment of patients with brain metastases from breast cancer. There is a continued need to reduce these disparities and improve access to care for at-risk populations affected by this highly prevalent malignancy. Research Sponsor: None.

2039 **Poster Session (Board #31), Fri, 8:00 AM-11:00 AM**

Affordable Care Act Medicaid expansion does not reduce guideline concordant cancer care disparities in vulnerable populations.

Michelle Ju, James-Michael Blackwell, Patricio Polanco, John C. Mansour, Sam C. Wang, Matthew R. Porembka, Herbert Zeh, Adam Charles Yopp; UT Southwestern, Dallas, TX; Department of Surgery, University of Texas Southwestern Medical Center, Dallas, TX

Background: The receipt of timely, guideline concordant cancer amongst racial/ethnic and socioeconomic vulnerable populations remains a significant health policy issue. The Affordable Care Act (ACA) with implementation of Medicaid Expansion sought to reduce cancer disparities by reducing uninsured rates, theoretically improving healthcare access and delivery. We assessed the impact of Medicaid expansion on racial/ethnic disparities in the receipt of timely guideline concordant cancer care. **Methods:** We identified patients between 40-64 years of age with all stages of cancer (lung, colorectal, breast, uterine, and cervical) in the National Cancer Database, 2012-2015. Patients were assigned to Medicaid expansion cohort based on state of residence and whether Medicaid expansion was enacted at date of diagnosis in that state. Guideline concordant care was defined based on NCCN guidelines. We constructed an ecological model with multivariate regression analysis on rate of guideline concordant care receipt with covariates including race/ethnicity, Medicaid expansion, SES, gender, Charlson-Deyo score, and treatment facility type. **Results:** We identified 445,952 patients, 12% Black, 6% Hispanic white, median age 55 years. Patients in the lowest SES quartile following Medicaid expansion had the greatest increase in rates of insured status, although all SES quartiles had increased insured rates compared to non-Medicaid expansion regardless of race/ethnicity. In our ecological model, the rate of receipt of guideline concordant care declined by 0.5% per year between 2012-2015. After adjusting for covariates, Asians were 2.8% less likely to receive guideline concordant care than non-Hispanic whites, Blacks 3.8% less likely, and Hispanics 6.3% less likely ($p < 0.0001$). Racial/ethnic disparities in receipt of guideline concordant cancer care remained after Medicaid expansion with no differential benefit. **Conclusions:** Insurance gains under the ACA Medicaid expansion did not affect the rate of guideline concordant care receipt. Significant racial disparities persist in the likelihood of receiving guideline concordant care, particularly among Hispanics. Further studies are needed to determine additional barriers to cancer care access/delivery and identify key targets aimed at improving equity. Research Sponsor: None.

2040 **Poster Session (Board #32), Fri, 8:00 AM-11:00 AM**

Dynamic 30-day readmission prediction for cancer patients via clinical embeddings.

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Background: Existing models typically predict unplanned 30-day readmission for cancer patients at discharge[1]. Performing prediction dynamically during hospital stay may allow earlier intervention for high risk patients. In addition, readmission risk may be associated with the outcome of a variety of labs and diagnoses. Models including all those elements may not be practical due to large number of variables relative to number of samples. Embeddings have the potential to represent medical concepts in low dimensional spaces[2]. In this study, we developed a machine learning model utilizing embedding representations of ICD and LOINC codes to dynamically predict readmission risk. **Methods:** This is a single institutional study examining inpatient 30-day unplanned readmissions from Jan 2013 to Dec 2016 (n = 16361 total, n = 5685 in hematology). The readmission rate was 18% (24% for hematology). We used gradient boosted trees models with 10-fold cross validation and included baseline factors that are typically available shortly after admission: gender, age, service, admission count within 6 months, insurance, emergency admission, admission year, allogeneic or autologous stem cell transplant (hematology only). For dynamic factors, we randomly selected a timepoint (TP, median = 2.4 days) during each visit. We utilized publicly available clinical embeddings[2] to generate 300 dimensional representations for ICD9s and LOINCs in the patients' Electronic Medical Records. We considered diagnoses (ICD9) between 6 months prior to admission and TP, and lab tests (LOINC) ordered between admission time and TP. We used records from Jan 2017 to Dec 2017 for prospective validation (n = 3785 total, n = 1424 in hematology), with 17% readmission rate (22% for hematology). **Results:** Prospective validation Area Under Receiver Operating Characteristic Curve (AUC) using baseline factors were 0.72 (average precision "AP" = 0.33) and 0.65 (AP = 0.32) for overall and hematology populations, respectively. By including dynamic factors, we obtained AUCs of 0.74 (AP = 0.4) and 0.7 (AP = 0.39) for overall and hematology populations, corresponding to 3% and 8% AUC (21% and 22% AP) improvements, respectively. **Conclusions:** We found that dynamic readmission prediction utilizing clinical embeddings improves the prediction performance comparing with using baseline factors only. The model shows potential to improve patient care and reduce costs by predicting and preventing readmissions when the patient is still in the hospital. [1] J Surg Oncol 2018; 117:1113-1118. [2] AMIA Jt Summits Transl Sci Proc. 2016;41-50. Research Sponsor: None.

2041 **Poster Session (Board #33), Fri, 8:00 AM-11:00 AM**

Prediction of mental health disorder onset and impact on emergency visits following a cancer diagnosis.

William Chen, Lauren Boreta, Steve E. Braunstein, Julian C. Hong; UCSF Department of Radiation Oncology, San Francisco, CA; University of California San Francisco, San Francisco, CA; Department of Radiation Oncology, University of California, San Francisco, San Francisco, CA

Background: Cancer patients are at increased risk of mental and emotional distress. The aim of this study is to investigate risk factors and timing of mental health disorder (MHD) onset following a cancer diagnosis, and evaluate its impact on emergency visits. **Methods:** All patients with a new onset diagnosis of malignancy (*ICD*-10 codes C00-C97, with conversion of *ICD*-9 codes) were identified from an institutional de-identified electronic health data warehouse. Demographic data, Charlson comorbidity index excluding cancer, mortality, and time to onset of a new MHD diagnosis (*ICD*-10 codes F00-F99) and emergency visits were extracted and used to calculate rates and Cox-model hazard ratios. A predictive logistic model of MHD was tested on an internal hold-out sample (25%). **Results:** A total of 110,306 patients with 338,208 person-years of follow up were identified with a new diagnosis of cancer from February 1980 to July 2019, of which 95,474 (86.5%) had no prior diagnosis of MHD. Actuarial rates of new MHD among previously MHD-free patients were 8.1% at 6 months, and 14.1% and 20.8% at 2 and 5 years. Median time to onset of MHD was fastest among head and neck cancer (57 days, HR 2.32 [2.1-2.6]), urinary organ cancer (94 days, HR 2.21 [2.0-2.4]), and lung and thoracic cancers (99 days, HR 2.47 [2.2-2.7]), compared to skin neoplasms (987 days, HR 1.0). Median time to onset was less than one year for all malignancies except for skin neoplasms and male genital cancers (840 days). Male sex, older age, Charlson score, divorce or legal separation, self-identification of a gender-neutral partner, African American or American Indian race, Hispanic ethnicity, current or former smoking status, and self-identification as Christian were associated with higher risk of MHD onset, while married status and native Hawaiian or Pacific Islander race were protective. A logistic model predicted new MHD with an AUROC of 0.72. Onset of new MHD was associated with greater rates of emergency visit (HR 1.92 [1.8-2.0], adjusted for cancer type and Charlson score), and patients with new MHD who experienced an emergency visit had a mean of 3.75+/-0.03 (SEM) total emergency visits versus 2.65+/-0.02 ($p < 0.0001$). Finally, onset of new MHD was associated with greater mortality even after adjusting for age, Charlson score and cancer type (HR 1.29, [1.23-1.35]). **Conclusions:** Onset of new mental health diagnosis after a cancer diagnosis was correlated with greater rates of emergency visits and mortality. Cancer patients with risk factors identified here may benefit from increased social and mental health support. Research Sponsor: None.

2042 **Poster Session (Board #34), Fri, 8:00 AM-11:00 AM**

Predicting the risk of VISIT emergency department (ED) in lung cancer patients using machine learning.

Pablo Rodriguez-Brazzarola, Nuria Ribelles, Jose Manuel Jerez, Jose Trigo, Manuel Cobo, Inmaculada Ramos Garcia, M Vanesa Gutierrez Calderon, Jose Luis Subirats, Ana María Galeote Miguel, Hector Mesa, Laura Galvez Carvajal, Leo Franco, Begoña Jimenez Rodriguez, Ana Godoy, Sofía Ruíz, Andres Mesas, Marcos Iglesias Campos, Irene López, Antonio Rueda Dominguez, Emilio Alba; Grupo de Inteligencia Computacional en Biomedicina, ETSI Ingeniería Informática, Universidad de Málaga, Málaga, Spain; UGC Oncología Intercentros, Hospitales Universitarios Regional y Virgen de la Victoria de Malaga, Instituto de Investigaciones Biomédicas de Málaga (IBIMA), Málaga, Spain; Hospital Universitario Regional y Virgen de la Victoria, IBIMA, Málaga, Spain; Hospital Regional Universitario de Málaga, Málaga, Spain; UGC Oncología Intercentros, Hospitales Universitarios Regional y Virgen de la Victoria de Málaga, Instituto de Investigaciones Biomédicas de Málaga (IBIMA), Málaga, Spain

Background: Lung cancer patients commonly need unplanned visits to ED. Many of these visits could be potentially avoidable if it were possible to identify patients at risk when the previous scheduled visit takes place. At that moment, it would be possible to perform elective actions to manage patients at risk to consult the ED in the near future. **Methods:** Unplanned visits of patients in active cancer therapy (i.e. chemo or immunotherapy) are attended in our own ED facilities. Our Electronic Health Record (EHR) includes specific modules for first visit, scheduled visits and unplanned visits. Lung cancer patients with at least two visits were eligible. The event of interest was patient visit to ED within 21 or 28 days (d) from previous visit. Free text data collected in the three modules were obtained from EHR in order to generate a feature vector composed of the word frequencies for each visit. We evaluate five different machine learning algorithms to predict the event of interest. Area under the ROC curve (AUC), F1 (harmonic mean of precision and recall), True Positive Rate (TPR) and True Negative Rate (TNR) were assessed using 10-fold cross validation. **Results:** 2,682 lung cancer patients treated between March 2009 and October 2019 were included from which 819 patients were attended at ED. There were 2,237 first visits, 47,465 scheduled visits (per patient: range 1-174; median 12) and 2,125 unplanned visits (per patient: range 1-20; median 2). Mean age at diagnosis was 64 years. The majority of patients had late stage disease (34.24 % III, 51.56 % IV). The Adaptive Boosting Model yields the best results for both 21 d or 28 d prediction. **Conclusions:** Using unstructured data from real-world EHR enables the possibility to build an accurate predictive model of unplanned visit to an ED within the 21 or 28 following d after a scheduled visit. Such utility would be very useful in order to prevent ED visits related with cancer symptoms and to improve patients care. Research Sponsor: Pfizer.

	AUC (95%CI)	F1 (95%CI)	TPR (95%CI)	TPN (95%CI)
21 d	0.75 (0.74-0.76)	0.77 (0.773-0.779)	74.3% (74.2%-74.4%)	67.9% (64.8%-65%)
28 d	0.75 (0.74-0.76)	0.77 (0.775-0.776)	73.7% (73.6%-73.8%)	65% (64.9%-65.1%)

2043 **Poster Session (Board #35), Fri, 8:00 AM-11:00 AM**

Development and validation of natural language processing (NLP) algorithm for detection of distant versus local breast cancer recurrence and metastatic site.

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Background: Electronic health records (EHR) are used for retrospective cancer outcomes analysis. Sites and timing of recurrence are not captured in structured EHR data. Novel computerized methods are necessary to use unstructured longitudinal EHR data for large scale studies. **Methods:** We previously developed a neural network-based NLP algorithm to identify no recurrence vs. metastatic recurrence cases by analyzing physician notes, pathology and radiology reports in Stanford's breast cancer database, Oncoshare (Cohort A). To validate this algorithm for local vs. distant recurrence, we identified a distinct Oncoshare cohort (Cohort B). Cases were manually curated for longitudinal development of local or distant recurrence and metastatic sites. A two-sided t-test was used to compare mean probabilities between local and distant recurrence cases. Next, we combined cases in Cohorts A and B to train and validate a novel NLP classifier that identifies metastatic site. The combined cohort was randomly divided into training and validation sets. Sensitivity and specificity were calculated for the NLP algorithm's ability to detect metastatic sites compared to manual curation. **Results:** In Cohort B: 350 metastatic cases were identified. Mean probability for local and distant recurrence was 0.43 and 0.79, respectively and differed significantly for patients with local vs. distant recurrence ($p<0.01$). In Cohorts A and B: 632 metastatic cases were used for determination of sites. Sensitivity and specificity were highest for detection of peritoneal metastasis followed by liver, lung, skin, bone and central nervous system (table). **Conclusions:** This NLP algorithm is a scalable tool that uses unstructured EHR data to capture breast cancer recurrence, distinguishing local from distant recurrence and identifying metastatic site. This method may facilitate analysis of large datasets and correlation of outcomes with metastatic site. Research Sponsor: None.

Sensitivity & specificity of extracting recurrence sites.

	Bone	Liver	Lung	Lymph Nodes	CNS	Peritoneum	Skin
N (cases)	252	98	94	101	37	15	16
Sensitivity	0.84	0.97	0.93	0.82	0.9	0.94	0.97
Specificity	0.77	0.77	0.6	0.6	0.5	1.0	0.5

Improved prognostication for lung cancer patients from computed tomography imaging using deep learning.

Felipe Torres, Shazia Akbar, Felix Baldauf-Lenschen, Natasha B. Leighl; University of Toronto, Toronto, ON, Canada; Altis Labs, Toronto, ON, Canada; Princess Margaret Cancer Centre, Toronto, ON, Canada

Background: Clinical TNM staging derived from computed tomography (CT) imaging is a key prognostic factor for lung cancer patients when making decisions about treatment, monitoring, and clinical trial eligibility. However, heterogeneity among patients, including by molecular subtypes, may result in variability of survival outcomes of patients with the same TNM stage that receive the same treatment. Artificial intelligence may offer additional, individualized prognostic information based on both known and unknown features present in CTs to facilitate more precise clinical decision making. We developed a novel deep learning-based technique to predict 2-year survival from pretreatment CTs of pathologically-confirmed lung cancer patients. **Methods:** A fully automated, end-to-end model was designed to localize the three-dimensional (3D) space comprising the lungs and heart, and to learn deep prognostic features using a 3D convolutional neural network (3DCNN). The 3DCNN was trained and validated using 1,841 CTs of 1,184 patients from five public datasets made available in The Cancer Imaging Archive. Spearman's rank correlation (R) and concordance index (C-index) between the model output and survival status of each patient after 2-year follow-up from CT acquisition was assessed, in addition to sensitivity, specificity and accuracy stratified by staging. **Results:** 3DCNN showed an overall prediction accuracy of 75.0% ($R = 0.32$, C-index = 0.67, $p < 0.0001$), with higher performance achieved for stage I patients (Table) . 3DCNN showed better overall correlation with survival for 1,124 patients with available TNM staging, in comparison to TNM staging only ($R = 0.19$, C-index = 0.63, $p < 0.0001$); however, a weighted linear combination of both TNM staging and the 3DCNN yielded a superior correlation ($R = 0.34$, C-index = 0.73, $p < 0.0001$). **Conclusions:** Deep learning applied to pretreatment CT images provides personalized prognostic information that complements clinical staging and may help facilitate more precise prognostication of patients diagnosed with lung cancer. Research Sponsor: None.

3DCNN performance by staging.

	Stage I	Stage II	Stage III	Stage IV	All Patients*
Number of Patients Survived >2 years	400	137	164	165	919
Number of Patients Died within 2 years	53	38	132	35	265
AUC	0.81	0.69	0.76	0.55	0.74
Accuracy	79.2%	66.3%	67.7%	66.7%	75.0%
Specificity	0.81	0.56	0.54	0.61	0.62
Sensitivity	0.73	0.65	0.81	0.52	0.70

*Includes 60 additional patients where staging was not available.

2045 **Poster Session (Board #37), Fri, 8:00 AM-11:00 AM**

Driving quality improvement: How clinical decision support can facilitate compliance with evidence-based pathways.

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Background: Cancer care is changing rapidly with more detailed understanding of disease and more numerous therapeutic choices. As treatment choice is more complex, mechanisms to improve compliance with evidence based treatment can improve the quality of cancer care. **Methods:** A retrospective cohort study was conducted from January 2014-May 2016 evaluating the impact of a clinical decision support system (CDSS) on compliance with evidence based pathways (EBP) across 9 statewide community based oncology practices. These EBP are developed with physician input on efficacy toxicity and value and incorporated in to a CDSS that is used within the Electronic Health Record (EHR) at point of care to alter the choice architecture a clinician sees when prescribing therapy. A multi-level logistic regression model was used to adjust for group effects on physician or practice behavior. SAS 9.4 software was used and GLIMMIX was applied. Individual physician benchmark compliance was evaluated using McNemar's test. **Results:** Regimen compliance with EBP was measured pre- and post- implementation of the CDSS tool across a large network encompassing 9 statewide practices and 633 physicians who prescribed over 30,000 individual patient treatment regimens over a 6 month period. The CDSS that is incorporated within the EHR significantly improved compliance with EBP across the entire cohort of practices, and in individual practices (see Table). Individual oncologists reached a target of 75% compliance more often (58% vs 72%) after implementation of the tool ($p < 0.001$). **Conclusions:** CDSS is a tool that improves compliance with EBP that is effective at improving targets of compliance broadly, at the practice, and at the individual clinician level. Clinical informatics solutions that influence physician behavior can be inclusive of physicians in design, iterative in process, and nudge as opposed to force clinician behavior to drive quality improvement. These clinical informatics solutions grow in importance as the complexity of cancer care continues to increase and we seek to improve upon the quality and value of care delivery. Research Sponsor: Texas Oncology, US Oncology.

Label	Odds Ratio of Regimen Compliance	95% LCL	95% UCL	Pr > |t|
Overall Post vs. Pre	1.48	1.25	1.76	0.0007
Practice A	1.60	1.33	1.94	0.0004
Practice B	1.13	0.88	1.45	0.2930
Practice C	1.39	1.08	1.79	0.0160
Practice D	1.85	1.53	2.24	< .0001
Practice E	1.76	1.32	2.36	0.0021
Practice F	1.71	1.38	2.11	0.0004
Practice G	1.23	0.96	1.57	0.0897
Practice H	1.37	1.12	1.67	0.0066
Practice I	1.46	1.30	1.63	< .0001

2046 **Poster Session (Board #38), Fri, 8:00 AM-11:00 AM**

Identifying and overcoming clinical trial enrollment barriers: Can an integrated clinical pathways tool help bridge the gap?

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Background: Barriers to clinical trial (CT) enrollment continue to be a national challenge, with only about 3% of adult cancer patients treated within a CT. A key recommendation from the 2013 NCI-ASCO Cancer Trial Accrual Symposium was to use information technology to enhance identification of potentially eligible patients for CTs. We assessed if the implementation of a Clinical Oncology Pathways System (COP) with integrated CT information increased enrollment of CT's, and categorized physician-identified reasons for non-enrollment. **Methods:** In 2018, Roswell Park Comprehensive Cancer Center (RP) implemented ClinicalPath pathways (formerly Via Oncology) for medical oncology. The COP software embeds interventional CTs that are open to accrual at RP in the pathway specific to a patient's disease type, stage and biomarkers. The provider is presented with relevant CTs and must select screening for the trial or provide a reason for bypassing the CT from a drop-down list prior to being presented standard care options. CT screening requests from the COP system from 6/1/18-5/31/19 were reviewed. Screening requests and actual enrollment data were matched. The accrual-to-study ratio (ASR), defined as the number of consented accruals divided by the number of CTs open to accrual at RP at any time during the period, was calculated for the study period and the baseline from 6/1/14-6/1/18. The reasons physicians did not elect to screen for CTs were summarized. **Results:** There can be multiple trials presented for each pathway decision.There were 1,606 decision points with at least one embedded trial. Of these, 1,289 decision points matched 2,242 CTs that were not selected for screening. 317 trials were selected for screening. The most common reasons for not screening were patient ineligibility (41%), provider bypassing the CT by selecting treatment "off pathway" (28%), patient not interested (12%), patient already on CT (8%) and "other" (9%). Audits confirmed that the majority of ineligible patients had co-morbidities such as organ dysfunction or brain metastasis that precluded them from the CT. Among the 317 trials selected for CT screening, 108 (34%) patients enrolled in CTs. The ASR increased from the four-year historical average baseline of 4.08 to 4.33 one year post-implementation. **Conclusions:** The use of COP with embedded CT was associated with a modest increase in ASR. Stringent eligibility criteria was the primary barrier to enrollment. Adopting a broader set of clinical trial eligibility criteria could increase enrollment to CT. Research Sponsor: Genentech.

2047 **Poster Session (Board #39), Fri, 8:00 AM-11:00 AM**

Machine learning algorithms to predict financial toxicity associated with breast cancer treatment.

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Background: Financial burden caused by cancer treatment is associated with material loss, distress, and poorer outcomes. Financial resources exist to support patients but objective identification of individuals in need is difficult. Accurate predictions of an individual's risk of financial toxicity prior to initiation of breast cancer treatment may facilitate informed clinical decision making, reduce financial burden, and improve patient outcomes. **Methods:** We retrospectively surveyed 611 patients who had undergone breast cancer therapy at MD Anderson Cancer Center to assess the financial impact of their care. All patients were over 18 and received either a lumpectomy or a mastectomy. We collected data using the FACT-COST patient-reported outcome measures alongside other financial indicators including income and insurance status. We extracted clinical and perioperative data from the electronic health record. Missing data were imputed using multiple imputation. We used this data to train and validate a neural network, LASSO-regularized linear model, and support vector machines. Data were randomly partitioned into training and validation samples (3:1 ratio). Analyses were informed by international PROBAST recommendations for developing multivariate predictors. We combined algorithms into a voting ensemble and assessed predictive performance using area under the receiver operating characteristics curve (AUROC), accuracy, sensitivity, and specificity. **Results:** In our validation sample, 48 of 203 (23.6%) women reported FACT-COST scores commensurate with significant financial burden. The algorithm predicted significant financial burden relating to cancer treatment with high accuracy (Accuracy = .83, AUROC = .82, sensitivity = .81, specificity = .82). Key clinical predictors of financial burden from linear models were neo-adjuvant therapy ($\beta_{regularized}$ 0.12) and autologous, rather than implant-based, reconstruction ($\beta_{regularized}$ 0.10). **Conclusions:** Machine learning models were able to accurately predict the occurrence of financial toxicity related to breast cancer treatment. These predictions may be used to inform decision making and care planning to avoid financial distress during cancer treatment or to enable targeted financial support for individuals. Further research is warranted to further improve this tool and assess applicability for other types of cancer. Research Sponsor: None.

2048 **Poster Session (Board #40), Fri, 8:00 AM-11:00 AM**

Semi-automated discovery of real-world patient pathway from U.S. electronic health records: Advanced non-small cell lung cancer (aNSCLC).

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Background: A good understanding of cancer care continuum presents opportunities to uncover unmet medical needs and improve outcomes and clinical workflow efficiency. However, patient care is poorly understood in real-world clinical practice. This study aimed to discover real-world patient pathways for advanced non-small cell lung cancer (aNSCLC). **Methods:** This study included patients diagnosed with aNSCLC (stage IIIB and above) at their initial diagnoses between 2011-2018 from the Flatiron Health electronic health records (EHR)-derived deidentified database. Overall survival (OS) was calculated using the Kaplan-Meier method. We also explored the application of process mining analytics (Heuristics Miner & Directly-Follows Graphs) to describe and visualize real-world patient pathways, following patients from initial diagnosis, through any National Comprehensive Cancer Network guideline-recommended companion diagnostics (CDx; including EGFR, ALK, ROS1, KRAS, BRAF, or PD-L1) and treatment patterns, until death or end of the study. **Results:** A total of 39,156 eligible patients were included. During a median follow-up of 0.78 years (interquartile range [IQR] 1.27), 28,801 (73.6%) patients died (median OS 11.6 months [95% CI 11.4 -11.8]). We established a semi-automated process discovery pipeline that transforms high-dimensional EHR datasets in table format as input into real-world event logs and produces a series of patient pathway graphs as output. The patient pathway graphs showed 19,878 (50.8%) patients had CDx testing within a median 11 days (IQR 18) and 29,241 (74.7%) patients started first-line therapy within a median 1.2 months (IQR 1.2) after the initial diagnosis. When we stratified analysis by years of initial diagnosis (2011-2014 vs 2015-2018), 38.8% (6808 of 17546) vs. 60.5% (13070 of 21610) patients had their first CDx testing within median 12 days (IQR 21) vs. 10 days (IQR 17) respectively. **Conclusions:** This study suggested an uptake of 56% increase of CDx utilization over the last 8 years in real-world clinical setting and that patient pathways can be analyzed and visualized in a semi-automated fashion. Research Sponsor: ROCHE DIAGNOSTIC INFORMATION SOLUTION.

2049 **Poster Session (Board #41), Fri, 8:00 AM-11:00 AM**

Concordance study of treatment guidance from an online patient assistance algorithm (OCPAP) and treatment recommendation of a multidisciplinary panel of oncologists in India.

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Background: OCPAP (online cancer patient assistance pathway) is an algorithm-based online platform for patients to help them understand their treatment options. It is based on basic inputs like cancer type, stage, patient's performance status and treatment received. It is developed by a team of oncologists from onco.com based on standard guidelines. Till date, more than 30,000 users from 18 countries have used OCPAP platform to get directional treatment recommendations. Onco.com also provides onco tumour board (OTB) services to help patients to get a detailed opinion from a multi-disciplinary panel of oncologists. We presented initial data on development of OCPAP™ at the ASCO Breakthrough Summit 2019 (OCPAP Breakthrough Abstract). Here we present a concordance analysis of treatment recommendations from OCPAP platform against opinion of OTB panel. **Methods:** We analysed data from 448 eligible cases (those with 15 types of solid cancers) where an OTB opinion was provided and compared it with OCPAP treatment recommendation. We entered data from 448 anonymised OTB case records in to the OCPAP platform and recorded the output in terms of treatment recommendations. The study was blinded by its very design as we took data of cases from the time when the platform was non-existent. **Results:** We compared and analysed the recommendation provided by OCPAP in terms of surgery, chemotherapy, targeted therapy, radiation, clinical trials, palliative care or best supportive care against the opinion of OTB panel. Overall the concordance rate was found to be 93% for all cases and it was above 90% for all types of cancers included, except for brain tumors where it was 78% mainly due to variation in surgical operability and imaging findings influencing the treatment recommendation. The concordance rate was above 90% for all stages of disease and was highest for metastatic disease where it was 95%. The reasons for discordance were mostly related to availability of more detailed insights about the disease for OTB, like clinical details, performance status, imaging findings, molecular data and oligometastasis. **Conclusions:** The treatment direction recommended by OCPAP was found to be consistent with the one provided by OTB panel for most solid cancers. This indicates that OCPAP is an effective and simple online tool for patients to understand their treatment options, validate their ongoing treatment and be able to actively participate in their treatment decisions. Research Sponsor: None.

2050 **Poster Session (Board #42), Fri, 8:00 AM-11:00 AM**

Ranking of therapeutic regimens for hormone receptor-positive, HER2-negative, metastatic breast cancer (MBC) using information theoretic network meta-analysis.

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Background: Hormone receptor-positive (HR+), HER2-negative (HER2-) metastatic breast cancer (MBC) is treated with targeted therapy, hormone therapy, chemotherapy, or combinations of these modalities. Evaluating the increasing number of treatment options is challenging, especially since few regimens have been compared head-to-head in randomized clinical trials (RCTs). Potential solutions include expert-driven guidelines (e.g. NCCN guidelines), algorithmic scales (e.g. the ASCO and ESMO Value Frameworks), traditional Bayesian network meta-analysis (NMA), and information theoretic (IT) NMA, a graph theory-based approach that also enables dynamic ranking of regimens over time. **Methods:** We used IT-NMA to rank regimens for HR+/HER2- MBC. The analysis includes RCTs of regimens identified from HemOnc.org and a recent large traditional NMA (Giuliano et al. 2019). Variables used in ranking include primary endpoints, no. of patients enrolled, p-value, hazard ratio for time-based outcomes (e.g. overall survival) or odds ratio for fixed endpoints (e.g. response rate), and year of publication. **Results:** The analysis included 238 RCTs enrolling 92,971 patients published between 1974-2019. There were 277 unique regimens, taking into account variations in dosage, frequency, and no. of cycles. As of 2019, out of 85 ranks, combinations of targeted therapy and hormone therapy (e.g. letrozole & palbociclib) are ranked the highest (Table). Over time, we observe that novel treatments tested in escalation trials tend to rise to the top of the rankings (e.g. paclitaxel & bevacizumab in 2007, driven by ECOG E2100), and monotherapy approaches tend to fall to the bottom. **Conclusions:** In 2019, the combinations of hormone or chemotherapy and targeted therapy are ranked higher than hormone therapy or chemotherapy alone. Our ranking result is similar to previous studies with a notably larger number of comparisons (Giuliano et al. is the largest published study, with 131 regimens/50,029 pts analyzed). Informatic theoretic NMA is a promising method of indirect rankings of treatment that also enables dynamic regimen ranking over time. Research Sponsor: U.S. National Institutes of Health.

Five highest and five lowest ranked regimens.

Rank	Value*	Regimen
1	22.8	Letrozole & Palbociclib
2	16.6	Letrozole & Ribociclib
3	11.1	Paclitaxel & Bevacizumab
4	9.7	Capecitabine, Paclitaxel, Bevacizumab
5	9.6	Anastrozole & Ribociclib
81	-15.6	Weekly paclitaxel
82	-15.8	Fulvestrant 500
83	-16.4	Letrozole
84	-17	Fulvestrant 250
85	-42.1	Tamoxifen 20

*Unitless number; higher is better

2051 **Poster Session (Board #43), Fri, 8:00 AM-11:00 AM**

An automated EHR-based tool for identification of patients (pts) with metastatic disease to facilitate clinical trial pt ascertainment.

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Background: Efforts to facilitate patient identification for clinical trials in routine practice, such as automating electronic health record (EHR) data reviews, are hindered by the lack of information on metastatic status in structured format. We developed a machine learning tool that infers metastatic status from unstructured EHR data, and we describe its real-world implementation. **Methods:** This machine learning model scans EHR documents, extracting features from text snippets surrounding key words (ie, 'Metastatic' 'Progression' 'Local'). A regularized logistic regression model was trained, and used to classify patients across 5 metastatic status inference categories: highly-likely and likely positive, highly-likely and likely negative, and unknown. The model accuracy was characterized using the Flatiron Health EHR-derived de-identified database of patients with solid tumors, where manually abstracted information served as standard accurate reference. We assessed model accuracy using sensitivity and specificity (patients in the 'unknown' category omitted from numerator), negative and positive predictive values (NPV, PPV; patients 'unknown' included in denominator), and its performance in a real-world dataset. In a separate validation, we evaluated the accuracy gained upon additional user review of the model outputs after integration of this tool into workflows. **Results:** This metastatic status inference model was characterized using a sample of 66,532 patients. The model sensitivity and specificity (95%CI) were 82.% (82, 83) and 95% (95, 96), respectively; PPV was 89% (89, 90) and NPV was 94% (94, 94). In the validation sample (N = 200 originated from 5 distinct care sites), and after user review of model outputs, values increased to 97% (85, 100) for sensitivity, 98% (95, 100) for specificity, 92 (78, 98) for PPV and 99% (97, 100) for NPV. The model assigned 163/200 patients to the highly-likely categories, which were deemed not to require further EHR review by users. The prevalence of errors was 4% without user review, and 2% after user review. **Conclusions:** This machine learning model infers metastatic status from unstructured EHR data with high accuracy. The tool assigns metastatic status with high confidence in more than 75% of cases without requiring additional manual review, allowing more efficient identification of clinical trial candidates and clinical trial matching, thus mitigating a key barrier for clinical trial participation in community clinics. Research Sponsor: Study sponsored by Flatiron Health, which is an independent subsidiary of the Roche group.

2052 **Poster Session (Board #44), Fri, 8:00 AM-11:00 AM**

Novel artificial intelligence (AI)-based technology to improve oncology clinical trial fulfillment.

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Background: Less than 5% of US adult cancer pts are enrolled on clinical trials. Challenges in clinical trial fulfillment limit available treatment options, slow enrollment and ultimately delay new therapies from reaching market. Pt screening requires multiple clinical team members to find pts that meet strict inclusion/exclusion criteria. We evaluated the impact of new technology, Deep Lens VIPER, in identifying more qualified pts for clinical studies, and reduction of staff burden. **Methods:** We implemented Deep Lens VIPER at Hoag Hospital (Newport Beach, California), accessing the electronic medical records and pathology systems (EMR/LIS) to effectively identify pts who are candidates for 20 ongoing recruiting clinical studies. VIPER was fed pt data from 5,706 surgical pathology pts over a 4-month period (October 1, 2019 - January 31, 2020). Proprietary AI identification and matching technology was configured to align cancer pts with those 20 clinical studies, each with unique study criteria. Following an initial machine-assisted triage step, a research coordinator was alerted when pts who met protocol criteria were ready for final approval steps. Results were analyzed and a qualitative assessment of usability was also performed. **Results:** VIPER was able to triage all 5,706 surgical pathology cases (100%), identifying 1,045 pts (18.3%) with malignant neoplasms that would qualify for further analysis for clinical trials enrollment. Further triage based on inclusion and exclusion criteria led to the identification of 150 previously unidentified pts for 16 of the 20 studies. The 16 different studies for which potential pts were identified, included 11 tumor types, 12 biomarkers and 3 basket studies. Working with the VIPER system, 1 novice care team member performed initial identification of all 150 previously unidentified pts. The VIPER system increased monthly candidate pt catchment for 16 of the 20 studies under investigation, which is approximately 600 patients annually added for final triage for studies being conducted. **Conclusions:** We demonstrate the use of an AI-based platform to identify pts for clinical trial enrollment who would be missed using traditional recruiting methods. One staff member effectively triaged participants from 20 different studies with unique inclusion/exclusion criteria. These studies were previously managed by 6 different care team members with limited time for recruitment. Scaling this platform to additional institutions and more studies is ongoing to validate these findings. Research Sponsor: Deep Lens, Inc.

2053 **Poster Session (Board #45), Fri, 8:00 AM-11:00 AM**

Model selection applied to 750 outpatient ICD-9 codes identifies hazards important for all-cause cancer mortality in 2 million veterans with 14 years of follow-up.

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Background: Cost-benefit analysis before undergoing cancer treatments can involve a broad array of factors, yet existing statistical algorithms are limited to a few of the most commonly observed competing risks. Using 20 years of Veteran medical records from the Veteran's Administration, we identify a broad array of outpatient descriptors providing contributions to computed mortality comparable in size to common cancers. **Methods:** 1,911,632 Veterans born between 1927 and 1968 with medical records extending from October 1, 2000 until either recorded death after October 1, 2005 (47%) or observation during CY 2019 were split equally into age-matched test and training sets. The 20 year-long record was split into three intervals: 5 years during which ICD codes were tallied, 14 years of waiting, and establishment of continuation in care during 2019. The 750 most common outpatient ICD9 codes were recorded as present/absent for each patient and used in a generalized linear model to predict subsequent mortality, subject to LASSO model selection and 10-fold cross validation. Gender was included as a covariate as well as age at time of prediction, up to the 4^{th} power. **Results:** The C-statistic for predicting mortality in 14 years of follow-up was 0.835 on training data and 0.833 on test data when using the 498 codes selected by LASSO. Prevalent codes with the largest model coefficients were (ICD 9 code: model coefficient, # alive/# deceased in test set) congestive heart failure (428.0: 0.66, 9k/48k), chronic airway obstruction (496.: 0.60, 42k/105k), and tobacco use disorder (305.1: 0.54, 107k/123k), while the prevalent codes most protective in comparison to baseline were hyperlipidemia (272.4: -0.21, 211k/225k) and colon cancer screening (V76.51: -0.16, 49k/39k). In comparison, observed cancer ICD 9 coefficients were lung (162.9: 1.03, 1k/7k), colon (153.9: 0.18, 3.1k/7.0k), and prostate (185.: 0.06, 16k/32k). 74 predictors contribute with coefficients greater than colon cancers, such as 'no household member able to render care' (V60.4: 0.28, 1.1k/4.2k). **Conclusions:** A wide variety of structured data contribute at a similar level of importance in prediction of 14-year mortality. While various selection biases, co-linearity of predictors, differences in treatments, and missing data are significant impediments to utilization of predictive models in clinical practice, we have demonstrated an ability to identify and quantify predictors from a large data set with model selection techniques. Research Sponsor: This work was supported by Department of Veterans Affairs, Office of Research and Development, Million Veteran Program MVP000 and MVP017.

2054 **Poster Session (Board #46), Fri, 8:00 AM-11:00 AM**

Novel evidence synthesis system to support living systematic reviews and living guidelines for cancer immunotherapy.

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Background: Systematic reviews that summarize the toxicity of Immune checkpoint inhibitors (ICIs) become outdated very soon after publication. Therefore, we reported results of a toxicity meta-analysis at 2019 ASCO meeting and informed the intent to create a living systematic review (LSR). LSRs combine human and machine effort and support rapid evidence synthesis and living clinical practice guidelines. Now, we report our experience maintaining a LSR on toxicity of ICIs. **Methods:** Steps include quarterly literature searches to identify new clinical trials reporting ICI-associated adverse events (AEs), AI-enabled screening of new citations which meet the inclusion criteria, automated cumulative meta-analysis and an online reporting platform. Standard data formats and protocols were designed for inputting text, tables and graphics. Software was written to interpret these data and output the information in the appropriate format, such as a forest plot and summary tables. Finally, a dynamic interface that enables user inputs and displays the associated output was designed. **Results:** The LSR is continuously updated incorporating toxicity data from new clinical trials as it becomes available. We have screened 8000 relevant citations and summarized the odds of Grade 3 or higher AEs and AEs of special interest in patient receiving ICIs. The results are updated on quarterly basis and are available online. The results are updated on quarterly basis and will be available on a website at the time of publication. Prototype with dummy data is available at this link. This interface can also be manipulated via user input to organize and sort data tables and forest plots by type of cancer, name or mechanism (PD-1 or PD-L1) of ICI agent, single agent or combination, type of control arm, line of treatment and several other clinically relevant filters. For example, a user can instantaneously generate a meta-analysis summarizing the risk of colitis or pneumonitis in metastatic lung cancer trials with pembrolizmuab. **Conclusions:** This LSR engine can prospectively synthesize toxicity data from ICI trials in an efficient manner providing accurate and timely information for advanced clinical decision support at point-of-care. Efforts are ongoing to improve efficiency of screening, improve AI-enabled processes for automated screening and data abstraction, and test across multiple clinical questions. Research Sponsor: None.

2055 **Poster Session (Board #47), Fri, 8:00 AM-11:00 AM**

Fragility index of trials supporting approval of anti-cancer drugs in common solid tumors.

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Background: The Fragility Index (FI) quantifies the reliability of positive trials by estimating the number of events which would change statistically significant results to non-significant results. Here, we calculate the FI of trials supporting approval of drugs for common solid tumors. **Methods:** We searched Drugs@FDA to identify randomized trials (RCT) supporting drug approvals by the US Food and Drug Administration between January 2009 and December 2019 in lung, breast, prostate, gastric and colon cancers. We adapted the FI framework (Walsh et al. J Clin Epidemiol 2014) to allow use of time to event data. First, we reconstructed survival tables from reported data using the Parmar Toolkit (Parmar et al. Stat Med 1998) and then calculated the number of events which would result in a non-significant effect for the primary endpoint of each trial. The FI was then compared quantitatively to the number of patients in each trial who withdrew consent or were lost to follow-up. Multivariable linear regression was used to explore association between RCT characteristics and the FI. **Results:** We identified 69 RCT with a median of 669 patients (range 123-4804) and 358 primary outcome events (range 56-884). The median FI was 26 (range 1-322). The FI was $\leq$10 in 21 trials (30%) and $\leq$20 in 31 trials (45%). Among the 69 RCT, the median number of patients who withdrew consent or were lost to follow up was 27 (range, 6-317). The number of patients who withdrew consent or were lost to follow-up was equal or greater than the FI in 42 trials (61%). There was statistically significant inverse association between FI and trial hazard ratio (p0,001) and a positive association with number of patients who were lost to follow-up or withdrew consent (p0,001). There was no association between trial sample size, year of approval or reported p-value and the FI. **Conclusions:** Statistical significance of trials supporting drug approval in common solid tumors relies often on a small number of events. In most trials the FI was lower than the number of patients lost to follow up or withdrawing consent. Post-approval randomized trials or real-world data analyses should be performed to ensure that effects observed in registration trials are robust. Research Sponsor: None.

2057 **Poster Session (Board #49), Fri, 8:00 AM-11:00 AM**

Core limitations in clinical trials leading to anticancer drug approvals by the U.S. Food and Drug Administration.

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Background: To date, a comprehensive evaluation of core limitations in clinical trials leading to anti-cancer drug approvals by the US Food and Drug Administration (FDA) has not been undertaken.The aim of this analysis was to assess the percentage of clinical trials with core limitations, defined as lack of randomization, lack of overall survival data, inappropriate use of crossover, and use of sub-optimal control arms that led to FDA approvals from 2014 to 2019. **Methods:** This observational analysis included all approved anti-cancer drug indications by the FDA from July 2014 through July 2019. All indications were investigated and each clinical trial evaluated for design, enrollment period, primary endpoints, and presence of core limitations. The standard of care therapy was determined by evaluating the literature and published guidelines 1-year prior to start of clinical trial enrollment. Crossover was examined and evaluated for optimal use. We then calculated the percentage of approvals based on clinical trials with any or all core limitations. **Results:** A total of 187 anti-cancer approvals were evaluated. The number of anti-cancer drug approvals doubled over time with 68 in first half of study period (June 2014 to December 2016) to 119 in second half of study period (January 2017 to July 2019). Of those, 125 (67%) were based on a clinical trial with at least one core limitation. 64 (34%) approvals were based on a single-arm clinical trial. Of the remaining 123 approvals based on randomized trials, 60 (32%) had a core limitation. Of all randomized trials, 37 (30%) lacked overall survival benefit, 31 (25%) had a sub-optimal control, and 17 (14%) used crossover inappropriately. **Conclusions:** The majority of cancer drugs are approved based on clinical trials with core limitations. Efforts to minimize core limitations at the time of clinical trial design are essential to ensure that new anti-cancer drugs being marketed truly improve patient outcomes over current standards. Research Sponsor: None.

2058 **Poster Session (Board #50), Fri, 8:00 AM-11:00 AM**

Gender-based disparities in clinical trials supporting FDA approval of oncology drugs.

Marjorie Zettler, Bruce A. Feinberg, Jonathan Kish, Ajeet Gajra; Cardinal Health, Dublin, OH

Background: Adequate gender representation in clinical trials of new drugs is critical in order to accurately detect possible differences in response and toxicity (Özdemir et al, JCO 2018). The under-representation of women in oncology clinical trials has been previously described, however data on registrational trials, which are the basis for drug approval and inform the prescribing information, is lacking. We conducted an analysis of the trials supporting Food and Drug Administration approval of oncology drugs over a 5-year period to evaluate the representation of women vs. men. **Methods:** Prescribing information for novel new drugs approved from 2014-2018 was reviewed for the proportions of men and women in the evaluable population of the supporting clinical trials. Sex-specific cancers were excluded. Prevalence estimates for the indications were obtained from the Surveillance, Epidemiology and End Results database and the published literature. A participation to prevalence ratio (PPR) was calculated for each trial by dividing the percentage of women in the trial by the percentage of women in the disease population. A PPR value closer to unity represents even gender distribution and the range 0.8-1.2 is considered to reflect an acceptable representation of women. Data are presented using descriptive statistics. **Results:** A total of 46 oncology drugs were approved based on 56 trials enrolling 13,862 patients (7941 [57%] men; 5,921 [43%] women). Of the 56 trials, 38 (68%) had a PPR within the 0.8-1.2 range, 15 (27%) fell between 0.4-0.7, and 3 (5%) had a PPR of 1.3. The proportion of trials with unbalanced gender representation was comparable for hematological malignancy and solid tumor indications and did not improve over time. Fewer unbalanced trials were Phase III or employed a randomized design. Nine of the 18 (50%) unbalanced trials enrolled $<$100 subjects, compared to 3 of the 38 (8%) balanced trials. **Conclusions:** A third of registrational trials for oncology drugs lacked balanced gender distribution. Of the trials lacking balance, the vast majority (80%) had under-representation of women. Phase I-II trials and smaller trials had greater gender disparity, a concerning finding in a precision medicine environment where an increasing number of registration trials have double digit accrual. Further research is needed to understand the implications of unbalanced gender accrual in registrational trials, and to develop strategies for preventing disparities. Research Sponsor: Cardinal Health.

2059 **Poster Session (Board #51), Fri, 8:00 AM-11:00 AM**

Performance status restriction in phase III cancer clinical trials.

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Background: Patients with good performance status (PS) tend to be favored in randomized clinical trials (RCTs), possibly limiting the generalizability of trial findings. We sought to characterize trial-related factors associated with the use of eligibility criteria that restrict patients by PS, and analyze patient accrual breakdown by PS. **Methods:** We searched ClinicalTrials.gov for phase III RCTs between 2003-2018. Randomized multi-arm trials assessing a therapeutic intervention in cancer patients were included. PS data were extracted from corresponding manuscripts. Trials with PS restriction Eastern Cooperative Oncology Group (ECOG) ≤ 1 were identified. Factors associated with PS restriction were determined, and trial patient accrual was analyzed. **Results:** Six-hundred trials were included with PS data for 238,213 patients. In total, 527 studies (87.8%) specified an upper PS restriction cutoff as part of their exclusion criteria, and 237 studies (39.5%) had a strict inclusion criterion of patients with ECOG PS ≤ 1. Enrollment criteria restrictions based on PS (ECOG PS ≤ 1) were more common among industry-supported trials ($P < 0.001$) and lung cancer trials ($P < 0.001$). Nearly half of trials that led to subsequent FDA approval included strict PS restrictions. Binary logistic regression revealed stable use of restrictive PS eligibility criteria between 2007-2018 ($P = 0.789$). The vast majority of patients enrolled across all trials had an ECOG PS of 0 to 1 (96.3%). Even among trials that allowed patients with ECOG PS ≥ 2, only 8.1% of enrolled patients had a poor PS (ECOG 2 or higher).Trials of hematologic cancers had the largest proportion of patients with ECOG PS ≥ 2 (8.7%), while lung, breast, gastro-intestinal and genitourinary trials all included less than 5% of patients with poor PS ($P < 0.001$). Only 4.8% of patients enrolled in trials that led to subsequent FDA approval had a poor PS. **Conclusions:** The use of PS restrictions in oncologic RCTs is pervasive, and exceedingly few patients with poor PS are enrolled. The selective accrual of healthier patients has the potential to severely limit and bias trial results. Future trials should consider a wider cancer population with close toxicity monitoring, to ensure generalizability of results, while maintaining patient safety. Research Sponsor: None.

2060 **Poster Session (Board #52), Fri, 8:00 AM-11:00 AM**

Trends in FDA cancer registration trial design over time, 1969-2020.

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Background: The FDA has issued hundreds of cancer drug indications, with many new drugs, expanded indications, and biosimilars approved in recent years. While the gold standard for regulatory approval is the randomized controlled trial (RCT), RCT design including selection of control arms can differ considerably. We sought to investigate trends and patterns in RCT trial design used to support FDA approvals in oncology. **Methods:** We reviewed the available FDA package inserts of oncology drugs (N=258) for RCTs cited to support initial and expanded indication approvals as of January 2020; biosimilars were excluded. RCTs were linked to the HemOnc ontology, which contains trial-level metadata including publication year, endpoints, and trial design. Log-linear regression was performed to evaluate trends in approvals over time by endpoint. Study drugs were categorized as cytotoxic therapy, targeted therapy, or immunotherapy. RCTs were categorized by four designs: escalation (adding a drug or increasing the drug dose in an established regimen), in-class comparison (comparing two drugs in the same therapeutic class), out-of-class switch (comparing drugs in distinct therapeutic classes), and de-escalation (removing a drug or reducing the drug dose in an established regimen). **Results:** We identified 556 registration trials, 372 (67%) of which were RCTs. Approvals have been increasing exponentially over time (R^2 0.9, $p<0.001$), both for RCTs reporting overall survival (OS) endpoints (R^2 0.77, $p<0.001$), and non-OS endpoints (R^2 0.67, $p<0.001$). Of the three most common trial designs (Table), in-class comparisons were least likely to report OS (28%; escalations 47%; out-of-class switches 43%, p=0.01 by Chi-squared). Class switches were common in immunotherapy trials compared to targeted or cytotoxic therapy. **Conclusions:** Despite growth in FDA approvals, a minority of registration trials report paradigmatic shifts in therapeutic approach (out-of-class switches), with the relative exception of immunotherapy trials. Escalation is the most common route to FDA approval, even though this design inevitably increases cost and toxicity. This suggests that new oncology drug approvals are not alone a useful metric of practice-changing innovation. Research Sponsor: U.S. National Institutes of Health.

Distribution of RCT design by therapeutic category.*

	All trials, n (%)	Cytotoxic therapy, n (%)	Targeted therapy, n (%)	Immunotherapy, n (%)
Escalation	217 (58)	99 (63)	154 (60)	26 (50)
In-class comparison	93 (25)	45 (29)	51 (20)	4 (8)
Class switch	54 (14)	5 (3)	51 (20)	**22 (42)**
De-escalation	11 (3)	9 (6)	2 (<1)	0 (0)

*some trials tested multiple categories

2061 **Poster Session (Board #53), Fri, 8:00 AM-11:00 AM**

Use of real-world data to understand barriers to interventional clinical trial enrollment in community oncology clinics (COC).

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Background: Increasing enrollment in clinical trials remains a national priority, yet there are limited data from COCs on the degree to which common trial exclusion criteria (EC) and socioeconomic factors play a role in low enrollment rates. **Methods:** We analyzed data from the nationwide Flatiron Health electronic health record (EHR) derived de-identified database. COC were eligible if they had given a clinical trial study drug to ≥2 patients (pts)/year. We included pts with one of eight advanced or metastatic solid tumors who received ≥1 line of systemic anticancer therapy between 1/1/2014 and 11/30/2019. We defined EC as either: creatinine > 1.5 mg/dl or Ccl < 45 ml/min, Hb < 9 g/dL, ANC < 1500/ul, plts < 100,000/ul, bilirubin > 1.5 upper limit of normal (uln) or AST/ALT > 2.5 uln within 30 days or ECOG performance status (PS) ≥ 2 within 60 days prior to start of therapy. We calculated the percentage of pts with ≥1 EC relative to the group of candidate pts, stratified by therapy line (1L, 2L, 3L+). We used multivariate logistic regression models to evaluate the effect of EC and socioeconomic factors (age, race, Medicaid) on the likelihood of receiving a clinical study drug for each line of therapy. **Results:** In this sample of 35 COCs, 26,988 pts received ≥1 systemic therapy. Pts with ≥ 1 EC: 28.4% in 1L, 34.2% in 2L, 37.4% in 3L. Percentages of pts with an ECOG PS ≥ 2 were: 15.6% (1L), 18.2% (2L), 19.8% (3L). Pts receiving a clinical study drug: 1.7% of 26,988 in 1L, 2.0% of 12,738 in 2L, 2.9% of 5,333 in 3L+, and 3.1% in any line. Excluding pts with ≥1 EC from the denominator modestly improved overall accrual: 2.0% of 19,729 in 1L, 2.3% of 8,588 in 2L, 3.7% of 3,470 in 3L+. In multivariate logistic regression, ECOG PS ≥ 2 was strongly associated with not receiving a study drug [odds ratio (95% CI); 1L: 0.25 (0.16-0.4); 2L: 0.28 (0.17-0.49); 3L: 0.21 (0.1-0.44)]. The likelihood of receiving a clinical study drug (any line) was lower for pts who are Black [0.63 (0.48-0.82)], Latino [0.49 (0.32-0.75)], and pts older than 70 years [0.63 (0.54-0.72)]. Medicaid pts were not significantly less likely to receive study drug [0.83 (0.64-1.07)]. **Conclusions:** In COC, common trial EC reduce pt availability for trials by > 25%. Poor PS is highly prevalent and influential. These EC and complex trial requirements challenge COC's ability to recruit representative pt populations. Future efforts to increase enrollment in trials must consider common EC along with well known barriers to enrollment of unrepresented groups. Research Sponsor: Flatiron Health, Inc.

2062 **Poster Session (Board #54), Fri, 8:00 AM-11:00 AM**

A pilot study of a wearable monitoring system as an adjunct to geriatric assessment in older adults with cancer.

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Background: Advances in health technology provide potential tools that can aid in assessing and monitoring the functional status of the growing older adult population diagnosed with cancer. We piloted a novel wearable monitoring platform, Sensing in At-Risk Populations (SARP), which consists of a smartwatch, software application for health monitoring, and a central data processing and analytics engine. **Methods:** This is a prospective single center, single arm study, utilizing the SARP platform to risk stratify older adults with cancer and determine correlation with treatment-related adverse events and healthcare utilization. Pts age ≥60 undergoing active treatment, were offered participation. Pts were instructed to wear the smartwatch for ≥7 days. We used Kruskal-Wallis to correlate wearable data with clinical outcomes: toxicity, ED visits, hospitalizations, and mortality. We also compared SARP data to independently collected ECOG PS, CARG score, ADLs, and IADLs. **Results:** From 8/2016 to 8/2017, 54 older adults were consented, and 26 had wearable data available for analysis. The average age was 72 years, with 18 males and 8 females. 12 pts had ECOG PS of 0, 12 with ECOG of 1, and 2 with ECOG of 2. 4 pts had CARG score of low, 17 intermediate, and 3 high. Energy intensity was significantly correlated with ED visits, with an effect size of 0.95 ($p = 0.04$). Similarly, energy intensity and hospitalizations had an effect size of 0.87 ($p = 0.06$). The CARG scores were noted to be significantly correlated with dose delay and dose reduction with an effect size 0.45 ($p = 0.05$) and 0.4 ($p = 0.05$), respectively. Spearman correlation analysis demonstrated that walking time, active time, and energy intensity positively correlate with ADLs and IADLs, and inversely correlated with ECOG PS and CARG risk. **Conclusions:** Though this is a limited study due to sample size, the overall trend demonstrated that the SARP platform offers an adjunct tool in assessing and risk stratifying older patients with cancer undergoing active therapy. Additional cohorts are now enrolled with an at-home monitoring system. Research Sponsor: AHRQ R01HS024394.

	Dose Delay		Dose Reduction		ED Visits		Hospitalizations	
	Effect Size	p-Value	Effect Size	p-Value	Effect Size	p-Value	Effect Size	p-Value
ECOG	0.08	0.78	0.11	0.81	0.24	0.68	0.03	0.94
CARG	**0.45**	**0.05**	**0.40**	**0.05**	0.92	0.40	1.18	0.18
ADL	0.46	0.43	0.50	0.29	0.46	0.42	0.44	0.48
IADL	0.20	0.83	0.12	0.99	0.18	0.71	0.07	0.89
Energy	0.56	0.36	0.10	0.85	**0.95**	**0.04**	**0.87**	**0.06**
Active	0.15	0.99	0.48	0.31	0.11	0.85	0.41	0.41
Walking	0.68	0.22	0.23	0.43	0.68	0.14	0.59	0.28
Stationary	0.68	0.22	0.23	0.43	0.68	0.14	0.59	0.28

2063 **Poster Session (Board #55), Fri, 8:00 AM-11:00 AM**

Home ePRO compliance in prostate cancer clinical studies.

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Background: Patient-reported outcomes (PRO) and electronic PRO (ePRO) play an important role in the development and approval of cancer products. Regulatory agencies are encouraging the inclusion of PRO-based endpoints that are indicative of clinical benefit in terms of patient symptoms and overall quality of life (QOL). Compliance with completion of ePRO assessments is an important component for obtaining accurate and high-quality data when conducting clinical trials. Traditionally, ePRO data in oncology trials has been collected mainly at clinic visits due to concerns over poor compliance at home. However, since symptoms and QOL can vary widely through a treatment course, it is often necessary to collect ePRO data more frequently in between clinic visits. It has been hypothesized that home completion, length of time in a study, and number of assessments may affect compliance. **Methods:** To address this hypothesis, ePRO compliance data was analyzed from two clinical studies in prostate cancer. Both studies used a handheld smartphone that contained an application to collect ePRO data. At the randomization visit, subjects completed ePRO assessments in clinic (2-3 questionnaires). Subsequently, all assessments were completed at home, including a daily diary and 1-4 questionnaires completed every 4-8 weeks for up to 14 months. Compliance was calculated as the number of assessments received divided by the number of assessments expected in a given assessment period. To evaluate assessment burden, each assessment period was categorized as requiring a lower number (daily diary and 1 questionnaire) or higher number (daily diary and 2-4 questionnaires) of assessments. **Results:** A total of 1,040 patients were included in the analysis. Overall compliance at the single clinic visit was 100%, which was expected since it was a required randomization visit. Overall compliance at home over 14 months was 80%. Compliance ranged from 78% to 89% over the duration of the studies, with no effect of time in the study on compliance. Compliance remained high even as patient numbers declined. Compliance when patients were required to complete a lower number of assessments (80%) was similar to compliance when patients were required to complete a higher number of assessments (79%). Compliance by region varied from 72% (Middle East) to 87% (Asia and Eastern Europe). **Conclusions:** The collection of ePRO at home provided high compliance that did not vary with length of time in the study or due to assessment burden. At home ePRO assessments provide an effective and feasible approach for recording symptoms and QOL in prostate cancer patients. Research Sponsor: ERT.

2064 **Poster Session (Board #56), Fri, 8:00 AM-11:00 AM**

Self-reported overall wellbeing (OWb), physical function (PFn), and PRO-CTCAE symptom scores in post-operative and chemotherapy patients.

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Background: A standardized, validated tool for capturing symptoms from cancer patients, PRO-CTCAE, has been used to reduce symptom burden, decrease acute care needs, and preserve quality of life. The association between specific PRO-CTCAE symptom scores and single item measures of OWb and PFn were characterized to understand symptom constellations. **Methods:** A novel Epic-based symptom management program (eSyM) was deployed for GI, GYN, and thoracic cancer patients starting chemotherapy (Memphis Baptist) or having surgery (WVU Medicine). Patients received automated prompts to complete surveys via the patient portal (MyChart) on a fixed schedule, approximately twice/week. Each survey included one OWb item, one PFn item, and at least 6 PRO-CTCAE items (pain, nausea, vomiting, fatigue, anxiety, insomnia). The OWb and PFn items, which were created *de novo*, included 5 ordinal response options with corresponding pictograms (emojis from very happy to very sad for OWb; a figure walking to one prone in bed for PFn). Composite scores were generated: 0 for no symptoms, 1-2 for mild/moderate symptoms, and 3 for severe symptoms. We describe OWb and PFn and analyze associations between these items and PRO-CTCAE symptom scores. **Results:** Between 9/10/19-1/22/20, we collected 908 eSyM responses from 166 chemotherapy patients at Baptist (Age, M = 65), and 480 eSyM responses from 97 postoperative patients at WVU (Age, M = 57). The OWb and PFn scores demonstrated moderate correlation with PRO-CTCAE symptom scores (Baptist r = 0.63; WVU r = 0.75), and moderate correlation with mean symptom scores among surgery patients at WVU (r = 0.74); but lower correlation among chemotherapy patients at Baptist (r = 0.53-0.55). Scores improved over time following surgery, but not after initiation of chemotherapy. Among the 730 eSyM responses with none/mild values for both OWb and PFn (52.9% of all responses), only 4.5% reported any severe symptom; among 651 responses with impairment of OWb and/or PFn, 45.2% reported at least one severe symptom. **Conclusions:** Integration of eSyM into the Epic EHR enabled tracking of OWb, PFn, and PRO-CTCAE items. When asked alongside PRO-CTCAE symptom items, two single item OWb and PFn measures provided distinct information and correlated with symptom burden. These results demonstrate the feasibility of integrating ePRO collection into routine post-operative and medical oncology care and that PRO-CTCAE items provide information that is distinct from that obtained from global metrics of well-being. Clinical trial information: NCT03850912. Research Sponsor: U.S. National Institutes of Health.

2065 **Poster Session (Board #57), Fri, 8:00 AM-11:00 AM**

Mobile apps: Breaking barriers to early cancer detection in underserved communities.

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Background: Despite being potentially curable with early detection and timely treatment, breast (BC) and cervical cancers (CC) remain leading causes of death for Colombian women. Lack of cancer screening education, tedious administrative processes, and geographical limitations hinder early cancer detection. Today, technological tools permeate all levels of society and could gather data for user risk stratification, deliver clear and customized information, and help with care coordination, tracking, and addressing communication, transportation, and financial barriers. We aimed to assess the effectiveness of a free mobile application (mApp) to reach women, understand misconceptions about cancer screening, identify users at risk for BC and CC, and coordinate screening tests in Cali, Colombia. **Methods:** The mApp, Ámate, was developed over 4 months and advertised to women ($\geq$14 years) in waiting rooms of 4 healthcare facilities in Cali, Colombia for 23 months. Ámate used educational, evaluative, and risk factor questions followed by brief explanations to assess the population's knowledge, educate users on BC and CC, and identify users in need of BC and/or CC screenings. Correct answers yielded points redeemable for cellular data. Women who required screening were subsequently navigated to a healthcare provider and enrolled in the national cancer program. **Results:** From August 2017-August 2019, 1,043 women from Cali downloaded Ámate and answered all questions. Misconceptions about BC included beliefs that BC can be prevented (87%), obesity does not increase the risk of BC (49%), deodorant causes BC (17%), and only women with a relative with BC can get BC (16%). For CC, misconceptions included that pap smears should not be performed while sexually active (64%), vaginal pain is an early sign of CC (44%), and only women contract HPV (33%). Overall, 31.5% (329) were identified as at-risk and needed a mammogram and/or pap smear. So far, 30% (98) were successfully navigated and completed their recommended screening test(s). Barriers to enrollment in these programs included patient unwillingness, using fake contact information, limited available appointments, and denied access due to healthcare coverage. **Conclusions:** Ámate is an accessible tool that identifies women at-risk for breast and cervical cancer and detects barriers to early cancer detection. Administrative obstacles exist and must be addressed to improve early cancer detection/screening. Ámate is currently being tested in other areas of Colombia and may be useful in other underserved countries. Research Sponsor: American Cancer Society, Susan G. Komen Foundation.

2066 **Poster Session (Board #58), Fri, 8:00 AM-11:00 AM**

MSK eConsent: Digitalizing the informed consent process to improve participant engagement and understanding.

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Background: eConsent was developed to digitize the research participant consenting experience with an educational engagement model. The eConsent platform tiers consent document content in an easy-to-navigate format, using videos, images, and access to supplementary information. We hypothesize that enhancing the consenting experience improves participant engagement and comprehension. **Methods:** Here we present two projects: 1) qualitative assessment of patient engagement in the eConsent process using a standardized 5-question survey sent to all patients who used it during 9 months in 2019, and 2) a report of our preliminary findings from exempt protocol, *Assessing Participant Engagement and Protocol Education in the Consent Process* (X19-055) that quantitatively compares paper and electronic consenting and a) assesses patient agency and b) tests comprehension of key consent elements in 2 protocols: *Storage and Research Use of Human Biospecimens* (06-107) and *Genomic Profiling in Cancer Patients* (12-245). **Results:** 1) 940 patients completed the qualitative experience survey (27% response). Most respondents (777; 83%) indicated that electronic consenting was very easy (371) or easy (406) to use. Only 25 (3%) said electronic consenting was somewhat difficult to use, 3 indicated it was difficult (0.3%), and 64 were neutral. Most (896; 95%) recommended electronic consenting to other MSK patients. Those who reported a 1 unit increase in technology discomfort, only reported a .48 unit increase in eConsent discomfort ($P < .001$). 2)Quantitative 10-question electronic tests were sent to each patient's portal account within 72h after consenting via paper or eConsent to protocols 06-107 and 12-245. To date, for 06-107: 18 paper consenters completed the test with a score of 76% vs 23 eConsent users who scored 80%. For 12-245: 43 paper consenters scored 69% vs 13 eConsent users scoring 80%. Scores are a surrogate marker for patient comprehension and show that 12-245 protocol participants' average testing scores are higher when participants are consented with eConsent vs paper ($P < .01$). 06-107 protocol participants' average test scores are trending toward eConsent improving patient understanding ($P = .11$). We will follow this trend as our sample size increases to a total of 500 participants. Patient agency questions received favorable responses from most patients (100%-84%). **Conclusions:** eConsent enhances participant engagement and understanding and does not impose a digital burden on participants. Research Sponsor: None.

2067 **Poster Session (Board #59), Fri, 8:00 AM-11:00 AM**

A prospective trial of standard versus multimedia counseling in patients undergoing endometrial cancer surgery.

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Background: A patient's understanding of surgery is often limited, especially in the setting of complex oncologic procedures. A recent review found that interventions such as the use of written materials, videos, and websites, improve patients' knowledge of the procedure and their satisfaction with decision making. We sought to determine if a video-based approach in patients undergoing robotic endometrial cancer staging improves satisfaction with perioperative counseling. Secondary objectives were physician satisfaction, patient comprehension, and visit length. **Methods:** From 2018-2019, patients were randomized to standard physician education or multimedia-based education, which included watching two novel animated videos followed by focused physician counseling. Basic demographic information was collected. Patient satisfaction was assessed using the Client Satisfaction Questionnaire-8 (CSQ-8, a validated satisfaction survey, scored 8-32) and a global satisfaction score (10-point scale). Physician satisfaction was assessed using a global satisfaction score. Comprehension was assessed with a 9 question survey at 3 time points. Descriptive statistics were used to compare groups. **Results:** Of 76 patients randomized, the majority were Caucasian (68%), 50-70 years old (70%), and had at least some college education (75%). Most patients had undergone prior surgery (83%) and one fourth had a prior cancer diagnosis. Demographic variables and surgical history were similar between groups. The video patients reported higher satisfaction on the CSQ-8 (31.57 ± 1.02 vs 30.62 ± 2.09, $p < 0.05$) and global satisfaction score (9.95 ± 0.23 vs 9.74 ± 0.55, $p < 0.05$). There was no difference in comprehension scores between groups at either the initial or postoperative visit. At the time of surgery, comprehension scores were higher in the standard education group compared to the video group ($p < 0.01$). There was no difference in physician satisfaction between groups. Among the video group, there was improvement in physician satisfaction between the first and second half of patients enrolled ($p < 0.05$). There was no difference in visit length. **Conclusions:** While multimedia education improved patient satisfaction in the preoperative setting, this was not clinically significant. Provider satisfaction improved over time with the use of a video aid. Multimedia education may be implemented in perioperative counseling based on provider preference and consideration should be made for further study of satisfaction after the initial implementation period. Clinical trial information: NCT03899441.
Research Sponsor: Fowler Fellowship Fund.

2068 **Poster Session (Board #60), Fri, 8:00 AM-11:00 AM**

The association between drug industry payments and NCCN guideline panel membership.

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Background: The high frequency of financial relationships between the pharmaceutical industry and influential oncologists who author clinical practice guidelines may influence guideline recommendations. Therefore, we assessed the financial relationships held by NCCN Guidelines panelists before and after joining the panel, compared to those held by a matched set of oncologists. **Methods:** Membership of NCCN Guidelines panels for the 20 most common cancers was obtained from archival guidelines and linked manually to Open Payments records of industry payments. We identified physicians who newly joined an NCCN panel during the August 2013-December 2018 study period, and we included medical oncologists who had at least 1 year of Open Payments data before and after joining. These medical oncologists who joined an NCCN panel (panelists) were matched 1:2 to medical oncologists with the same gender, institutional affiliation, and medical school graduation year, who did not join an NCCN panel (non-panelists). The dollar value of industry payments was then calculated over the 1 year before (pre-join) and after (post-join) the date that each panelist joined. We used generalized linear models to assess differences in industry payments between the panelists and matched non-panelists in the pre-join period. We used difference-in-difference estimation (DiD) to assess whether joining an NCCN panel was associated with increased payments in the post-join period. **Results:** There were 54 panelists and 108 non-panelists (matched from 1447 eligible oncologists at NCCN institutions). Mean per-oncologist payments among panelists were greater than non-panelists in the pre-join period ($11,259 vs $3,427, p = 0.02). From the pre-join to post-join period there was a similar increase in mean per-oncologist payments among panelists and non-panelists ($2,236 vs. $1,569, DiD estimate +$667, p = 0.77). **Conclusions:** Medical oncologists who were selected to an NCCN Guidelines panel had greater financial ties to industry compared to peer oncologists who were not selected. This difference was present prior to joining; oncologists did not experience a greater increase in financial payments from industry in the 1-year period after joining an NCCN panel. These results suggest an opportunity to reduce the potential influence of industry in oncology clinical practice guidelines through the selection of guideline panelists with fewer ties to industry. Research Sponsor: None.

2069 **Poster Session (Board #61), Fri, 8:00 AM-11:00 AM**

Actionable policy barriers for receiving standard of care treatment among unresected stage III non-small cell lung cancer (NSCLC) patients in the United States.

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Background: Recent data suggests that a significant number of good performance, unresectable stage III non-small cell lung cancer (NSCLC) patients do not receive standard-of-care treatment, i.e. concurrent chemoradiotherapy (cCRT) followed by durvalumab, despite being eligible. However, little is known about actionable policy barriers to delivery of cCRT to this patient population. **Methods:** The National Cancer Database (2004-2016) was used to identify unresected stage III NSCLC patients aged 18-79 years with Charlson comorbidity score ≤ 1. cCRT was defined as the initiations of chemotherapy (CT) and radiation therapy (RT) that were $\leq$14 days (n = 53,444) apart. The remaining treatment groups included sequential CRT (sCRT; n = 16,666), CT only (n = 15,416), RT only (n = 11,579), and no first course treatment (n = 16,691). Multinomial logistic regressions were used to examine the likelihoods of receiving different treatment modalities, controlling for patient demographics, Charlson comorbidity score, health insurance, facility type, social deprivation index (SDI, a comprehensive socio-economic measure; higher SDI indicates lower socioeconomic status [SES]), driving time to facility, diagnosis year, and region. **Results:** Of the total 113,796 patients assessed (median age 66 years), most were male (55.7%), non-Hispanic white (81.7%), and with SDI score $\geq$50 (51.3%). 29.5% had Charlson comorbidity score = 1 while the rest had 0. In adjusted analyses (predicted margins), 47.0% patients received cCRT (sCRT: 14.6%; CT only: 13.5%; RT only: 10.2%; no treatment: 14.7%). Compared to the privately insured, Medicaid, Medicare, and uninsured patients were more likely to receive RT only (relative risk ratios [95%CI]: 1.93 [1.77-2.11]; 1.51 [1.41-1.61]; 1.80 [1.61-2.01], respectively) and no treatment (1.84 [1.71-1.99]; 1.54 [1.45-1.63]; 2.19 [2.01-2.40], respectively) rather than cCRT (all $p < .001$). Moreover, higher SDI was associated with higher likelihood of receiving RT only (highest vs lowest SDI scores: 1.42 [1.33-1.52]), or no treatment (1.46 [1.38-1.55]) rather than cCRT (all $p < .001$). Longer driving time was associated with higher likelihood of receiving CT only ($>$ 120 mins vs $<$ 30 mins: 1.24 [1.10-1.39]), or no treatment (1.33 [1.18-1.50]) rather than cCRT (all $p < .001$). **Conclusions:** Health policies should focus on patients who are not privately insured and live in neighborhoods with low SES. Moreover, helping their transportation needs may also improve the likelihood of receiving cCRT. Research Sponsor: AstraZeneca.

2070 **Poster Session (Board #62), Fri, 8:00 AM-11:00 AM**

Opioid prescribing patterns among generalists & oncologists for Medicare Part D beneficiaries from 2013-2017.

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Background: In response to the opioid crisis, recent policies aiming to reduce opioid prescribing, misuse, & abuse have generated concern that patients with cancer pain may unintentionally experience reduced access to necessary opioid therapy. It is unknown how opioid prescribing patterns have changed between generalists and oncologists during this era. **Methods:** We conducted a longitudinal repeated cross-sectional study estimating adjusted annual national trends in opioid prescribing among generalists & oncologists using the Medicare Part D Prescriber Public Use Files 2013-2017. Poisson models estimated annual adjusted predicted mean rates of opioid prescribing-per-1,000 total prescriptions & long-acting opioid prescribing per-1,000 opioid prescriptions. Poisson models estimated adjusted incidence rate ratios (aIRRs) to quantify annual changes in prescribing rates. **Results:** From 2013-2017 the annual adjusted predicted mean rate of opioid prescriptions per 1,000 total prescriptions decreased from 53.4 to 41.3 among generalists (aIRR = 0.78; $p < 0.01$) and from 133.2 to 105.9 among oncologists (aIRR = 0.83; $p < 0.01$). The rate of long-acting opioid fills per 1,000 opioid prescriptions decreased from 96.0 to 87.0 (aIRR = 0.87; $p < 0.01$) and 235.1 to 222.5 (aIRR = 0.95; $p < 0.01$) for generalists & oncologists, respectively (Table). **Conclusions:** We found large declines in overall opioid prescribing rates among generalists (-22%) and oncologists (-17%) from 2013-2017. Long-acting opioid prescribing rates decreased over 2.5-times more among generalists than oncologists. Opioid policy & advocacy have been effective in reducing the extent of opioid prescribing in the Medicare population but how much of the decrease in prescribing by oncologists is 'appropriate' versus 'inappropriate' deserves further investigation. Research Sponsor: U.S. National Institutes of Health.

	All opioids				Long Acting opioids			
	Generalists		Oncologists		Generalists		Oncologists	
	aIRR (95% CI)	P	aIRR (95% CI)	P	aIRR (95% CI)	P	aIRR (95% CI)	P
2013	Ref		Ref		Ref		Ref	
2014	0.98 (0.97-0.99)	< .01	0.97 (0.95-0.98)	< .01	0.98 (0.97-0.99)	< .01	1.00 (0.98-1.02)	1.00
2015	0.92 (0.91-0.92)	< .01	0.92 (0.91-0.94)	< .01	0.94 (0.93-0.95)	< .01	1.01 (0.99-1.04)	0.24
2016	0.85 (0.85-0.86)	< .01	0.88 (0.87-0.90)	< .01	0.92 (0.91-0.93	< .01	0.99 (0.97-1.02)	0.52
2017	0.78 (0.77-0.78)	< .01	0.83 (0.82-0.85)	< .01	0.87 (0.86-0.88)	< .01	0.95 (0.93-0.98)	< .01

2071 **Poster Session (Board #63), Fri, 8:00 AM-11:00 AM**

Timing of US Food and Drug Administration (FDA) cancer drug approvals relative to publication of clinical trial results.

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Background: Publication of clinical trial results in peer reviewed literature is essential to inform clinicians regarding the use of new anti-cancer treatments, which often have a low therapeutic ratio and require careful assessment of risks and benefits. Publication of registration trials should precede FDA approval to facilitate evaluation and implementation of new therapies. The timing of trial publication relative to FDA drug approvals has not been systematically investigated. **Methods:** We collected all FDA drug approvals for a cancer indication between 2000-19. Trials were identified using FDA labels as well as drugs and publications indexed on HemOnc.org. Approvals for generics/biosimilars, non-oncology indications and label revisions without supportive evidence were excluded. Dates of approval, the approval pathway, approval type (new vs expansion), and the first full publication related to the registration were recorded. Trials and approvals were matched using available metadata. We calculated the proportion of drugs approved prior to publication overall and for those receiving accelerated approval (AA). We used logistic regression to compare rates of pre-publication approval by approval pathway and by new vs expanded approval. **Results:** Among a total of 378 drug approvals, 139 (37%) had pre-publication approval. Of these, the median overall time from approval to publication was 140 days (IQR 64-281 days). For those with approval after publication, median time from publication to approval was 157 days (IQR 72-359 days). The number of drugs approved pre-publication rose by 27% between the first and last quarters of the study period, though, the proportion decreased as more anti-cancer drugs have been approved in recent years (Table). More drugs were approved pre-publication through AA than regular approval (46% vs 34%, OR 1.66 [95% CI 1.03-2.70], p=0.04) and as new approvals vs. expanded approvals (45% vs 32%, OR 1.76 [95% CI 1.15-2.70], p=0.01). **Conclusions:** A substantial minority of FDA approvals occur before trial results are published, with the odds being higher for drugs receiving AA and for new approvals. Since clinicians rely upon published results to inform risk/benefit decisions, efforts are needed to ensure trial results are published by the time of FDA approval of new cancer drugs and indications. Research Sponsor: U.S. National Institutes of Health.

Years	Fraction of pre-publication approvals, n/N (%)	Fraction of AA pre-publication approvals, n/N (%)
2000-05	30/46 (67)	10/15 (67)
'06-10	33/61 (55)	5/14 (36)
'11-15	38/103 (37)	15/28 (54)
'16-19	38/170 (22)	11/32 (34)

2072 **Poster Session (Board #64), Fri, 8:00 AM-11:00 AM**

Mismatch between mortality burden and number of FDA registration trials in highly lethal cancers.

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Background: Treatment successes in cancer are achieved through new drugs tested in clinical trials. However, drug discovery has been disparate across cancer types for various reasons. We sought to investigate if the number of trials used to support United States Food and Drug Administration (FDA) drug approvals is proportional to the incidence and mortality burden of highly lethal cancers, i.e. those with an expected relative mortality of >5% per *Cancer Statistics, 2020* (Siegel et al.). **Methods:** All FDA labels for 258 antineoplastic cancer drugs approved as of January 2020 were reviewed for citations of registration trials supporting initial approval and additional indications. Trials were identified by matching described characteristics (e.g., patients enrolled, clinical trial NCT codes) to publications indexed on HemOnc.org. Trials were labeled by cancer type studied and type of trial (randomized vs non-randomized). **Results:** We identified 559 registration trials in total. Results for the six highly lethal cancers are shown in the table. The percent of registration trials was roughly proportional to incidence, but not mortality burden. For example, despite the 22% expected mortality burden of lung cancer, it had a share of only 11% of registration trials whereas breast cancer has an expected 7% mortality burden, with a share of 14% of registration trials. Chronic myeloid leukemia is expected to cause 1,130 deaths in 2020 (0.2%) and has had 20 registration trials (3.6%). The highly lethal cancers had a higher rate of randomized trials supporting approval than other cancers (84% vs 56%, $p<0.001$ [Chi-square]). **Conclusions:** While the findings may in part be due to disease biology (e.g., pancreatic ductal adenocarcinoma has proven resistant to many novel therapies), our evaluation highlights a potential mismatch between resources and needs. Randomized trials were more often used to support new drug approvals in highly lethal cancers. These findings will be important in regulatory policy. Research Sponsor: U.S. National Institutes of Health.

Cancer type	Expected Cases, 2020 (%)	Expected Deaths, 2020 (%)	Registration Trials (%)	Of which, Randomized (%)
Lung*	228,820 (13)	135,720 (22)	59 (11)	46 (78)
Colorectal	147,950 (8)	53,200 (9)	33 (6)	26 (79)
Pancreas**	57,600 (3)	47,050 (8)	9 (2)	8 (89)
Breast	279,100 (15)	42,690 (7)	80 (14)	74 (92.5)
Prostate	191,930 (11)	33,330 (5)	31 (5)	25 (81)
Liver & Bile duct	42,810 (2)	30,170 (5)	7 (1)	5 (71)
Subtotal	948,210 (52)	342,160 (56)	219	184 (84)
Total	**1,806,590**	**606,520**	**559**	**375 (67)**

*Includes small cell and non-small cell histologies **Includes adenocarcinoma and neuroendocrine histologies

2073 **Poster Session (Board #65), Fri, 8:00 AM-11:00 AM**

Reliability and correlations among quality measures for lung, breast, and colorectal cancer.

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Background: Alternative payment models for oncology seek to improve quality and reduce spending. Yet the ability to measure high-quality care across oncology practices remains uncertain. We characterized quality of care for oncology practices using registry and claims-based measures of processes, utilization, end-of-life care, and survival and assessed correlations of practice-level performance across measure type and cancers. **Methods:** Using SEER-Medicare data, we studied individuals with newly diagnosed lung (N = 95,635), breast (N = 78,736), or colorectal (CRC, N = 51,385) cancers in 2010-2015 treated in oncology practices with $\geq$20 patients (502, 492, and 347 practices, respectively). We measured receipt of guideline-recommended treatment and surveillance (processes), hospitalizations or emergency department visits during 6-month chemotherapy episodes (utilization), care intensity in the last month of life (EOL), and 12-month survival (lung and CRC only). We calculated summary process, utilization, and EOL measures for each patient (number of measures met divided by the number for which the patient was eligible). We used hierarchical linear models with practice-level random effects to estimate summary measures and survival for each practice. We calculated practice-level reliability (a measurement's reproducibility) for each measure based on the between-measure variance, within-measure variance, and sample size. **Results:** Few practices had $\geq$20 patients eligible for most measures (38%, 37%, and 31% of practices had $\geq$20 patients for any lung, breast, and CRC measures, respectively). Measure reliability was low. Only 13%, 7%, and 20% of measures for lung, breast, and CRC, respectively, had a median reliability across practices $\geq$0.7. Among practices with $\geq$20 patients with summary measures of each type within cancer, correlations across measure types were low (all correlation coefficients (r)$\leq$0.21 except a weak correlation of the CRC process summary measure with 1-year CRC survival, $r = 0.38$, $p < 0.001$). Summary process measures were minimally or not correlated across cancer type (lung, breast, CRC; all correlation coefficients $\leq$0.16). **Conclusions:** Claims-based measures of care processes, utilization, EOL care, and survival are limited by small numbers of fee-for-service Medicare patients across practices, even after pooling 6 years of data. Measures have poor reliability and are poorly correlated across measure or cancer type. Additional research is needed to identify reliable quality measures for practice-level alternate payment models. Research Sponsor: Arnold Foundation.

2074 **Poster Session (Board #66), Fri, 8:00 AM-11:00 AM**

Physician whistle-blower's experiences in hematology-oncology safety litigation against pharmaceutical companies.

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Background: Some clinicians have reported initial series of severe or fatal adverse drug reactions (ADRs) that affected large hematology-oncology patient numbers and for which pharmaceutical manufacturers subsequently paid large settlements or fines for allegedly failing to inform physicians about such ADRs. Based on their large human costs ($>$ 1,000 serious illnesses or deaths) and large financial costs ($>$ $100 million in settlements or fines), we have termed these ADRs as titanic ADRs. At a Senate hearing on one titanic, Vioxx, (a COX-2 inhibitor that was evaluated for colorectal cancer prevention), the clinician reporter was termed a "whistleblower" by a senator although this individual had not filed a formal whistleblower lawsuit. We identified physicians who would fit this characterization of whistleblowers and had published titanic hematology-oncology ADR reports in high impact journals. **Methods:** Hematology-oncology titanic ADRs were identified by collaborators with two NIH-funded drug safety networks (RADAR and SONAR (1998-2019)). Exclusion criteria included having also filed a whistleblower lawsuit. Qualitative research analyses evaluated content of statements made by whistleblowers to national reporters or at congressional hearings. **Results:** 18 physicians who reported titanic hematology/oncology-associated ADRs in peer-reviewed literature and discussed their findings in national news media outlets are included. Titanic ADRs included death, nephrogenic systemic fibrosis, coronary artery disease, and venous thromboembolism related to COX-2 inhibitors, heparin, gadolinium dye, thalidomide, lenalidomide, epoetin, and darbepoetin. Related financial settlements ranged from $100 million to $4.85 billion. Whistleblowers were from the United States, Denmark, and Germany. Primary motivations were public health and medical awareness. Whistleblowers reported having gone through lawsuits and having had executives request that the whistleblowers' university terminate employment. One whistleblower was quoted saying "I believe that the lawsuit is an attempt to silence me." **Conclusions:** Clinician whistleblowers of titanic hematology-oncology ADRs experienced reputational, financial, and personal threats. Motivations for reporting titanic ADRs were mainly public health and medical awareness focused. This differs from our previous study on clinicians publishing on non-titanic ADRs, where the primary motivation was scientific curiosity. Research Sponsor: American Cancer Society.

2075 **Poster Session (Board #67), Fri, 8:00 AM-11:00 AM**

Resource and reimbursement barriers to comprehensive cancer care (CCC) delivery: An Association of Community Cancer Centers (ACCC) survey research analysis.

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Background: CCC delivery is recommended in guidelines, required by accreditation bodies, and essential for high-quality cancer management. Barriers, such as insufficient reimbursement and lack of specialist staff, prevent consistent access to and delivery of CCC, particularly supportive oncology services. Challenges especially persist in community programs, where access to philanthropy and similar funding is limited. ACCC conducted a representative survey of its member programs to elucidate capacity and barriers to CCC delivery in the community/academic setting in order to inform policy and value-based payment reform. **Methods:** Survey development methodology included item generation with expert review, iterative piloting and cognitive interviews to achieve content and internal validity. An online survey was piloted at the ACCC 2018 Annual Meeting and sent to member programs via email link. The final survey included 22 questions on availability and funding for supportive services. Twenty-seven supportive oncology services were assessed for availability, reasons not offered, reimbursement/funding and patient payment. Analyses were conducted with SAS. **Results:** 172 of 704 ACCC member programs responded and completed the majority of survey as of 10/7/19. Despite a high proportion of programs offering supportive oncology services, gaps between cost and reimbursement were present for all (Table). Deficits in reimbursement are compensated by patient out-of-pocket payments, grants and donations. Most centers report needing more staffing in psychology (61%), social work (60%), navigation (59%), nutrition (57%), palliative care (56%), genetic counseling (52%), and financial counseling (53%). Gaps were observed regardless of region or practice type. **Conclusions:** There is a lack of sufficient reimbursement, staffing, and budget to provide CCC across the U.S., regardless of region or practice type. Oncology care models and reimbursement policies must include CCC services to optimize delivery of care. Research Sponsor: Association of Community Cancer Centers.

Reimbursement for selected supportive services.

n variable, max n = 172	Service offered within cancer program (%)	≤50% cost covered by reimbursement (%)	≤74% cost covered by reimbursement (%)	Reimbursed, but not sufficiently (%)	Rarely/never get paid for service (%)
Distress management	92	33	44	43	22
Fertility preservation	42	47	47	43	0
Genetic counseling	77	29	44	66	11
Patient navigation	92	33	51	9	73
Palliative care	79	33	54	52	2
Survivorship care planning	86	34	49	46	22
Nutrition consults	90	37	55	35	35

2076 **Poster Session (Board #68), Fri, 8:00 AM-11:00 AM**

Annual trends in opioid prescribing for patients (Pts) with metastatic non-small cell lung cancer (mNSCLC): Cancerlinq data analysis, 2010 to 2017.

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Background: Despite opioid misuse and abuse, opioids remain a mainstay for management of cancer pain. Government, payers, and institutions have implemented policies to reduce opioid use. The impact of these restrictions on oncologist prescriptions (Rx) of opioids and management of cancer pain in pts with cancer is not well known. **Methods:** A retrospective, observational analysis used deidentified EHR data from ASCO's CLQ Discovery database. Study cohort included pts with mNSCLC diagnosis and >1 clinical encounter (including opioid Rx) from CLQ clinician during 2010-2017. Opioids included DEA schedule II and III opioid drugs prescribed for cancer pain, excluding cough suppressants. Annual Rx rates were defined as the number of mNSCLC pts who had $\geq$ 1 opioid Rx dated 2010-2017 per CLQ total mNSCLC pts who had ≥ 1 clinical encounter in the year. Annual rates demonstrate trends in opioid prescribing patterns over time. **Results:** 18,106 pts with mNSCLC clinical activity between 2010 and 2017 were identified. Overall, 39.8% of pts had opioid Rx in 2010-2017. Annual Rx rates increased from 2010-2015 and fell 2016-2017 (see table). Hydrocodone was the second most frequently prescribed opioid overall (N=4211 pts), but Rx rates began to decline in 2012. Tramadol and acetaminophen + codeine Rx rates gradually increased throughout the time period. DEA initially scheduled Tramadol as schedule IV in 2014. **Conclusions:** Opioids are commonly prescribed by oncologists for patients with mNSCLC. Rx rates have declined since 2015, likely due to increased government, payer, and institutional restrictions on access. Hydrocodone Rx declined since 2012, perhaps exacerbated by reclassification from schedule III to schedule II by the DEA (October 2014). Rxs for schedule IV and III opioids (known to be of lower potency) increased modestly, likely due to comparatively fewer prescribing restrictions. Additional research is needed to understand whether the decline continues and the impact on management of cancer pain, particularly among metastatic patients. Research Sponsor: ASCO and Concerto HealthAI.

Year of Activity	Number of Pts With Diagnosis N	Pts With Opioid Rx N (%)	Pts with Hydrocodone Rx Among Opioid Rx Pts	Pts with Tramadol and/or Acetaminophen + Codeine Rx Among Opioid Rx Pts
2010	2520	449 (18%)	118 (26%)	15 (3%)
2011	2647	550 (21%)	212 (39%)	22 (4%)
2012	4084	878 (21%)	324 (37%)	53 (6%)
2013	4823	1256 (26%)	440 (35%)	87 (7%)
2014	4953	1579 (32%)	535 (34%)	136 (9%)
2015	5336	1807 (34%)	589 (33%)	160 (9%)
2016	5067	1676 (33%)	541 (32%)	169 (10%)
2017	4061	1235 (30%)	398 (32%)	145 (12%)

2077 **Poster Session (Board #69), Fri, 8:00 AM-11:00 AM**

Pivotal trial endpoints and prices of cancer drugs in the US and Europe.

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Background: A key clinical outcome for new cancer drugs is improvement in overall survival (OS), defined as time from the date of randomization to the death from any cause. However, many cancer drugs are approved by regulators based on changes to surrogate measures of OS, such as progression-free survival or overall response rate. When surrogate measures are not validated, they can provide misleading information about drug efficacy. We categorized pivotal trial endpoints for recently-approved cancer drugs in the US and Europe as showing improvements in OS vs non-OS surrogates, and evaluated the correlation with drug prices. **Methods:** We identified new drugs FDA-approved between 2009 and 2018 that were indicated to treat solid and hematologic tumors in adults and that had also been approved by the EMA and Swissmedic by December 2019. Launch prices were extracted and adjusted to average sales prices for monthly treatment costs in the US and compared to currency-adjusted ex-factory monthly treatment costs in Germany, Switzerland, and England. Pivotal clinical trial primary endpoints were collected from the drug labeling and FDA medical reviews for the US, and the EMA public assessment reports for Europe, and categorized as OS in any trial vs. not. Pearson's correlation tests assessed the association between launch prices and OS vs non-OS endpoints in each country. **Results:** 54 drugs were approved by the FDA, EMA, and Swissmedic during the study period. In the US, 30 (56%) were approved based on OS by contrast to 35 (65%) in the EMA. The number of cancer drugs approved by the FDA based on OS decreased in the past years. By contrast, the number of approved cancer drugs by the EMA based on OS were stable. There was no association for the US ($p = 0.05$), Germany ($p = 0.13$) and England ($p = 0.12$), while Switzerland revealed an association ($p = 0.03$) between OS endpoint and price. **Conclusions:** Reductions in use of OS endpoints as the basis for cancer drug approval in the US is concerning. Drug pricing should be better aligned with the benefit that drugs provide to patients, as measured by clinical trial outcomes such as OS. Research Sponsor: Swiss Cancer Research Foundation.

2078 **Poster Session (Board #70), Fri, 8:00 AM-11:00 AM**

The clinical impact of ASCO "choosing wisely" recommendations on staging imaging for early stage breast cancers: An interrupted time-series analysis utilizing SEER-Medicare data.

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Background: The "Choosing Wisely" (CW) list, released by the American Society for Clinical Oncology (ASCO), highlights low-value procedures. In 2012, the CW recommendations advised against the use of staging imaging, including Positron Emission Tomography (PET), Computerized Tomography (CT) and radionuclide bone scans, for the staging of early breast cancer at low risk for metastasis. The objective of this study was therefore to assess the impact of the ASCO CW recommendations on staging imaging among early stage breast cancers. **Methods:** Women above the age of 66 with an early stage incident breast cancer diagnoses between 2010 and 2015 were identified within the linked SEER-Medicare data. The primary outcome of interest was the proportion of patients with a claim for staging imaging in the six months following the breast cancer diagnosis. Negative binomial regression, adjusting for pre-recommendation trends, was performed to estimate the changes in the rate of imaging staging within each year following the release of the recommendation. **Results:** A total of 50,004 women were identified during the study period. Prior to the release of the recommendations in 2012, the staging imaging rates among women newly diagnosed with early stage breast cancers were 5% greater in 2010 ($p<.01$) and 4% greater in 2011 ($p<.01$). Following the release of the recommendations, staging imaging rates did not decrease significantly in 2013 (2%;$p=0.18$). Imaging rates did, however, significantly decrease by 13% in 2014 ($p<0.01$) and by 16% in 2015 ($p<0.01$). **Conclusions:** The CW recommendation was associated with a significant decrease in unadvised staging imaging among incident early stage breast cancer diagnosis in the second and third year following its release. These findings demonstrate an improvement in the proportion of potentially inappropriate staging imaging in early stage breast cancers. The creation and dissemination of resources, such as the CW recommendations, serves as a powerful tool to improve clinical practice, quality of care, and patient safety from secondary malignancies, anxiety, and overdiagnosis. Research Sponsor: UAMS Laura Hutchins Distinguished Chair in Hematology Oncology.

2079 **Poster Session (Board #71), Fri, 8:00 AM-11:00 AM**

Understanding practice variation with a clinical pathways system: Differences by physician and practice factors, and changes in practice over time.

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Background: Clinical oncology pathways aim to support clinical decision-making and reduce unwarranted practice variation across an enterprise. The Dana-Farber Cancer Institute (DFCI) implemented web-based oncology pathways with DFCI-customized content in each disease center and at each of its satellites. Our pre-specified aim was an on-pathway rate of 70-85%. **Methods:** Treatment decisions were electronically captured as on- or off- pathway. Monthly metrics about usage and on-pathway rate were shared with users on a monthly basis. Physicians were categorized into quintiles based on the calculated on-pathway performance during the first 90 days of each individual's use of the platform. On-pathway rates were then calculated for days 91-360 to study changes in behavior over time. Physician and practice factors were examined to determine any differences by initial on-pathway quintile classification. **Results:** 122 physicians were eligible for inclusion in this analysis (minimum 5 navigations in each study period). On-pathway rates showed significant variability in the initial 90-day period: quintile 1 median 100%, quintiles 2-4 80.2%, and quintile 5 50% (Table). In the follow-up period, median on-pathway rates shifted into the pre-specified goal range for all groups. Physicians in quintiles 1 or 5 of initial on-pathway rate were more likely to have fewer total navigations than were physicians in quintiles 2-4 (p=0.003). While no other physician or practice characteristic differed significantly by on-pathway rate group, physicians in the first or last quintile were more likely to be in an academic setting, have a PhD, or navigate fewer pathways. **Conclusions:** Over time, the deployment of a web-based clinical pathways program resulted in greater uniformity in physician practice, based on on-pathway rate. Familiarity with the pathways platform and its navigation, monthly feedback about usage, and evolution of content over time are some factors that might have played a role. Research Sponsor: None.

Comparison of on-pathway rate between 0-90 days of use and 91-360 days of use, by quintile group.

	0-90 Days of Use			91-360 Days of Use			
Quintile Group	**Range**	**Median (IQR)**	**Mean±STD**	**Range**	**Median (IQR)**	**Mean±STD**	**P-value***
Quintile 1 (n = 26)	94.7-100%	100% (100-100%)	99.4±1.7%	54.5-100%	84.0% (77.8-95.8%)	84.1±13.2%	<0.0001
Quintiles 2-4 (n = 72)	66.7-94.1%	80.2% (75.9-87.5%)	80.8± 8.1%	38.5-100%	80.6% (69.7-84.9%)	77.2±13.0%	0.024
Quintile 5 (n = 23)	37.5 – 66.0%	50% (50-58.3%)	52.2± 8.0%	48.3 – 87.5%	71.1% (60-77.8%)	70.2±11.6%	<0.0001

* Paired t-test

2080 **Poster Session (Board #72), Fri, 8:00 AM-11:00 AM**

Association of financial conflicts of interest with academic success among junior faculty in hematology and oncology.

Angela J. Fought, Andrew A. Davis, Melissa M. Shaw, Vinay Prasad, Suneel Deepak Kamath; University of Colorado Denver, Denver, CO; Robert H. Lurie Comprehensive Cancer Center, Feinberg School of Medicine, Northwestern University, Chicago, IL; Northwestern University, Chicago, IL; Oregon Health & Science University, Portland, OR; Cleveland Clinic Taussig Cancer Institute, Cleveland, OH

Background: Financial conflict of interest (COI) represents a complex issue in hematology and oncology. Little is known about when COIs develop during a career and if these correlate with early career success. We evaluated self-reported COIs for junior faculty members at 10 academic cancer centers and examined if these financial relationships with industry correlated with measures of academic career success. **Methods:** The study evaluated 229 assistant professors from the top 10 cancer centers based on the 2018 US News Cancer rankings. Faculty characteristics were determined from hospital websites including the number of years since completing fellowship. Data regarding National Institute of Health (NIH) funding were obtained. Industry funds (Sunshine Act funds; SAF) were identified from the Centers for Medicare & Medicaid Services (CMS) Open Payments database from 2013-2017. Self-reported COIs were obtained from the American Society of Clinical Oncology (ASCO) or American Society of Hematology (ASH) disclosures databases, and through review of disclosures from recent publications. Measures of academic success included h-index and number of publications. We assessed the influence of number of COIs and SAF received on measures of academic success. **Results:** Of the 229 included faculty, 45% were female, 39% graduated fellowship in 2015 or later, 35% were double-boarded, 40% had dual degrees and 15% received NIH funding. Approximately 46% of faculty had at least 1 COI. COIs (ASCO/ASH) were positively correlated with COIs self-reported in publications and total SAF (Spearman correlations 0.57 and 0.54, both $P < 0.01$). The development of COIs and the number of SAF increased with years in practice (Spearman correlations 0.37 and 0.28, both $P < 0.01$). COIs and SAF correlated with h-index (Spearman correlation 0.40 and 0.41, both $P < 0.01$). After adjusting for years since fellowship, linear regression demonstrated that log-transformed h-index and number of publications were associated with SAF ($P < 0.01$) and COIs (ASCO/ASH) ($P = 0.01$). **Conclusions:** Financial COIs were present in nearly half of the faculty and increased with more time since completing fellowship. Measures of academic success were positively correlated with COIs (ASCO/ASH) and SAF. These data suggest that cultivating industry relationships may aid faculty in establishing early academic success. Research Sponsor: None.

2081 **Poster Session (Board #73), Fri, 8:00 AM-11:00 AM**

Adoption of behavioral restrictions as anti-infective measures: A survey among solid tumor patients.

Eliya Shachar, Leora Ferro, Shira Peleg Hasson, Waller Emmanuel, Ido Wolf; Tel Aviv Sourasky Medical Center, Tel Aviv, Israel; Medison Pharma, Tel Aviv, Israel; Tel Aviv Sourasky medical center, Tel Aviv, Israel

Background: Despite lack of evidence, a wide range of rigorous behavioral and social restrictions are recommended in various guidelines and websites in an attempt to mitigate infections. These include patient guided sites. We aimed to study the practices of patients with solid tumors treated with active therapy. **Methods:** We conducted an anonymous survey among cancer patients treated at a tertiary care center, addressing behavioral approach to infection prevention, by assessing adopted social (seven items), environmental (five items), and dietary (eight items) limitations, as well as compliance to influenza vaccinations. Clinical data included neutropenic fever (NF), and therapy myelosuppressive potential. Multivariable Poisson regression adjusted for sex, age, disease status, therapy to estimate the impact of these restrictions. **Results:** 214 patients with solid tumors responded to the survey, the majority female (59%), with a median age of 63. The most common tumor types included breast (28%), lung (14%), and colon (9.3%). Most (68%) were treated with chemotherapy, 17% with immunotherapy, 11% with biologicals and 3% with chemo-immunotherapy. Only 6% were admitted for NF. Sources of information regarding restrictions included physicians (4%), nurses (32.9%), and internet (9.8%); the majority were self-imposed. 53% maintained environmental limitations (traveling, sun exposure, hair dying), 37% adopted social restrictions (abstained from children, public places), and 21% affirmed dietary constraints (raw vegetables, tap water consumption). Females practiced stricter environmental and dietary restraint ($p < 0.05$), with a numerical trend reflecting stricter female social measures ($p < 0.4$). With no difference in practices among patients treated for a malignant disease and curative intent, and no difference in practice across therapies, in those treated with chemotherapy and immuno-therapy. 37% affirmed difficulty in adherence to these limitations. **Conclusions:** Our findings indicate that despite lack of evidence, cancer patients adopt anti-infective behavioral measures, which have a deleterious impact on quality of life. These practices are being used even among patients at low or no risk of NF. These findings call for implementation of an education program and development of practical instructions enabling patients to resume their normal life Research Sponsor: None.

2082 **Poster Session (Board #74), Fri, 8:00 AM-11:00 AM**

Telemedicine visits reduce time to biopsy, travel time and costs for interventional radiology patients.

Suken Shah, Joseph Erinjeri, Qiu Xia Guan, Christian Otto, Stephen Barnett Solomon; Memorial Sloan Kettering Cancer Center, New York, NY

Background: Telemedicine has been utilized to increase access to care for patients in primary care practices and more recently, specialty practices. The purpose of the study was to test the hypothesis that adding a telemedicine clinic practice could decrease the time to biopsy, travel time and cost for interventional radiology (IR) clinic patients. **Methods:** Telemedicine visits were performed by a physician or advanced practice provider (PA or NP) at a single institution, academic medical center to patients at 3 MSK regional locations in NY and NJ. Total patient encounters and data from November 2017 to October 2019 were analyzed. Primary outcome measures were wait time from the IR referral to biopsy procedure visits, patient travel time and travel cost, stratified by in-person vs telemedicine visit. Round-trip travel distance and costs for patients were calculated by determining the offset travel. Cost (economic) benefit was the sum of: Federal cost per mile for travel, toll and parking costs, and doctor visit lost wages. **Results:** There were 172 MSK Regional site telemedicine visits. There was a significant reduction in time from referral to biopsy for telemedicine visits compared to in-person visits (12 vs 17 days, $p < 0.0001$). Additionally, there was a significant reduction in travel time for telemedicine visits vs travel time to Manhattan for an in-person visit ($p < 0.0001$). Telemedicine visit patients had to travel 367 less hours than an in-person visit and saved a total of 11,222 in miles that they did not have to travel. Telemedicine patients accrued $14,652 in economic benefits due to reduced travel costs and lost wages from work. **Conclusions:** Telemedicine significantly reduced the time to biopsy, travel time and cost for Interventional Radiology patients compared to in-person visits. Telemedicine for IR patients increases access to care for patients and allow for more efficient use of physician time and resources. Research Sponsor: None.

2083 **Poster Session (Board #75), Fri, 8:00 AM-11:00 AM**

Documentation patterns and impact on observed side effects of the CANKADO ehealth application: An exploratory analysis of the PreCycle trial.

Tom Degenhardt, Nadia Harbeck, Peter A. Fasching, Rachel Wuerstlein, Diana Lüftner, Ronald E. Kates, Johannes Schumacher, Claudia Wenzel, Timo Schinkoethe, Marcus Schmidt; University of Munich, LMU, Munich, Germany; Brustzentrum der Universität München (LMU), Munich, Germany; Erlangen University Hospital, Department of Gynecology and Obstetrics, Comprehensive Cancer Center Erlangen-EMN, Friedrich-Alexander University Erlangen-Nuremberg, Erlangen, Germany; Breast Center, Dept. Obstetrics & Gynecology, University of Munich (LMU) and CCCLMU and West German Study Group, Munich, Germany; University Hospital Berlin, Charité Campus Benjamin Franklin, Berlin, Germany; West German Study Group, Moenchengladbach, Germany; Palleos Healthcare Services Gmbh, Wiesbaden, Germany; CANKADO Service GmbH, Cologne, Germany; CANKADO Service GmbH, Munich, Germany; Department of Obstetrics and Gynecology University Hospital Mainz, Mainz, Germany

Background: PreCycle (NCT03220178), a multicenter, randomized phase IV Intergroup trial evaluates the impact of ePRO assessment on quality of life (QoL) in HR+/HER2- locally advanced or metastatic breast cancer patients (pts) treated by palbociclib (P) and an aromatase inhibitor or P+fulvestrant. Pts willing to use the web/APP-eHealth solution CANKADO are eligible. Patients are randomized (2:1, stratified by therapy line) to the active (CANKADO PRO-React) or inactive inform arm. Primary endpoint is time to deterioration (TTD) of QoL. **Methods:** The trial started in 2017 and is ongoing (81 centers); regular safety reports are routinely provided to the study sponsor. Analysis of distribution of serious adverse events (SAE) was initiated by the trial leadership and performed using the Oct 15, 2019 safety report. Data that could bias primary or secondary endpoints were not analyzed. Bayesian inference (non-informative prior) was used to estimate probabilities; no corrections for potential multiplicities were made. **Results:** At data cut-off, 261/281 randomized patients had received study medication and provided CANKADO documentation. At time of evaluation, a total of 40298 days were documented. CANKADO was used on 59% (+/-10%) of all days over a 2-year period. SAEs were observed in 26/175 (14.9%) of all active-arm patients vs. 18/86 (20.9%) of inform-arm patients (90% probability of reduction in inform patients). Total SAEs were 36 (active) vs. 27 (inform); corresponding SAE incidence per hundred patients was 20.6 vs. 31.4, a relative reduction of about one-third. **Conclusions:** CANKADO is well accepted and used regularly by pts in PreCycle, so far over a 2-year period. The present (unplanned) analysis suggests a potentially substantial, clinically relevant reduction in relative SAE incidence among 1stL pts using PRO-React, with a more modest decrease overall. This analysis is preliminary, representing a snapshot, and cannot provide a definitive explanation for the observed SAE reduction. PreCycle will continue to enroll patients in order to further evaluate the potential benefits of interactive eHealth support. Collaborators: WSG WOMEN´S HEALTHCARE STUDY GROUP, CANKADO, Pfizer, AGO-TraFo, AGO-B, Deutsche Gesellschaft für Hämatologie und Medizinische Onkologie e.V. Sponsor: Palleos Healthcare GmbH Keywords: eHealth, Adverse Events, Palbociclib Clinical trial information: NCT03220178. Research Sponsor: Palleos Healthcare GmbH.

2084 **Poster Session (Board #76), Fri, 8:00 AM-11:00 AM**

Administration of immune checkpoint inhibitors using teleoncology model of care in Far North Queensland: A multicenter review of safety outcomes.

James Fletcher, Sebastian Kang, Amy Brown, Sabe S. Sabesan, Megan Lyle, Ritwik Pandey, Andrew Lui, Natalie Rainey, Barbara Kelly, Andrew Lachlan Schmidt, Abhishek Jagdish Joshi; Liz Plummer Cancer Centre, Cairns and Hinterland Hospital and Health Service, Cairns, QLD, Australia; Townsville Hospital and Health Service, Townsville, QLD, Australia

Background: The Teleoncology model of care, as developed and implemented across health services in Far North Queensland (Australia), improves access to specialist oncology services, including telehealth supervised administration of Oncology drugs for patients in rural/remote towns. There is limited published data regarding the safety of checkpoint inhibitor immunotherapy when it is administered via Teleoncology. Aim: Evaluate safety of immunotherapy administration via Teleoncology, including immune-related adverse events (irAE), treatment delays, hospital admissions and interhospital transfers, in comparison to a retrospective control population. **Methods:** Retrospective review of all patients treated with immunotherapy via Teleoncology as part of Cairns and Hinterland Hospital and Health Service (CHHHS) and the Townsville Teleoncology Network (TTN) between January 2015 and April 2019. A retrospective cohort treated at Townsville Cancer Centre over the same time period was used as a control group. **Results:** Fifty-one patients received a total of 624 cycles of immunotherapy (all single agent anti-PD-1/L-1) via Teleoncology. The control population included 142 patients who received 1697 cycles of immunotherapy. Baseline characteristics were well matched between groups. Compared to the control population, patients treated via telehealth did not have statistically significant differences in the rate of Grade 3+ irAE (13.7% v 8%), hospital admissions (13.7% v 7.4%) or protocol suspensions due to immune toxicity (16% v 10%). One patient with Grade 3+ irAE required interhospital transfer for investigation and management, which occurred within 24 hours of presentation to hospital. There were no treatment-related mortalities in either group. **Conclusions:** Checkpoint inhibitor immunotherapy can safely be delivered using the Teleoncology model of care in rural and remote centres. The incidence of toxicity for single agent immunotherapy was predictably low and not significantly different between groups, however the numbers in this retrospective study were small. The time to recognition and management of immune mediated toxicity in rural and remote centres is an important factor that was not assessed in this study and will be considered in future work. Research Sponsor: None.

2085 **Poster Session (Board #77), Fri, 8:00 AM-11:00 AM**

TeleTriage at a high-volume specialty cancer center: Aligning patient volume and need with available resource.

Stutman E Robin, Jason Napoli, Erika Duggan, Danny Joseph, Eoin Dawson, Rennie Mohabir, Lee Erickson, Christian Otto, Jeffrey S. Groeger; Memorial Sloan Kettering Cancer Center, New York, NY

Background: The Memorial Sloan Kettering (MSK) Urgent Care Center (UCC) functions as the emergency room for MSK. With 23,000+ visits annually, increasing volume and acuity means more days over capacity. Patients experience increased wait times to see clinicians, complete evaluation, and transfer to an inpatient bed. The UCC TeleTriage Program is a remote triage program which aims to align patient volume and need with available resources, improve patient experience, and streamline flow through the UCC. By managing resources more efficiently and expediting initial evaluation, the program promotes timely patient access to care, while maintaining MSK's standard of care. **Methods:** UCC TeleTriage began July 2018 with the Gastrointestinal Medical Oncology service. The Service Nurse refers patients to TeleTriage on weekdays, from 9a.m.- 4:30p.m. The TeleTriage clinician contacts each patient within 30 minutes of referral, takes the history, and determines the initial plan. Patients are directed to a local ER, clinic, or UCC based on level of acuity, real-time GPS, and specific need. For stable patients coming to UCC, TeleTriage focuses on initiating testing prior to registration in UCC. **Results:** TeleTriage patients have (virtual) contact with a UCC clinician within 30 minutes of referral, whereas non-TeleTriage patients wait 110 minutes or more. TeleTriage patients are discharged from UCC up to 42 minutes more rapidly. TeleTriage patients who receive imaging prior to registration in UCC receive a final disposition up to 93 minutes sooner. About 4% of TeleTriage patients are managed at home. In a small number of TeleTriage patients with severe complications of cancer-treatment, significant morbidity was avoided due to early intervention and coordination of care. **Conclusions:** TeleTriage patients have contact with a UCC clinician measurably faster than non-TeleTriage patients. Their evaluation is also started earlier. By managing less acute patients at remote sites or at home, TeleTriage can help patients avoid unnecessary travel, (time) expenditure, and hospital contact. TeleTriage patients who come to UCC, spend less time in UCC than non-TeleTriage patients and they discharge faster. By utilizing cancer care expertise, TeleTriage can significantly impact patient outcomes and utilize resources more effectively. Research Sponsor: Memorial Sloan Kettering Cancer Center.

TPS2086 **Poster Session (Board #78), Fri, 8:00 AM-11:00 AM**

Implementing a clinical risk prediction tool for patients undergoing active cancer treatment.

Nathan Handley, Adam Binder, Michael Li, Aliya Rogers, Valerie Pracilio Csik; Thomas Jefferson University, Philadelphia, PA; Albert Einstein College of Medicine-Montefiore, Bronx, NY; Thomas Jefferson University and Hospital, Philadelphia, PA; Sidney Kimmel Cancer Center of Thomas Jefferson University, Philadelphia, PA; Sidney Kimmel Cancer Center, Philadelphia, PA

Background: Acute care utilization (ACU), encompassing both emergency department visits and hospitalizations, is common in patients with cancer, with nearly three quarters of patients with advanced disease hospitalized at least once in the year after their diagnosis. Efforts to prospectively identify these patients prior to ACU have led to the development of a variety of scoring systems for specific cancer patient populations, including the elderly and those initiating palliative infusional chemotherapy. Prospectively identifying patients may enable early interventions to reduce ACU. However, few studies have demonstrated effective implementation of such prediction tools in clinical practice. We developed an oncology risk score (ORS) for active oncology patients (defined as patients with an active cancer diagnosis in the last 12 months who had a Medical Oncology encounter in a 180-day period) to prospectively determine risk of ACU. Patients are defined as high risk (18% of patients, accounting for 57% of historical ACU), intermediate risk (25% of patients, accounting for 25% of ACU), or low risk (56% of patients, accounting for 18% of ACU) by the ORS. We are currently deploying a pragmatic implementation initiative to evaluate the impact of targeted nurse navigator (NN) outreach to patients defined as high risk for ACU by the ORS. **Methods:** The ORS is embedded within the health system electronic medical record. The ORS will be queried on a weekly basis. NNs will contact identified patients, prioritizing patients not yet identified by the navigation team by other means. Following chart review, NNs will either meet patients in person (if a visit is already planned within 24 hours) or complete standard navigation outreach and documentation (consisting of phone call and barrier assessment, as well as appropriate nursing intervention) if no visit is planned. NNs will determine follow up cadence based on clinical judgement. Efficacy will be determined using a case-control method. Case patients will be OCM patients defined as high risk by the ORS (historical n = 289); control patients will be non-OCM high risk patients (historical n = 388). The total number of patients in the case and control groups, as well as the proportion of patients in the group utilizing acute care, will be monitored over time. Proportion of high risk patients known to navigation will be tracked. ACU in medium and low risk groups will also be monitored. Targeted outreach to high risk patients using the ORS began on 2/5/2019. Research Sponsor: None.

TPS2087 **Poster Session (Board #79), Fri, 8:00 AM-11:00 AM**

A multi-stakeholder platform to prospectively link longitudinal real-world clinico-genomic, imaging, and outcomes data for patients with metastatic lung cancer.

Michael W Lu, Guneet Walia, Katja Schulze, Michelle Yuri Doral, Sophia L. Maund, Sarah Gaffey, Moran N Cabili, Ariel B. Bourla, Robert J. Green, Eric C. Santos, Roy S. Herbst, Anne C. Chiang, Lee S. Schwartzberg; Genentech, Inc., South San Francisco, CA; Genentech, Inc., San Francisco, CA; Foundation Medicine, Inc, Cambridge, MA; Flatiron Health, New York, NY; Cancer and Hem Ctrs of Western Michigan, Grand Rapids, MI; Yale Cancer Center, New Haven, CT; West Cancer Center and Research Institute, Germantown, TN

Background: Making personalized diagnostics and treatments a reality for every cancer patient necessitates comprehensively capturing the patient journey. Real-world data has shown promise for the future of clinical research and advancing precision medicine. However, certain limitations exist such as data quality management as well as bias and confounding factors associated with retrospective analyses. We present a multi-stakeholder platform to prospectively collect and link real-world clinico-genomic, imaging, and outcomes data to longitudinal blood genomic profiling for lung cancer.
Methods: This study is enrolling approximately 1000 patients with metastatic non-small cell lung cancer or extensive-stage small cell lung cancer who will initiate standard-of-care systemic anti-neoplastic treatment, regardless of line of therapy, at 20 community oncology and academic practices within the Flatiron Health network. Relevant clinical data points from both structured and unstructured fields will be collected through the electronic health records via technology-enabled abstraction, eliminating the need for case report forms. Digital pathology and clinical images at standard-of-care visits will be collected. Blood samples for circulating tumor DNA (ctDNA) profiling using FoundationOne Liquid will be collected at three timepoints: enrollment, first tumor assessment, and end of treatment. Tumor tissue samples may be submitted at baseline for genomic profiling using FoundationOne CDx. Overall survival follow-up will occur until death, withdrawal of consent, loss to follow-up, or end of study. The objectives are to evaluate 1) the feasibility of building a scalable, prospective platform and 2) the associations between ctDNA and real-world clinical outcomes, including overall survival. Enrollment is ongoing. Clinical trial information: NCT04180176. Research Sponsor: Genentech, Inc.

TPS2088 **Poster Session (Board #80), Fri, 8:00 AM-11:00 AM**

Technology-enabled longitudinal monitoring of patient-reported outcomes (PROs) to individualize care of immune-related adverse events (irAEs) in patients (pts) treated with immune checkpoint inhibitors (ICIs).

Pavlos Msaouel, Michael L. Van Alstine, Clara Oromendia, Jianjun Gao, Yinghong Wang, Bilal A. Siddiqui, Arlene O. Siefker-Radtke, Amishi Yogesh Shah, Leah Shaw, Lidia Lopez, Andrew Leonard Laccetti, Nizar M. Tannir, Michael Elashoff, Christopher Logothetis; The University of Texas MD Anderson Cancer Center, Houston, TX; Project Ronin, San Mateo, CA; Department of Genitourinary Medical Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX; University of Texas MD Anderson Cancer Center, Houston, TX; MDACC, Houston, TX; Memorial Sloan Kettering Cancer Center, New York, NY; Department of Genitourinary Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX

Background: ICIs have become the therapeutic standard for many cancers but are associated with unique and diverse irAEs that often occur at home. Appropriately timed and specific interventions are critical to recovery. Thus, there is a need to effectively & efficiently monitor in real time pts treated with ICIs. To improve outcomes, we have activated a clinical trial developed to determine the feasibility and safety of an electronically enabled strategy to remotely monitor symptoms and prompt communication that will guide and inform specific patient-driven "course corrections" in response to potential irAEs. **Methods:** This is an adaptive prospective trial that uses a mobile irAE-specific PRO application we developed to monitor and alert the care team in real time when severe symptoms are reported. In parallel with the mobile symptom collection, serum and urine biomarkers are collected at baseline, first tumor restaging, and upon the development of irAEs. Optional stool microbiome analyses are also performed. To facilitate the generalizability of our inferences, we are using broad inclusion criteria: ECOG performance status ≤ 3; any line of ICI given as standard of care or as part of therapeutic clinical trials; elderly pts are included. Because the relationship between PROs and irAEs is currently undefined, we designed our trial to use adaptive symptom thresholds that will notify the healthcare team of suspicion for irAEs. The mobile application will use these dynamic thresholds to determine whether or not to alert the healthcare team. The positive and negative predictive value of each symptom for identifying subsequent irAEs will be assessed at scheduled interim analysis time points. The care teams' responses to the alerts, and all of the clinical outcomes for the pts over time will be collected as part of the trial. The primary goal of the trial is the assessment of the predictive power of the mobile PRO symptom collection in combination with serum and urine markers to identify grade 2 or higher adverse events that require intervention (e.g., dose modifications, hospitalizations, and therapeutic interventions) within two weeks of symptom onset. Effective remote monitoring of irAEs will leverage our understanding of ICI toxicity and empower pts to be effective partners in their care. The trial has currently enrolled 17 pts towards the enrollment target of 100 pts. Clinical trial information: PA19-0095. Research Sponsor: Project Ronin.

TPS2089 **Poster Session (Board #81), Fri, 8:00 AM-11:00 AM**

ApricityRx companion digital therapeutic for evidence-based mitigation and phenotype-linked molecular characterization of irAEs in patients receiving immune checkpoint therapy (ICT).

Matthew T Campbell, Tian Zhang, Lynda Chin, Allison Betof Warner, Matthen Mathew; The University of Texas MD Anderson Cancer Center, Houston, TX; Duke Cancer Institute, Durham, NC; Apricity Health LLC, Houston, TX; Memorial Sloan Kettering Cancer Center, New York, NY; Columbia University Medical Center, New York, NY

Background: Presentation of immune-related adverse events (irAEs) is heterogeneous and unpredictable in patients receiving immune checkpoint therapy (ICT). ICT has been approved for cancer patients as single agent, combination of dual ICT, ICT plus chemotherapy, and ICT plus targeted therapy. Given the ever increasing complexity in recognizing and managing irAEs, coupled with the lack of skilled resources and clinical experience in real world practice, there is increasing demand for digital solutions that can detect early toxicity and support evidence-based interventions in real world practice. To this end, we have developed ApricityRx, a companion digital therapeutic for end-to-end irAE management. In addition to (i) teaching patients about immune-related toxicities and (ii) empowering them to monitor key symptoms and vital signs, ApricityRx continuously analyzes the combined patient-reported data and longitudinal EMR data to (iii) detect symptom-triggers and lab test-triggers of irAEs, and (iv) activate the clinical team to triage, evaluate and treat in a timely fashion, while (v) providing access to synthesized longitudinal patient information and expert guidance on evidence-based management and care. In a feasibility trial conducted in a community setting, we demonstrated two-thirds of the study participants completed on average 5 eCheck-ins per calendar week (overall average 4 times per week), with 5% of the check-ins resulting in notifications alerting the clinical team to evaluate for the early signs of an irAE. **Methods:** To accelerate translational research in irAEs and to develop predictive biomarkers for risk stratification, we are launching a single-arm, open-label study that utilizes ApricityRx in patients receiving ICT alone or in combination. The objectives of the study will include (i) defining the operative characteristics of ApricityRx as an irAE mitigation strategy; (ii) identifying patients and time points for phenotype-triggered biospecimen collection and molecular characterization. The study aims to enroll initially up to 100 participants per site, with a total target of 1,000. Research Sponsor: Apricity Health.