Abstracts From the NCCN 21st Annual Conference: Advancing the Standard of Cancer Care™

The following abstracts were accepted for presentation at the NCCN 21st Annual Conference: Advancing the Standard of Cancer Care™ General Poster Session at The Westin Diplomat in Hollywood, Florida, on March 31 and April 1, 2016. Additional abstracts presented at the conference are available at NCCN.org.

Best Practices in Implementation and Use of Clinical Practice Guidelines

AB2016-1. Discriminatory Power of a 15-Item Distress Screening Tool Among Those at Risk for Depression: Implications for Triage After Distress Screening

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From Cancer Support Community, Research & Training

Background: The American College of Surgeons' Commission on Cancer and NCCN recommend distress screening for all patients with cancer. Providing this service is essential for the patient, but is not without added burden to clinicians who are already taxed with meeting the needs of a growing population of cancer survivors. Thus, streamlining the screening process may be beneficial if it can be performed in an evidenced-based manner. In this study, we describe the patients who triggered a positive result for risk for depression on a distress screening tool and explore a strategy to identify concerns most highly associated with a heightened risk for depression in order to facilitate triage postscreening. **Methods:** Patients in a community-based cancer support organization completed a Web-based distress screening tool at intake. Patients rated 15 items according to the question, "Today, how concerned are you about…?" using a Likert scale (0, not at all; 4, very seriously), including a 4-item depression subscale. A depression score was calculated as the sum of the 4 items, and a score ≥6 triggered a positive result for risk for depression. Additionally, an overall distress score was calculated as the number of distress items rated ≥2 (range, 0–15). Participants who triggered a positive result for depression were then categorized using the overall distress score as high scorers (≥13; n=91) and low scorers (≤8; n=105). The item discrimination index (IDI) was calculated for each distress item as the percent difference in concerned (≥2) responses between high and low scorers. **Results:** A total of 868 members from 26 geographically diverse community-based cancer support affiliates (78% female; median age, 57 years) were screened for distress; 364 patients (42%) triggered a positive result

for risk for depression. A positive result was associated with younger age, single marital status, Latino ethnicity, and lower income (*P*<.01). Among those at risk for depression (n=364), distress items with the greatest discriminatory power (IDI≥0.7) were pain, making a treatment decision, and finding meaning or purpose. For example, of those at risk for depression, 96% with overall high distress rated pain a concern versus only 24% with lower overall distress. **Conclusions:** These results highlight which of the 15 items have the greatest discriminatory power to characterize the causes of distress among cancer survivors who are at risk for depression. For clinicians, results suggest targeted follow-up screening items (ie, pain, treatment decision-making, finding meaning) that prioritize patients with the greatest distress level for further triage and supportive care services. Further analyses should assess whether these approaches allow for more efficient implementation of distress screening in clinical practice.

AB2016-2. NCCN Guidelines in Action: The First Year — A Report From a Community Hospital

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Background: According to the NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast and Ovarian (Daly M et al, NCCN.org) an elevated risk for breast cancer is determined by a 5-year risk of >1.67 on the Gail Model, lifetime risk of >20% on a model largely dependent on family history, or a known familial or genetic risk syndrome. A community hospital developed a high-risk breast cancer screening program based on the NCCN Guidelines and lessons learned from a prior pilot program. First-year data were collected from 16,562 women presenting for screening mammography. We report on the findings of the first year. **Methods:** A retrospective descriptive analysis of data collected from October 1, 2014 to September 30, 2015, was conducted to assess the processes and impact of using the NCCN Guidelines for Genetic/Familial High-Risk As-

sessment: Breast and Ovarian to guide the program. A nurse practitioner conducted individualized phone consultations with women identified as having an elevated risk based on the NCCN Guidelines. To manage the potential volume of women identified, enrollment was limited to women aged 35–55 years who presented for a screening mammogram with a lifetime risk of ≥25% on the Tyrer-Cuzick model combined with a 5-year risk of ≥1.67% on the Gail model, or who had a male relative with breast cancer. Exclusion criteria were history of cancer, lobular or ductal carcinoma in situ, or prior thoracic radiation therapy. **Results:** Of the 16,562 patients screened, 3.7% (n=613) were determined to be at an elevated risk and were invited for consultation; of these, 50% (n=306) completed a consultation including validation of risk and communication of clinical and lifestyle recommendations. Of those, 98% (n=299) had a validated elevated risk, 93% (n=285) were recommended for yearly MRI, 34.4% (n=98) were referred for MRI from the program, it is unknown if 65.6% (n=187) were referred for MRI by their primary clinician physician (PCP), and 91% (n=279) were eligible for chemoprevention but opted out. Of the 306 patients, 48% (n=131) were eligible for genetic counseling, 27 genetic counseling appointments were scheduled but only 19 were kept, and genetic testing was conducted on 8% of patients (n=11), 7 of whom had negative results, 2 had mutations (*CHEK2* and *PALB2*), and 2 had variants of unknown significance. Barriers that hindered the full potential of the program were poorly integrated services, little collaboration between the program and PCPs, and difficulty engaging all women identified at increased risk. **Conclusions:** Further research is needed to understand the uptake of program recommendations among patients, and barriers that a clinician encounters implementing a program for high-risk breast cancer screening. Findings will be used to improve processes during the second year of the program. A qualitative study is planned to explore factors affecting the uptake of genetic counseling. A point-of-service model could be considered, in which patients receive consultation regarding risk-reducing medication and genetic counseling at consultation.

AB2016-3. Clinical Actionability of Panel Testing for Genes in the 1.2015 NCCN Guidelines for Hereditary Breast and Ovarian Cancer

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Background: Genetic testing for hereditary breast and ovarian cancer (HBOC) is rapidly evolving with the introduction of multigene panels, although their clinical impact is currently poorly defined. The publication of the NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast and Ovarian, Version 1.2015 included additional genes compared to earlier versions, although limited specific guidance is provided for some of these genes (to view the most recent version of these guidelines, visit NCCN.org). In a recently published study (Desmond A, et al; JAMA Oncol 2015), we began to explore the frequency and types of clinical decisions that may result from panel testing in a representative clinical population. This report expands on that work with additional case studies and analyses focused specifically on those genes mentioned in the Version 1.2015 of the NCCN Guidelines. **Methods:** We prospectively enrolled more than 1,000 *BRCA1/2*-negative patients at 3 academic medical centers. Germline testing was performed on all 12 non-*BRCA1/2* genes listed as "Intervention Warranted" in the NCCN Guidelines: *ATM, CDH1, CHEK2, PALB2, PTEN, STK11, TP53,* and the Lynch syndrome genes (*MLH1, MSH2, MSH6, PMS2,* and *EP-CAM*). For patients found to have these gene mutations, we evaluated which of these findings would warrant consideration of a change in care by comparison with management recommendations based on personal and family history alone. **Results:** It was determined that 51 patients harbored mutations in 1 of the 12 specified genes. In most cases (>90%), the patient or family had cancers syndromic for the gene they carry, arguing that these results are clinically relevant. A change in care would be considered for approximately half of patients (25/51), either via enhanced screening or potential surgical intervention. Patients with no change in management most often had moderate penetrance mutations and were either already eligible for breast MRIs (based on personal/family history) or were breast cancer survivors (and for whom new breast screening recommendations were not evaluated). A change in care would be considered for an even larger fraction of these patients' first-degree relatives (33/47) if also found to be mutation-positive. **Conclusions:** In appropriately referred patients, testing for genes listed in the Version 1.2015 NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast and Ovarian yields clinically relevant findings with the potential management impact for substantially more patients than *BRCA1/2* testing alone. These data may help inform the development of best practices and more detailed recommendations based on the Version 1.2015 NCCN Guidelines.

NCCN 21st Annual Conference Abstracts

AB2016-4. 2016 Analysis of Evidence and Timeline of NCCN Guideline Development

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From Genentech

Background: The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) provide recommendations based on the best treatment evidence available at the time they are derived, and are continuously updated through a transparent process to reflect new data. We previously reported on trends regarding the transparency process. This report will analyze the timeliness of panel meetings and quality of data that lead to decisions made by the NCCN Guidelines Panel for high-prevalence tumor types. **Methods:** Panel meeting minutes for the NCCN breast, colon, and non–small cell lung cancer panel meetings between June 2010 and December 2015 were reviewed for the meeting date, submission request, decision made, and references provided. Submission requests were accessed to extract the date. References were analyzed for quality of evidence as defined by publication type and level of evidence. **Results:** Results included analysis of 176 panel decisions and 252 references across the 3 disease areas. The levels of evidence most cited were phase III data for category 1 (n=8; 89%), 2A (n=28; 40%), 2B (n=6; 38%), and 3 (n=1; 100%) recommendations, and retrospective analyses (n=15; 32%) for decisions to not update the NCCN Guideline. Most of the references cited to support panel decisions were full publications or electronic publications (n=85; 71%). The primary end points of references most cited to support category 1 and 2A recommendations were overall survival, progression-free survival, or disease-free survival (n=50; 42%). The average times from publication of reference to panel meetings were 1,117 days for full publications, 190 days for conference data, and 42 days for electronic publications. The average time to a panel meeting was 49 days from an external submission. The average time from an FDA approval to a panel meeting decreased from 41 days in 2010 to 10 days in 2015. The percentage of interim meetings convened for decisions by reference type is shown in Table 1. **Conclusions:** NCCN Guidelines panel members actively update guidelines as new data are available and strive to be timely by convening additional interim meetings to address FDA approvals. Decisions with higher category ratings were more often supported by higher levels of evidence and full publications, and are consistent with NCCN definitions for category ratings.

AB2016-4. Table 1. Percentage of Interim Meetings Convened by Reference Type

Reference Type	Breast		Colon		NSCLC	
	N*	Interim Meetings (%)	N*	Interim Meetings (%)	N*	Interim Meetings (%)
Data presented at conference	10	40%	17	6%	24	54%
ePub/ahead of print	6	50%	1	100%	14	21%
Full publications	42	14%	25	20%	50	18%
External submissions	23	30%	15	20%	36	14%
FDA approval	5	100%	3	100%	33	52%

*Number derived from all meetings.

AB2016-5. Reengineering Delivery of Guideline-Recommended Care: The 4R Oncology Model in Breast Cancer Care

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Background: Care for patients with breast cancer is a complex process delivered by multiple domains (eg, surgery, radiology, medical oncology, internal medicine) across organizations, fraught with fragmentation and lack of coordination. The Institute of Medicine reports this impacts delivery of guideline-recommend care and patient outcomes (IOM, 2001, 2005, 2013). We developed a unique approach that facilitates delivery of guideline-recommended cancer care using project management principles and systems engineering: 4R (Right Information, Right Care for the Right Patient at the Right Time). We explore distinct features of the 4R oncology model with patients with breast cancer and health care providers. **Methods:** 50 semi-structured interviews were conducted with patients (n=12), breast cancer care physicians (n=17), mid-level providers/nurses (n=16), and health administrators (n=5) from 3 cancer centers. Results were analyzed via the framework approach of qualitative research. **Results:** Ninety-six percent (48/50) agreed with the features of 4R care sequence templates (patient's individual project plans, developed based on clinical guidelines, with timing, sequencing, and dependencies of key care events) personalized to patient clinical characteristics, comorbidities, life stage, needs and choices. Although 100% (n=17) of physicians agree with a defined goal of care, "project goal," only 44% (7/16) of mid-levels/nurses agree (*P*=.0003). All patients (12/12) and mid-levels/nurses (16/16) agree with a "quarterback" approach in the form of a "project" lead physician and lead care organizer, compared with 71% (12/17) of physicians (*P*=.0588, .0445). A cross-domain team including the patient with assigned tasks was impor-

NCCN 21st Annual Conference Abstracts

tant to 100% (n=17) of physicians and 56% (n=9) of mid-levels/nurses (*P*=.0027). A minority of interviewees felt that metrics (32%; 16/50) and reimbursement considerations (42%; 21/50) were important (Table 1). **Conclusions:** Providers and patients generally support the 4R model and expect that care sequences will enable better adherence to guidelines. The disagreement on some features indicates a need for flexibility of implementation in different settings. Our current pilot of the 4R model in early breast cancer may lay the foundation for best practices using systems engineering principles to deliver guideline-recommended cancer care. The features of the 4R oncology model may inform cancer care practice, suggesting innovative, practical, and patient-centric approaches to support and improve quality of care.

AB2016-5. Table 1. 4R Features					
4R features	All % (#)	Patients	Physicians	Mid-Level/ Nurses	Admin
Care Sequence	96 (48)	100 (12)	100 (17)	88 (14)	100 (5)
Defined goal of care	78 (39)	83 (10)	100 (17)	44 (7)	100 (5)
Quarterback - LP - LCO	90 (45)	100 (12)	71 (12)	100 (16)	100 (5)
Cross domain team	84 (42)	92 (11)	100 (17)	56 (9)	100 (5)
Metrics aligned to IOM dimensions of quality	32 (16)	0 (0)	59 (10)	13 (2)	80 (4)
Reimbursement considerations	42 (21)	0 (0)	94 (16)	6 (1)	80 (4)

Bioinformatics/Information Technology Sciences

AB2016-6. Precision Imaging Metrics Manager: The Workflow Solution for Quantitative Imaging Assessment of Tumor Response for Oncology Clinical Trials

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Background: Oncology clinical trials at cancer centers increasingly depend on imaging as a surrogate end point to demonstrate efficacy and safety of therapeutic agents. Uniform and reliable analysis of imaging data can be challenging across sites, particularly when imaging reviews are not sufficiently timely or accurate in the implementation of response assessment criteria. An in-house centralized service can improve the management of tumor metrics for oncology clinical trials. However, most cancer centers currently do not have a formalized informatics workflow system in place. **Methods:** The Tumor Imaging Metrics Core (TIMC) of the Dana-Farber/Harvard Cancer Center (DF/HCC) developed the Precision Imaging Metrics Manager as a complete Web-based workflow solution for independent site reviews. Highlights of the system are as follows:

- Clinical trial staff can access the secure, password-protected Web site—any scan, anytime, anywhere—to request scan assessments and view results, including annotated images and graphs.

- Online training and certification ensures that reviewers assess the scan according to the study protocol with the help of integrated imaging response criteria conformance checks.

- After electronic sign-off, assessment is locked and the clinical team is automatically alerted that results are ready.

- On-time results ensure that the clinical team receives independent confirmation of progression/response before the patient is evaluated in the clinic.

Results: The Precision Imaging Metrics Manager (PIM) is currently used by 5 NCI-designated Cancer Centers around the United States, for more than 1,000 active clinical trials and more than 15,000 imaging assessments per year. Prior to implementation of the PIM system at a major NCI-designated Cancer Center, more than 25% of scans had assessment problems due to errors in percent change calculations, misidentification of baseline/nadir scans, selection of inappropriate overall response, application of incorrect response criteria, or incomplete/conflicting data records. After implementation of the system, assessment errors decreased to 3% after response criteria logic checks were applied. **Conclusions:** Use of PIM v2.0 at patient accrual sites provides greater standardization, reliability, and confidence, which improves the assessment of treatment response or tumor growth, resulting in time and cost savings for sponsors, and improved efficiency and confidence for investigators.

Clinical Oncology

AB2016-7. Effect of Oncotype DX Recurrence Score and Recurrence Score-Pathology-Clinical Score on Management Decisions in Early-Stage Breast Cancer

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Background: The Oncotype DX recurrence score (RS) is widely used for assessment of risk of recurrence (ROR) and prediction of chemotherapy benefit in patients with early-stage breast cancer. Patients with high RS (>31) derived substantial benefit from chemotherapy, whereas patients with low RS (<18) do not. Patients with intermediate RS (18–31) tumors do not clearly benefit, but uncertainty in the estimate cannot exclude a clinically important benefit. In order to take into account clinicopathologic factors that also provide independent prognostic utility, Tang formulated the Recurrence Score-Pathology-Clinical score (RSPC) risk index. The objective of our study was to compare ROR by RS and RSPC and how it affects management decisions. **Methods:** We conducted

NCCN 21st Annual Conference Abstracts

a chart review of 109 patients with 21-gene RS. The RSPC risk index was calculated for each patient. A comparative analysis was performed with stratification of patients into low (LR), intermediate (IR), and high (HR) groups by RS and RSPC. Cutoffs for low, intermediate, and high risk by RSPC were set to 11%, 11%–21%, and 21% risk of distant recurrence at 10 years, corresponding to the ROR associated with the RS categories. A retrospective analysis was performed with the calculated RS and RSPC scores. We used Student t test to analyze how patient age, tumor size, and grade affected the RSPC. **Results:** RS classified the following proportions of patients into 3 risk groups for distant recurrence: LR, n=54 (49.5%); IR, n=49 (45%); and HR, n=6 (5.5%). RSPC classified the following proportion of patients into 3 risk groups for recurrence: LR, n=76 (69.7%); IR, n=23 (21.1%); and HR, n=10 (9.2 %). RSPC reclassified 36 (73.47%) patients in the IR group: 30 (61.2%) to the LR group and 6 (12.2%) to the HR group. RSPC reclassified 3 (50%) patients from the HR group to the IR group and none to the LR group. RSPC reclassified 8 (14.8%) patients from the LR group: 1 (1.85%) to the HR group and 7 (12.96%) to the IR group. Hence, a total of 47 (43.12%) patients were reclassified to a different group. In the RS classifications, patients who did not receive chemotherapy were: LR, 44 (81.5%); IR, 15 (30.6%); and HR, 0 (0%). In the RSPC reclassifications, patients who did not receive chemotherapy were: LR, 54 (71.1%); IR, 4 (17.4%); and HR, 1 (10%). **Conclusions:** A total of 47 (43%) patients were reclassified by RSPC, which was most helpful in reclassifying the IR group. Given that RSPC reclassified 30 (61%) patients from the IR group to the LR group, it would have spared these patients from chemotherapy. Among the other factors, grade 3 disease shifts the RS from the IR to the HR group; size >2 cm and age <50 years shift the RS values up, but patients stay within the IR group. Our data suggest that RSPC reclassifies more patients into the LR group, thus being able to safely avoid chemotherapy in more patients. RSPC represents the integration of Oncotype DX RS and clinicopathologic factors, further refining prognostic accuracy and ultimately reducing the number of patients who receive chemotherapy.

AB2016-8. Interim Results of a Phase II Trial of Sorafenib Plus Doxorubicin in Patients With Advanced Hepatocellular Carcinoma Who Progressed on Sorafenib Monotherapy (NCT01840592)

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Background: Retrospective analysis of 14 patients with advanced hepatocellular carcinoma (HCC) treated with sorafenib plus doxorubicin (S+D) after progression on sorafenib demonstrated a median progression-free survival (PFS) and overall survival (OS) of 3.4 and 10.1 months, respectively. We hypothesize that S+D may have synergistic activity in patients with HCC after sorafenib failure through inhibition of Raf-1 by sorafenib promoting D-induced ASK-1–mediated apoptosis. **Methods:** A single-arm phase II study evaluated S+D in patients with advanced HCC with RECIST 1.1 radiologic progression on sorafenib; ECOG performance score of 0–1; Child-Pugh class A liver function; and adequate bone marrow, renal, hepatic, and cardiac function. The primary end point was OS at 6 months (OS6). *Statistical Plan:* 2-stage design; unacceptable OS6: 50%, acceptable OS6: 72%; type I and II errors: 5% and 15%, respectively. *Secondary End Points:* Median PFS, median OS, tolerance to S+D, response rate by RECIST 1.1, and associations between previous length of exposure to sorafenib and OS and PFS. **Results:** Starting April 2012, 27 patients have been enrolled to date. Study population consists of 23 men with a median age of 65 years (range, 24–82 years) and a median Karnofsky performance status of 80%. The median duration of prior sorafenib was 3.8 months (range, 1.3–27.7 months). The median cumulative doxorubicin dose was 285 mg/m^2 (60–360 mg/m^2), and the median starting dose of sorafenib was 400 mg daily (range, 200–800 mg). First-stage results of 15 patients indicate that the OS6 was 87% (95% CI, 56%–96%), with a median PFS of 4.1 months (95% CI, 1.6–8.6) and median OS of 16.5 months (95% CI, 6.3–not reached). Eleven of 15 patients were alive at 6 months. Neither OS nor PFS were associated with previous sorafenib duration (P=.8 and .4, respectively). There was 1 (6%) partial response and 12 patients had stable disease (80%), of whom 5 (42%) had disease stability for ≥4 months. Grade 3 and 4 adverse events experienced by ≥10% of the 15 patients in the first stage of the study were: *hematologic:* lymphopenia (67%), neutropenia (46%), anemia (20%); *liver function:* elevated aspartate transaminase (27%) and alanine transaminase (20%), hyperbilirubinemia (13%); *laboratory:* hyponatremia (27%), hypophosphatemia (20%); and clinical: hypertension (20%), ascites (13%), gastrointestinal bleed (13%). One patient discontinued treatment due to toxicity. There were no treatment-related deaths. **Conclusions:** With OS6 of 87% and 11 of 15 patients alive at 6 months, the first-stage decision rule

requiring 8 of 15 patients to be alive at 6 months was met. The study is now completing accrual of its second stage prior to definitive study data analysis, and is currently at 27 of a total target enrollment of 30 patients. Reported adverse events are similar to those of each agent. Pretreatment and posttreatment ASK-1 and pERK expression levels in biopsied tumor tissue samples were obtained and will be assessed and presented at a later time, in conjunction with full study results.

AB2016-9. Phase I Study of Bendamustine and Fractionated Stereotactic Radiotherapy of Patients With 1 to 4 Brain Metastases From Solid Malignancies

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Background: Bendamustine (BD) is a multifunctional alkylating agent with a purine-like ring system. It causes intrastrand and interstrand crosslinks between DNA bases, induces apoptosis, downregulates inhibitors of apoptosis, and induces nonapoptotic cell death (mitotic catastrophe). These mechanisms of action make it likely to also function as a radiosensitizer. **Methods:** Standard 3+3 design was used in this phase I trial of BD and fractionated stereotactic radiotherapy (FSRT) for patients (Karnofsky performance status [KPS] ≥70) with 1 to 4 untreated brain metastases. Lesions ≥5 cm or involving leptomeninges, thalamus, basal ganglia, or brainstem were excluded. The primary end point was the recommended phase II dose of BD + FSRT. Secondary end points were (1) BD pharmacokinetics (PK) and (2) tissue drug quantitation using high-performance liquid chromatography/tandem mass spectrometry (LC/MS/MS). After consent, eligible patients having planned resection of brain metastases also received BD (40 mg/m^2 intravenously) on days 1, 2, and 3, with surgical resection on day 3. Plasma for BD PK was obtained on day 1 or 2. FSRT was started 4 weeks after surgery (day 1 if no surgery). Patients received 30 Gy in 5 daily fractions. BD (30-minute intravenous infusion) was started 1.5 hours before FSRT. Dose level 1 was 40 mg/m^2 intravenously for 5 days and dose level 2 was 50 mg/m^2 intravenously for 5 days. **Results:** 18 patients (age 35–52 years; median 54.5 years) were enrolled with brain metastases from solid tumors (5 melanomas, 9 non–small cell lung carcinomas, 2 breast carcinomas, 1 renal cell carcinoma, 1 thyroid carcinoma). Thirteen

patients underwent surgical resection of their tumors and received preoperative BD. An assay for measuring BD was developed and specimens are currently being measured. Only patients receiving BD with concurrent FSRT were used to determine maximum tolerated dose. One of initial 3 patients developed drug-related dose-limiting toxicity (DLT; grade 3 elevation of liver function tests [LFTs] 3 days after fifth daily dose of BD, which returned to grade 1 at 15 days; she had prior chemotherapy for breast carcinoma). Dose level 1 was expanded to 6 patients. Additionally, 6 patients completed dose level 2 + FSRT and had no DLT. Seventeen patients have died with progressive metastases at 2, 2, 3, 3, 4, 4, 4, 4, 5, 5, 7, 9, 9, 16, 17, 17, and 19 months since consent. One patient is alive at 43 months. Six patients were removed from study (3 due to progression of brain metastasis during the postoperative period, 1 withdrew consent to receive oral sorafenib, 1 patient developed grade 3 elevation of LFTs 11 days after the third dose of preoperative BD at 40 mg/m^2/d; this patient's LFTs returned to normal 8 days after stopping Cymbalta). One patient was admitted on postoperative day 8 for pneumonia and acute exacerbation of chronic obstructive pulmonary disease, responding to oxygen and intravenous antibiotics. **Conclusions:** BD at a dose of 50 mg/m^2 intravenously for 5 daily treatments is the recommended phase II dose of BD combined with 30 Gy of FSRT, and was well tolerated. The level of BD in brain metastases can be quantified using LC/MS/MS.

AB2016-10. Meaningful End points for Therapies Approved for Hematologic Malignancies

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Background: Although extension of life is the ultimate objective of all cancer therapies, improved overall survival (OS) may not always be the most appropriate measure for determining the success of a therapy. In hematologic malignancies (HMs) and certain solid tumors, other end points (eg progression-free survival or response rate) have been accepted as indicators of achievement of meaningful clinical benefit. For several HMs, leading clinicians worked with the FDA to establish non-OS end points appropriate for regulatory approval. More recently, when ESMO formulated their Magnitude of Clinical Benefit Scale to focus on OS, they explicitly stated that it was "developed only for solid cancers." Here, we revisit the end points in clinical trials supporting HM drug approvals in the United

NCCN 21st Annual Conference Abstracts

States. **Methods:** We identified new drugs and new indications FDA approved for HMs from January 2002 to July 2015, as well as the end points and magnitudes of benefit of the trials that were the basis for regulatory approval, as reported in the label at approval. Approvals were classified by end point type. **Results:** Of the 63 approvals for HMs from 2002–2015, one therapy was approved based on OS (rituximab expansion to first-line, 2006), 16 (25%) on progression end points, and 46 (75%) on response metrics. Of 23 approvals that were based on trials using an active comparison arm, 16 had median progression end points in the approved label. The median magnitude of benefit versus comparator was 71% improvement (range, 26–127), with a median hazard ratio of 0.55 (range, 0.16–0.72). **Conclusions:** In HMs, it is typically more accepted to define a drug's benefit based on non-OS end points, as documented in 62 FDA approvals since 2002. This has been driven by the need to gain meaningful clinical benefit for patients earlier, while also avoiding practical challenges such as longer periods of survival achieved (and the resultant long timeframe required to determine OS), limitations of crossover trial design, lack of an effective standard-of-care comparator, and confounding of OS measures by multiple subsequent lines of therapy. Value metrics that diminish the worth of non-OS measures risk impairment of patient outcomes in HMs, and limited access to these essential treatments. Techniques that attempt to establish threshold criteria for assessing stratified levels of value (and thereby potentially influence patient access to treatments) must be informed by clear understanding of the evidence behind the metrics for success, as well as realistic expectations for the nature and magnitude of meaningful benefit based on results historically shown to be achievable.

AB2016-11. Clinical Presentations of 106 Patients with Germline *PALB2* Mutations: Looking Beyond Breast and Ovarian Cancer

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From Invitae Corporation

Background: *PALB2* is now known to be a moderate- to high-penetrance breast cancer predisposition gene. Because genetic testing is most often performed in high-risk patients, it is not surprising that our laboratory's data are consistent with PALB2 presenting as a high-penetrance gene in a subset of patients. In this case series, we describe the clinical presentation (hormone receptor status, age of onset, presence of multiple primaries, and reported family history) of 106 *PALB2* mutation carriers, for the purpose of further delineating the spectrum of cancers reported in *PALB2*-affected families. **Methods:** 106 sequential patients referred for genetic testing and were found to have a pathogenic or likely pathogenic mutation in *PALB2* as well as a personal or family history of cancer were selected. Variants were classified using a point-based system that closely adheres to the American College of Medical Genetics and Genomics guidelines. Deidentified personal and family histories provided by ordering clinicians were examined. **Results:** Among the 106 patients assessed (100 females, 6 males), 79 were affected with cancer and 27 were unaffected carriers. Of the 79 patients with cancer, almost half were ≤49 years old and 5 patients were <35 years. 14% presented with bilateral breast cancer and 14% presented with breast cancer and an additional primary tumor. 8% had triple-negative breast cancer. 13% reported a personal history of pancreatic cancer (4 of which were males). 73% of affected carriers described a significant family history of cancers. Of the unaffected patients (eg, carriers), their average age was 45 years, with 22% aged >60 years at the time of testing. **Conclusions:** In this case series, we observed early-onset breast cancer and multiple primary cancers in both the patient and at-risk family members consistent with a high-penetrance effect of *PALB2* in a subset of families. This includes a remarkable group of patients who presented with multiple primary tumors, including prostate, colorectal, thyroid, endometrial, papillary urothelial, gastric, melanoma, and urinary tract cancers. More research is needed to understand the relationship between *PALB2* and other cancer risks, particularly in males because they represented <1% of patients tested in this study. Furthermore, consistent with current guidelines, our study suggests that clinicians need to consider *PALB2* mutation status in the context of family history to inform risk assessment and management decisions.

Correlative/Genomic

AB2016-12. Exosomal RNA-Based Liquid Biopsy Detection of EML4-ALK in Plasma From Patients with Non–Small Cell Lung Cancer

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From Exosome Diagnostics

Background: Molecular profiling to direct targeted therapy has revolutionized cancer treatment. For example, the tailored therapy of patients with non–small cell lung cancer (NSCLC) carrying somatic EML4-ALK rearrangements with ALK inhibitors has shown to be associated with substantial clinical response. A prerequisite of this approach is highly sensitive and specific diagnostics to detect and monitor the prognostic biomarker. Today's tissue-based diagnostics, like FISH, are limited by complications of biopsy and tech-

nical challenges. Therefore, biomarker assessment in plasma circulation would be a valuable alternative to tissue-based testing and provide a simple new option for identifying and monitoring patients with NSCLC who are EML4-ALK–positive. We previously demonstrated the feasibility of detecting EML4-ALK fusion transcripts in 6 plasma samples from patients known to be positive by tissue FISH testing (the gold standard). Here we present more comprehensive performance characteristics of this diagnostic test analyzing the exosomal expression of EML4-ALK in plasma of patients with NSCLC. **Methods:** We developed a diagnostic test to monitor the expression of EML4-ALK fusion transcripts in low-volume plasma samples of patients with lung cancer. The Exosome Diagnostics ALK assay comprises column-based isolation of total vesicular RNA from 0.5–2.0 mL patient plasma, followed by discrete detection of EML4-ALK variants v1, v2, and v3 via qPCR. Assay quality is confirmed by inclusion of internal and external controls. Following validation on both synthetic and human samples, we monitored variant-specific expression of EML4-ALK in a cohort of >20 plasma samples from patients with NSCLC. The data was analyzed for concordance with time-matched tissue and aligned with patient's response data. **Results:** Applying our diagnostic test for EML4-ALK fusion variants, we were able to identify the predictive biomarker in exosomal RNA transcripts isolated from patient plasma. We determined the variant-specific expression profile of EML4-ALK fusion transcripts in a cohort of patients with NSCLC with high sensitivity and specificity, and observed high concordance of the qPCR-based plasma results with FISH-based tissue information. **Conclusions:** Liquid biopsies represent a low-risk and viable approach to testing for predictive cancer markers in patients with NSCLC, both at diagnosis and in response to therapy. Here, we demonstrate the capability of our validated diagnostic test to determine expression of rare EML4-ALK fusion transcripts in plasma as a sensitive alternative to repeat biopsy. Monitoring discrete EML4-ALK fusion variants would enable effective personalized treatment and has clear clinical application.

Outcomes and Health Services Research

AB2016-13. The Effect of Lenalidomide Dose Modification on Outcomes in Patients With Myelodysplastic Syndromes

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From [a]Kimmel Cancer Center/Johns Hopkins, [b]Celgene Corporation, and [c]Genesis Research

Background: Clinical studies of patients with lower-risk myelodysplastic syndromes (MDS) have demonstrated the efficacy of lenalidomide, with ≤4 cycles required to achieve response. Dose modification (DM) of lenalidomide has been used to manage toxicities and sustain therapy. This study evaluated whether DM of lenalidomide in patients with MDS is associated with longer duration of therapy (DOT) and improved outcomes in a real-world setting. **Methods:** This retrospective study evaluated a US claims database with >25 patients from January 2008 to December 2013. Eligible patients had ≥2 outpatient claims or ≥1 inpatient claim with an MDS diagnosis, plus continuous enrollment ≥12 months before and ≥6 months after the first claim. Patients with stem cell transplantation were excluded. DM was defined as a dose change, a 10–60 day dose interruption, or both. Treatment subgroups were based on presence or absence of DM at any time during treatment and receipt of <4 versus ≥4 cycles of lenalidomide. DOT and progression to acute myeloid leukemia (AML), next therapy, high-risk disease, and transfusion dependence were compared for patients with and without lenalidomide DM; time to progression (TTP) was defined as a composite of the above measures. A Cox proportional hazards model was used to adjust for age, sex, and comorbidity risk. **Results:** 529 patients met the inclusion criteria, 245 (46%) with DM and 284 (54%) without DM. Most patients initiated lenalidomide at 10 mg/d; the most common DM was a decrease to 5 mg/d. Age and comorbidity did not differ between patients with and without DM (P=.647 and P>0.9, respectively). For patients with DM, median time to DM was 1.9 months and median DOT was 12.6 months. For those without DM, median DOT was 1.9 months (P<.0001). Median TTP was 20.6 months and 13.7 months for patients with and without DM, respectively (adjusted hazard ratio, 0.703; 95% CI, 0.541–0.914; P=.009). Patients with DM had significantly longer times to AML (P=.018), next therapy (P=.002), and high-risk disease (P=.043) compared with patients without DM. Of 302 patients (57%) treated with <4 cycles of lenalidomide, 69 (23%) had ≥1 DM; 233 (77%) had no DM. Conversely, of 227 patients (43%) treated with ≥4 cycles of lenalidomide, 176 (78%) had ≥1 DM and 51 (22%) had no DM. In patients with ≥4 cycles of lenalidomide, DOT was 16.5 months and 10.9 months for patients with and without DM, respectively (P=.007). The 51 patients able to receive ≥4 cycles without DM had similar TTP compared with the 176 patients who received ≥4 cycles with DM (P=.72). **Conclusions:** For US patients medically managed with lenalidomide for MDS, DM during treatment was associated with a longer therapy duration, and increased

NCCN 21st Annual Conference Abstracts

times to AML, high-risk disease, and next therapy versus patients who discontinued therapy without DM. Although the decision to use DM versus discontinuation can be challenging, these data suggest quality of care for patients with MDS can be maintained through lenalidomide DM as a strategy to sustain therapy beyond 3 cycles and achieve the TTP benefits associated with continued treatment.

AB2016-14. Real-World Treatment Patterns of Patients on Chemotherapy versus Targeted Therapy in First-Line Advanced Non–Small Cell Lung Cancer: Understanding Key Challenges in the Pre–Immuno-Oncology Era

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From [a]Bristol-Myers Squibb, Cramerton, [2) b]Cardinal Health, and [c]Bristol-Myers Squibb, Princeton

Background: Research shows that targeted therapy (TT) is underused in first-line non–small cell lung cancer (NSCLC) because of multiple factors including clinical versus molecular patient profiling. Understanding the impact of this behavior is critical if similar underuse of immuno-oncology (IO) therapies is to be avoided. This study evaluated treatment patterns in first-line therapy of advanced NSCLC to underscore some of the potential challenges that may be faced by new therapies introduced into the advanced NSCLC treatment paradigm. **Methods:** Using Inovalon's MORE[2] Registry claims data, patients with advanced NSCLC treated with TT or chemotherapy identified by ICD-9 codes from July 2013 to July 2014 were selected. Inclusion criteria were patients aged >18 years who received first-line systemic therapy within 6 months of diagnosis. Exclusion criteria included those with SCLC, with secondary malignancies, and in clinical trials. TT included erlotinib, ceritinib, afatinib, crizotinib, ramucirumab, or bevacizumab monotherapy. Time to next treatment (TTNT) was defined as time from end of primary treatment to start of next therapy. Analysis included frequency distributions, chi-square tests, and *t* tests. **Results:** Of 5,319 patients with advanced NSCLC, 13% (687) received TT in first-line, 52% were female, median age was 66 years, and mean Charlson comorbidity index (CCI) was 2.2. On average, patients received 2 lines of treatment (range, 1–12). TT patients were older, more likely to be female, and had lower CCI than chemotherapy patients. TT patients had significantly longer treatment duration and follow up, more treatment lines, fewer adverse events (AEs), and were more likely to be tested for mutations compared with chemotherapy patients (Table 1). Overall, molecular diagnostic testing rates were low across both TT and chemotherapy-treated patients. **Conclusions:** The use of TT in first-line advanced NSCLC results in favorable clinical outcomes for patients. Further, molecular diagnostics appear to be underused. Additional research is needed to understand barriers to routine use of molecular diagnostics and appropriate TT use for first-line advanced NSCLC. This may enable better access to emerging therapies such as IO agents.

AB2016-14. Table 1. Patient Population

	All Patients (N=5319)	TT Patients (N=687)	Chemotherapy Patients (N=4,632)	*P* Value
Mean age	66.3 y	68.1 y	65.7 y	<.0001
Female	52%	64.5%	49.9%	<.0001
Mean CCI	2.2	2.1	2.2	<.0001
Mean follow up from first-line start	13.1 mo	19.3 mo	12.2 mo	<.0001
Patients with ≥2 lines	41%	48%	40%	<.0001
Mean number lines per patient	2.0	2.0	1.7	<.0001
Mean duration, first-line	3.8 mo	9.0 mo	3.1 mo	<.0001
Mean TTNT, first-line	4.3 mo	2.9 mo	4.5 mo	<.0001
Mean number of AEs per patient	3.0	2.9	3.4	<.0001
Pts with mutation testing	11.5%	13.8%	11.2%	.045

AEs were counted if treated based on claims.

Quality Improvement

AB2016-15. Evaluation of Boxed Warning Adherence to Hepatitis B Screening Before Rituximab Therapy Initiation: A Retrospective Analysis

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From Cleveland Clinic, Florida

Background: There is an established boxed warning with rituximab requiring hepatitis B virus (HBV) screening for all patients before therapy initiation. Reactivation of HBV can lead to fulminant liver failure, cirrhosis, and death. The purpose of this study is to evaluate guideline adherence to HBV screening before initiation of rituximab treatment and to develop an internal process improvement communication. **Methods:** This study was submitted to the IRB for approval. A retrospective chart review of patients on rituximab was conducted using electronic medical records (EMR) at the Cleveland Clinic Florida (CCF). Data collected included: patient alive or expired, ordering physician, department of ordering physician, HBV screening before therapy initiation, screening result, and action taken by physician after pharmacy alert. For any patients found to

NCCN 21st Annual Conference Abstracts

be actively receiving rituximab therapy and were HBV-positive, we notified the ordering physician immediately in person and via e-mail. For patients who had not received HBV screening initially, the ordering physician was sent an educational alert. After 30 days, we checked to see if the physician ordered an HBV screening after receiving our alert. We also sent an alert to pharmacists to check for HBV screening before approving rituximab orders. **Results:** A total of 122 patients from January 1, 2015 to July 1, 2015 were found to have received rituximab therapy. Of these, 14 patients (11.47%) had no record of HBV screening in their CCF EMR; 2 of the 14 patients had expired. This brought the total number of patients actively receiving rituximab therapy without a prior history of HBV screening to 12 (9.8%). No patients were found to be HBV-positive. We alerted the ordering physicians immediately via a physician alert e-mail and waited 30 days for a follow-up action. We received physician responses on 100% of the alerts within 30 days. All but 1 patient (91.7%) had an HBV screening panel placed for their next laboratory work; this patient was previously scheduled for a clinic appointment outside of the 30 day study window and will be screened at that time. **Conclusions:** Most ordering physicians were very supportive of the pharmacy team's assistance in identifying at-risk patients. All ordering physicians are now aware that the FDA requires HBV prescreening before initiating rituximab. Possibly adding a flag to our Beacon Oncology ordering system to screen patients on rituximab for HBV before initiating therapy is being discussed as a next step.

AB2016-16. Improving the Identification of Surrogate Decision-Makers for Patients in the Ambulatory Setting of a Comprehensive Cancer Center: A Quality Improvement Project

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From The Ohio State University Comprehensive Cancer Center

Background: Despite surveys demonstrating patients' desire for improved communication regarding identifying surrogate decision-makers and completing advance directives, ambulatory clinics are not routinely addressing this need. Therefore, many patients are uneducated on this topic, resulting in inappropriate surrogates and/or surrogates who are unprepared to address the often critical choices they face. The objective of this study was to provide staff education to improve documentation in the electronic medical record (EMR) of each patient's preferred surrogate and to provide patients the opportunity to complete a healthcare power of attorney (HCPOA). **Methods:** Baseline data on documentation of preferred surrogate and HCPOA completion was obtained for a random sample of patients seen during March 2014 in the gynecologic oncology (GO) and palliative care (PC) clinics. Nursing staff were trained to discuss advance directives with patients, emphasizing the selection of a surrogate and completion of an HCPOA. Subsequently, all patients seen in those clinics between April 2014 and July 2014 were to be counseled on surrogacy and HCPOA, with EMR documentation. All competent patients were asked to identify their preferred surrogate. If their preferred surrogate was c/w the Ohio statutory default priority (spouse, children, parents, siblings, other relative), it was documented and they were offered the option of completing an HCPOA. If their preferred surrogate was not consistent with the Ohio statute, they were informed of this and advised to complete an HCPOA form to assure that their preferred surrogate would be their legal surrogate. If completed in the clinic, the HCPOA form was scanned into the EMR. If patients preferred, they could take the forms home to review and complete. In either case, the decision and plans were documented in the EMR. **Results:** Baseline data for a sample of patients demonstrated that an HCPOA was scanned into the EMR at the GO clinic for 19% of patients at site 1 and 28% at site 2, and 28% in PC clinic. A discussion of surrogacy was documented in the EMR at rates of 19%, 24%, and 43%, respectively. After implementation of the intervention, data was available for 991 GO visits and 263 PC visits, for which there was documentation in the EMR of surrogate/HCPOA in 633 (64%) of GO visits and 225 (86%) of PC visits. **Conclusions:** Our study demonstrates that the identification and documentation of the appropriate surrogate in the outpatient setting is feasible and sustainable. The implementation of this process throughout OSU and James clinics will ultimately allow patients the opportunity to identify their preferred decision-maker, improving the likelihood that their preferences and values will be honored.

Young Investigator Awards

Clinical Oncology

AB2016-17. CDX2 as a Prognostic and Predictive Biomarker in Stage II/III Colon Cancer

Piero Dalerba, MD[a,b]; Debashis Sahoo, PhD[b,c]; Soonmyung Paik, MD[d,e]; Xiangqian Guo, PhD[f,g]; Greg Yothers, PhD[d]; Nan Song, PhD[d]; Nate Wilcox-Fogel, MS[h]; Erna Forgó, MD[f]; Pradeep S. Rajendran, BS[b]; Stephen P. Miranda, BA[b]; Shigeo Hisamori, MD, PhD[b]; Jacqueline Hutchison[b]; Tomer Kalisky, PhD[i]; Dalong Qian, MD[b]; Norman Wolmark, MD[d,j]; George A. Fisher, MD,PhD[h]; Matt van de Rijn, MD, PhD[f]; and Michael F. Clarke, MD[b,h]

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NCCN 21st Annual Conference Abstracts

[c]Department of Pediatrics and Department of Computer Science and Engineering, University of California San Diego; [d]The National Surgical Adjuvant Breast and Bowel Project, NRG Oncology; [e]Severance Biomedical Science Institute, Yonsei University College of Medicine; [f]Department of Pathology, Stanford University; [g]Department of Biochemistry and Molecular Biology, Medical School of Henan University; [h]Department of Medicine, Division of Oncology, Stanford University; [i]Faculty of Engineering, Bar Ilan University; and [j]The Allegheny Cancer Center at Allegheny General Hospital

This manuscript is available at N Engl J Med 2016;374:211–222.

Epidemiology/Risks

AB2016-18. Geographic Disparity in the Use of Hypofractionated Radiotherapy Among Elderly Women Undergoing Breast Conservation for Invasive Breast Cancer

Erin F. Gillespie, MD; Rayna K. Matsuno, PhD; Beibei Xu, PhD; Daniel P. Triplett, MPH; Lindsay Hwang, BS; Isabel J. Boero, MS; John P. Einck, MD; Catheryn Yashar, MD; and James D. Murphy, MD

From University of California, San Diego

This abstract is available at Int J Radiat Oncol Biol Phys 2015;93(Supplement):e9–10.

Clinical Oncology

AB2016-19. Safety and Clinical Outcome of CD19-Targeted 19-28z CAR-Modified T Cells in Adults With Relapsed or Refractory B-Cell ALL

Jae H. Park, MD; Isabelle Riviere, PhD; Yvette Bernal, MS; Terence Purdon; Elizabeth Halton, RN, MS, ANP; Xiuyan Wang, PhD; Michel Sadelain, MD, PhD; and Renier J. Brentjens, MD, PhD

From Memorial Sloan Kettering Cancer Center

This abstract was presented at the 57th ASH Meeting; December 5–8, 2015; Orlando, Florida. Abstract 682. Available at: https://ash.confex.com/ash/2015/webprogram/Paper86688.html.

AB2016-20. Geriatric Assessment Metrics Are Associated with Hospital Length of Stay in Pre-Bone Marrow Transplant Multiple Myeloma Patients

Ashley Rosko, MD[a]; Craig C. Hofmeister, MD, MPH[a]; Yvonne A. Efebera, MD, MPH[a]; Don M. Benson, MD, PhD[a]; Douglas Sborov, MD[a]; Samantha Jaglowski, MD, MPH[a]; Steve Devine, MD[a]; Tanya Wildes, MD[c]; James E. Gillahan[b]; Desiree Jones[a]; Ying Huang, MS[a]; and Christin E. Burd, PhD[c]

From the [a]Division of Hematology, and [b]Departments of Molecular Genetics and Molecular Virology Immunology and Genetics, The Ohio State University; and [c]Division of Medical Oncology, Washington University School of Medicine

This abstract was presented at the 57th ASH Meeting; December 5–8, 2015; Orlando, Florida. Abstract 3200. Available at: https://ash.confex.com/ash/2015/webprogram/Paper85543.html.

Best Practices in Implementation and Use of Clinical Practice Guidelines

AB2016-21. Evaluation of a Novel Psychological Intervention to Improve Decision Satisfaction and Decrease Regret in Women Considering Fertility Preservation

Terri Lynn Woodard, MD; Laura Covarrubias, MSPH; Andrea Michele Bradford, PhD; and Leslie R. Schover, PhD

From The University of Texas MD Anderson Cancer Center

Background: ASCO guidelines recommend that reproductive-age individuals at risk for cancer-related infertility be informed of their risk and referred to reproductive specialists early in the course of treatment planning. In addition, the NCCN Guidelines for Adolescent and Young Adult Oncology explicitly recommend referral to a mental health professional to assist with complex decision-making if needed. Most efforts to address survivors' fertility concerns have focused on the medical aspects of fertility preservation (FP), with less emphasis on psychological and decision support needs. There are limited data on the efficacy of psychological interventions in women considering FP. Our objective is to determine whether incorporating a psychological assessment and intervention into the standard FP consultation improves satisfaction with decision-making and decreases decision regret. We report baseline and 1-month follow-up data for current study participants. **Methods:** Women aged 18–40 years at risk of cancer-related infertility referred to the FP service at a tertiary cancer center were adaptively randomized to usual care (consultation with a reproductive endocrinologist and nurse) or intervention (usual care plus 3 sessions of psychological assessment and counseling with a licensed clinical psychologist). Levels of decisional satisfaction and regret were measured at follow-up assessments. **Results**: To date, 20 participants have been recruited and 19 completed baseline and 1-month assessments. Of these, 10 patients were randomized to usual care and 9 to intervention. Average patient age was 32.7 years (range, 2–44). At baseline, 70% of women (n=7) in usual care and 80% (n=8) in the intervention reported high levels of satisfaction with their decision. For those in usual care, this number dropped to 50% (n=5) compared with 78% (n=7) in the intervention. Women in the usual care group had lower levels of decisional regret at 1 month than those in the intervention group (16.5 vs 22.2). However, more women in the usual care group pursued assisted reproductive technology than in the intervention group (44.4% vs 30%). Women receiving psychological assessment and counseling reported high satisfaction with the intervention (mean Client Satisfaction Questionnaire score of 28 out of 32). **Conclusions**: Our preliminary data suggest that incorporating a psychological assessment and intervention into a standard FP consultation is feasible and can potentially improve decision satisfaction over time. The reason for higher levels of decision regret in the intervention group warrant further investigation. Women receiving the intervention were highly satisfied with the care provided.