Fall 2020 SWOG PALLIATIVE & END of LIFE CARE CMTE Meeting – Virtual

SUMMARY

Date: September 24, 2020 **Time:** 2:45 – 4:45 pm CT

Agenda:

Welcome and Introductions – Co-Chairs

Committee Liaison Updates (Patient Advocates/ Nursing)

<u>Committee Member Discussion: Syndemic of COVID 19 and Social Injustice – Impact at an Institutional/Personal level</u> – Marie A. Bakitas, DNSc, NP-C, FAAN

Plenary: "Assessing the Older Adult with Cancer: Predicting Treatment Tolerability and Outcomes" - Grant Williams, MD

Proposed Concepts Discussion

Active Study Updates

Secondary Analysis

New Business

Closing Comments and Adjourn

Additional Information

Chat Box Comments

Welcome

0:00:50

Marie Bakitas opened the meeting.

- Introduced her cochairs Mark O'Rourke and Robert Krouse
- Started with announcements
 - Said speakers who went beyond their allotted time would be not muted but drowned out by Christy Klepetko playing guitar

Krouse noted the echoing continued.

• Jeff, tech from IMS, said he was working on it.

Committee Liaison Updates: Patient Advocates

0:03:30

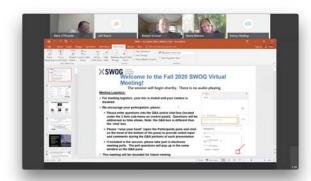
O'Rourke said next part of meeting would be to hear from patient advocates.

• Advocate Valerie Fraser would provide update on advocate activities

Fraser said committee's work was essential for advancing care for patients and their caregivers during the most critical times of their illness.

0:04:30

Fraser spoke of COVID's making this time even more difficult for these patients.



0:04:44

Fraser spoke of her experience after diagnosis 13 years earlier.

- Was compelled to make a difference for patients through research advocacy
- Introduced committee's strong team of advocates

PALLIATIVE AND END OF LIFE CARE COMMITTEE

Frank Meyskens, M.D.

Bernard Parker, M.D.

Data Coordinators:

Kate Castro, M.S., R.N.

NCORP Representative:

Co-Chairs: Robert S. Krouse, M.D. Mark A. O'Rourke, M.D.

Marie A. Bakitas, DNSc, NP-C, FAAN

Executive Officer:

Katherine Crew, M.D., M.S.

Statisticians: Katherine Guthrie, Ph.D.

Garnet Anderson, Ph.D. Kathryn B. Arnold M.S. Danika Lew, M.A.

. Nurse: Joan Long, R.N., O.C.N.,

CRA:

Connie Szczepanek, R.N., B.S.N.
Joyce N. Tull. R.N., M.S.N.

Roxanne Topacio & Monica Yee

Amanda R. Dinsdale, M.H.A., C.C.R.C

Patient Advocates:

Lee Jones Carol Seigel Valerie Fraser Michelle Denault

Protocol Coordinator: Christy Klepetko,

Protocol Coordinator II Clinical Trial Project Manager:

Vanessa Benavidez, B.S., CCRC, ACRP-PM

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0:05:27

- Lee Jones is lead advocate for Survivorship Committee
 - o Survivor of stage 4 colon cancer
 - Research advocate on many levels in state of Virginia
- Carole Seigel is lead advocate for the GI Committee
 - Lost her husband to pancreatic cancer
 - Led her to research advocacy
- Michelle Denault is committee's newest advocate
 - o Survivor of stage 4 lymphoma
 - o Took part in immunotherapy trial
 - o Active with patients on social media
- Encouraged members to learn more about full team of SWOG advocates under the Our Network link on swog.org

0:07:20

Echoing stopped.

Meet the Palliative & End of Life Care Committee Advocates



- Valerie Fraser Lead P&EOL Committee Advocate
 Advocate participation in S1820; S2016; ACCEPT,
 HOPE, MAID and Hopefulness Intervention; early input
- Lee Jones Lead Advocate C
 Survivorship Committee C
 Advocate participation in S1820 A
- Advocate participation in S1820 from beginning in Survivorship Committee thru PCEOLC
- Carole Seigel Lead Advocate GI Committee
- Advocate participation in S2016; ACCEPT;
 Pal Care Pancreatic; early input
 Hopefulness & INTIMACY planning



Michelle Denault - Communi Advocate Stage 4 Lymphoma Survivor

Committee Member Discussion: Syndemic of COVID 19 and Social Injustice 0:07:35

Bakitas acknowledged unprecedented times we are facing.

Noted that she had been assembling her presentation on 9/11

SWOG Clinical Trials Partnerships (SWOG-CTP)

SWOG-CTP is an independent, limited liability corporation with its own leadership, processes, and funding agreements. But the mission of SWOG and SWOG-CTP is the same – significantly improve lives through cancer clinical trials and translational research.

SWOG-CTP meets this mission two ways:

- · Obtains/distributes industry support for federally-funded SWOG trials
- Runs rigorous, scientifically-relevant, industry-supported trials with no federal funding through the Preferred Partnership Program (PPP), focusing on platform studies within or across disease types

PLEASE EMAIL CTP@SWOG.ORG WITH YOUR INTEREST, APPLICABLE IDEAS, AND/OR INDUSTRY CONTACTS

For more info please visit: https://thehopefoundation.org/about/swog-clinical-trials-

SWOG RESEARCH

SWOG CLINICAL TRIALS PARTNERSHIPS

0:08:30

- Included that event as part of remembrance
- Remembrance of victims of 9/11, COVID-19, and those affected by social injustice and racism
- Rather than a moment of silence, Bakitas advocated speaking up about what is important to us

Remembrance

- September 11
- •Covid-19
- Social injustice& racism

LET'S NOT STAY SILENT!



0:09:27

Bakitas noted that as palliative care providers, important to assess where patient is before proceeding with our agenda.

• Bakitas wanted to assess where group is in this meeting

Syndemic

- A syndemic is concept developed in early 90s
- Illustrated how communities most highly impacted by new epidemics are those that have already been facing critical threat to health
- Syndemics sustained by broader set of political, economic, and social factors
 - Had a perfect storm of these

What is a Syndemic & What does this have to do with Palliative & EOL Care?

- Syndemic a concept developed in the early 1990s in the context of the HIV epidemic to illustrate how communities most highly impacted by new epidemics are those that are already facing critical threats to health.
- Syndemics are strongly influenced and sustained by a broader set of political-economic and social factors.
- Conditions do not simply co-occur; the synergy among epidemics made each worse.

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- Syndemic is not just co-occurrence of these conditions
- Is synergy that develops among these conditions that makes them worse
- Bakitas said cancer care field already aware of care disparities
 - o Higher morbidity and mortality in underrepresented groups
- Also have racial injustice
- COVID pandemic makes for triple threat
- Synergy among multiple epidemics makes each worse

0:11:38

COVID-19 and social injustice

- Bakitas said she wanted to have conversation about this
- Before meeting had invited several members to reflect on answers to questions given in slide
- Bakitas asked members to raise hands to speak up
- Asked Heidi Deininger to speak

Deininger introduced herself as clinical research nurse in Michigan Cancer Research Consortium NCORP.

- Part of Trinity Health
- Mission is to be compassionate, transforming healing presence in community
- Pandemic brought cancer research program to halt
- Pivoted to work with infectious disease department
- Did early studies with remdesivir and plasma
- Rapidly saw magnitude of health inequalities
- Became clear COVID was not socially neutral disease
 - o Large number of incarcerated patients
- Had entered a war zone
- Only within last month that they've started to reemerge and ramp up oncology research program
- Also initiating palliative care research
 - o E.g., URCC study cochaired by Bakitas

Syndemic of COVID-19 & social injusti-

- How is this impacting cancer & palliative care research at an institutional level?
- Positive
- Negative
- How is this impacting cancer & palliative care researchers at a personal level?
 - Positive
 - Negative

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- In immediate community, epidemic reflects long-standing economic and political inequalities
- But it has motivated them to levels of advocacy and community engagement
- Deininger said a core institutional value for them is serving those most vulnerable
- At personal level they tell themselves the worst is over
- Palliative care social worker tells them they're feeling lasting physical and emotional impact of suffering they witnessed
- Pandemic reminds us of collective humanity
- Reminded to pause, grieve, and put oxygen mask on first
- One of her greatest joys was to meet young African-American man who had spent 50 days in ICU and had gotten both remdesivir and convalescent plasma
 - Had all comorbidities
 - o He spoke of weight he had lost and exercises he was doing
 - o Said he had a second chance
 - Would make most of it
 - Deininger felt her team had made a difference
- Have a new lens for viewing work they do
- Hope that ways they are transformed in ways that benefit future
- Said we live life forward but understand it backwards

0:16:00

Bakitas invited Ishwaria Subbiah to speak.

- Subbiah thanked Bakitas for doing this
- Won't have solutions here, but recognition we're not alone in these struggles is much appreciated
- Said level of distress she sees in patients is unprecedented
 - o Cancer diagnosis on top of everything else
- Level of distress she carries into work is also much higher
 - o Emotional reserve is not there like before
- Has learned over last 6 months that that lack of emotional bandwidth is not going to change
- Has taken self-protection strategies

- Now more than ever appreciates multidisciplinary nature of team
- Truly have to go through it as a team
- Time when she's had to share many elements of her practice with people outside
- So much suffering in the world now that you can't look at someone else's suffering and say that's not my problem because I don't look like them
 - o Said this is how they've always governed their practice, but now ...
 - Feels compelled to be vocal in saying we should not look at the problems of others and say that's not my problem

0:18:45

Bakitas invited Valerie Fraser to speak.

Fraser said was challenging time for patients, particularly patients struggling with end of life issues.

- Hearing more and more about difficulty of dealing with devastating cancer diagnosis on top of fear of pandemic and of they or their families being exposed to the virus
- Very stressful times for cancer patients
- Fraser suggested it was time for more out of the box thinking about how to change clinical trials
 - o Particularly for the most vulnerable

0:20:30

Bakitas noted meeting had started couple minutes late, and she should be moving on to developing studies but would call on Bernard Parker to say a few words.

Parker thanked committee for opportunity.

- Noted he agreed with previous speakers' comments
- Appreciated in particular what Subbiah spoke of
- Said we take steps forward and then back, so good idea to learn from history, particularly previous pandemics
 - o Learn by observing what's going on outside of the US as well

- Painful period and has impacted his clinical work
- Has also lost 2 family members from COVID
- Noted he was now in uniform and had to carry himself in official mode
- Thanked all involved in cancer research and patient care
 - Said they are the heroes
- Noted he had been deployed to New Mexico few months earlier to work among COVID patients
 - o Really affected his perspective

0:24:10

Frank Meyskens spoke.

- Said he faced severe cardiac event late last year
- Was in hospital for 46 days and barely survived
- When he woke up, heard about COVID
- Now worries about it every day
- Particularly striking how many staff members have approached him to discuss COVID and how to deal with it
- No doubt that it is a real syndemic

0:25:04

Bakitas thanked speakers and others for their contributions.

• Said one of the things that had most impressed her has been personal outreach of colleagues to her

Proposed Concepts Discussion

0:26:08

Bakitas introduced Vincent Chung and Virginia Sun to present a study in development.

Chung presented S2016.

- Randomized phase 3 trial of primary palliative care intervention to improve QoL in patients with metastatic pancreatic cancer
- Palliative care is an important element of care for these patients as it is an aggressive disease
- Thus important to be aggressive in managing symptoms and attending to QoL
- Said palliative care (PC) is considered gold standard of care for cancer patients
 - But significant shortage of PC specialists
 - Can't meet current or future demands
- So scalable approach is needed to meet demand
- Have seen in other studies that comprehensive patient assessment administered centrally by advanced practice nurses can identify needs early and guide interventions
- That is basis for this clinical trial

S2016: Randomized Phase III Trial of a Primary Palliative Care Intervention to Improve Quality of Life in Metastatic Pancreatic PI: Vincent Chung and Virginia Sun

- · Palliative care (PC) represents an important aspect of care for pancreatic cancer patients, where aggressive symptom management and attention to QOL needs are critical.
- · PC is considered the gold standard of care for cancer patients, the significant shortage of PC specialists cannot meet current or future
- · Scalable approaches are essential to meet the growing demand for PC.
- · A comprehensive patient assessment administered centrally by an advanced practice nurse can help to identify needs early which can then guide interventions.

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0:27:27

- Eligibility criteria include
 - Metastatic pancreatic cancer
 - Enrolled within 8 weeks of diagnosis
 - ECOG PS 0-2
 - English speaking and reading
 - Patients 18 years +
 - Willing to complete questionnaires
- Patients and their families complete baseline surveys
- Then randomized to intervention or to attention control arm:
 - Intervention: Personalized PC plan developed based on their baseline survey
 - Phone assessments over 3 months



- · Eligibility criteria include:
- Metastatic pancreatic adenocarcinoma
 Enrolled within 8 weeks of initial diagnosis of pancreatic cancer
- 4) Ability to read, speak, and understand English
- Age 18 years and older
- Willing to complete questionnaires

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- o Attention control: Get NCI Coping with Advanced Cancer booklet
 - Regular SoC
- Assessments at 3 and 6 months

0:28:33

Statistics

- 170 evaluable patients
 - o 85 per arm
- Number will be needed to detect 8-point difference in FACT-Hep between the arms at 3 months
- Assuming normally distributed outcome with 90% power and 1-sided alpha of 0.025
- Expect 4 years of accrual
 - o 4–5 per month
- Grant submitted to NCI on June 5
- Will be reviewed Oct 19
- Should hear back soon

Bakitas noted there would be time at end of meeting for additional questions.

- Introduced Jaroslava Salman to present on depression, screening, and treatment in patients requesting medical aid in dying
- Noted Chuck Blanke was co-PI

Statistical Plan



- Randomization will be stratified by ECOG performance score (0-1 vs. 2).
- A total of 170 evaluable participants (85 per arm) will be required to detect an 8-point difference (SD 16) in FACT-Hep between arms at 3 months, assuming an approximately normally-distributed outcome, 90% power and a 1-sided alpha=0.025.
- The anticipated accrual completion timeframe is 4 years, assuming a minimum of 4-5 accruals per month across all sites, with at least 10-15 participating sites.
- NIH R01 grant submitted 6/5/20 will be reviewed 10/19/20

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0:29:51

Salman presented a study to accurately estimate the rate of depression in patients making their first oral request for medical aid in dying (MAID).

- Primary objective is to estimate prevalence of clinically significant depression assessed by the Hospital and Anxiety Depression Scale (HADS) at end of life
- Secondary objectives include
 - o Assessing feasibility for phase 3 depression treatment trial proposal
 - Describe patients' willingness to complete a questionnaire regarding depressive symptoms at end-of-life
 - Estimate acceptance of psychiatric referral for patients seeking MAID (acceptance of a referral vs actually attending an appointment with psychiatrist)
 - Ascertain rates of anti-depressant use for any reason in patients making the request
 - o Capture non-psychiatrist-assessed rates of decisional capacity as assessed by the physician evaluating a patient for MAID eligibility
 - Estimate the proportion of patients with clinical depression who go on to use MAID

A Study to Accurately Estimate the Rate of Depression in Patients Making Their First Oral Request for Medical Aid-in-Dving (MAID).

Jaroslava Salman, MD, FACLE Charles Blanke, MD, F.A.C.P., F.A.S.C.O.

Objectives

Primary: To estimate the prevalence of clinically significant depression as assessed by Hospita Anxiety and Depression Scale instrument (HADS score>11) among patients at end-of-life making their first request for MAID..

- Assess feasibility for phase III MAID SWOG depression treatment trial proposal
- Describe patients' willingness to complete a questionnaire regarding depressive symptoms (Hospital Anxiety and Depression Scale, HADS) at end-of-life
- Estimate acceptance of psychiatric referral for patients seeking MAID (acceptance of a referral vs actually attending an appointment)
- Ascertain rates of anti-depressant use (any purpose) in patients seeking MAID
- Capture non-psychiatrist-assessed rates of decisional capacity as assessed by the physician evaluating a patient for MAID eligibility.
- Estimate the proportion of patients with clinical depression who go on to use MAID

0:32:48

- MAID is legal in 10 US venues
 - All require patients requesting MAID to have decisional capacity
 - But no formal definitions of decisional capacity in MAID
 - May or may not include lack of depression
- Incidence of true depression in MAID patients has been estimated in small study at ~25%, but that figure has not been verified
- Proactive screening for depression is inconsistent across centers that participate in these laws
 - Thus we lack knowledge about the rate and significance of depressive symptoms at end-of-life in relation to MAID

Background

- Medical-aid-in-dying (MAID) or Death with Dignity (DWD) is legal in 10 United States' venues
- All require the patient requesting MAID to have decisional capacity
- There are no formal definitions of decisional capacity in MAID but may or may not include lack of depression
- The incidence of true depression in MAID patients has been estimated at ~25%1, but that figure has not been verified
- Proactive screening for depression is inconsistent across centers therefore, we lack knowledge about the rate and significance of depressive symptoms at end-of-life in relation to MAID
- It remains unknown how identifying and treating clinically significant depression in patients requesting MAID could impact their choice and ultimately, the use of MAID?
- 58% of psychiatrists feel depression may render patients incompetent to choose MAID²
- Treatment of depression, even near end of life, reduces the desire to die³
- · Physicians involved in MAID may mandate psychiatric evaluation for competence/capability But they very rarely do so⁴, despite high rates of depression
- Multiple publications have suggested MAID rules may not adequately protect patients with

- Really remains unknown how identifying and treating clinically significant depression in patients requesting MAID could impact their choice and ultimately the use of MAID?
- Many psychiatrists feel depression may in some cases render patients lacking in capacity to consent
- But know that treating depression near end of life reduces the desire to die sooner
- Physicians involved in MAID may ask for psychiatric evaluation for capacity but rarely do so
 - o Rarely refer patients for any mental health assessment
 - Despite fairly high rate of depression
- Multiple publications have suggested MAID rules may not adequately protect patients with mental illness

0:34:56 Eligibility

- Enroll adult patients at select cancer centers making their first oral request for MAID
 - o Second oral request has not been made yet
- Patients can be on an antidepressant but for indication other than clinical depression
 - o Patients often on these for sleep, appetite, anxiety
- No history of treatment-refractory depression
- No history of suicide attempts

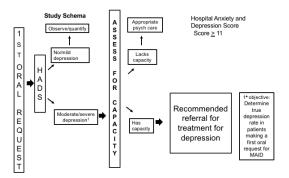
Eligibility

- · Adult patients at select cancer centers making their first oral request for MAID
- Second oral request for MAID has not been made yet
- Patients may be on an antidepressant but for indication other than clinical depression (e.g. sleep, anxiety disorder)
- No history of treatment-refractory depression
- · No history of suicide attempts

0:35:41

Schema

- Patient making first oral request asked to complete questionnaire (HADS)
 - o HADS designed to detect anxiety and depression in medically ill patients
 - o Focuses on emotional and cognitive rather than physical symptoms
 - As patients can have physical symptoms for other reasons
- Patients scoring no or mild symptoms are observed
 - o Further quantification of their symptoms
- Patients with moderate to severe level (11+) formally assessed for capacity by evaluating physician
 - o If patient deemed to lack capacity, referred to psychiatric care
 - If patient has capacity, recommended a referral for treatment of depression
 - Will help determine true depression rate in the patients making first request for MAID



0:37:29

Depression screening and treatment

- Proactive screening for depression in these patients is currently neither mandated nor required as SoC practice in patients requesting MAID
 - o Institutions may have different algorithms
 - May involve screening for depression
 - o Salman said City of Hope does not do screening
- HADS self-reported questionnaire often used in oncology
 - o Demonstrated to be sensitive in community and inpatient cancer studies
 - Scores >=11 likely indicating depression
- Patients >=11 referred for further assessment and treatment
- Treatment may include medication (antidepressant or stimulant) or brief psychotherapy
 - o Will also depend on patients' openness to treatment

Depression Screening & Treatment

- Screening for depression is currently neither mandated nor required as a standard of care practice in patients requesting a MAID
- Hospital Anxiety and Depression Scale (HADS) is a self-report questionnaire frequently used in oncology
- It has been demonstrated sensitive in community and inpatient cancer studies, with subscales of < 7 not present, 8-10 doubtful. >11 definite. Reported Cronbach's alpha of 0.84-0.89.
- Patients scoring at or higher than 11 points would be referred for further assessment and treatmen by a psychiatrist
- Treatment may include medication (e.g. antidepressant and/or stimulant) and/or brief psychotherapy intervention

0:38:56 Statistics

- Goal of 120 patients
- Allows estimate of true depression rate with 95% CI
- After 6-month startup, study expected to accrue 7/month
- If does not accrue >50%, by end Q6, rate will be deemed inadequate to support phase 3 study

Bakitas said they would collect questions and pass them to presenter.

• Also hoped Blanke might address some at end of meeting

.....

Plenary: "Assessing the Older Adult with Cancer: Predicting Treatment Tolerability and Outcomes"

0:39:34

Bakitas introduced plenary speaker Grant Williams

- From U Alabama at Birmingham (UAB)
- Medical training in Philadelphia and at UC-Chapel Hill
- Earned MPH in translational and clinical sciences at UAB
- Director of cancer and aging program in Cancer Outcomes and Survivorship Institute
- Medonc with focus in GI oncology, also codirects caregiver and bereavement support service for Center for Palliative and Supportive Care
- Said he would present exciting science in geriatric and oncology research

Williams introduced himself

- Geriatrician oncologist in GI cancers
- Research focuses on geriatric assessments, sarcopenia, comorbidity, and frailty
- Talk is on assessing older adults with cancer and predicting treatment tolerability and outcomes

Statistics & Funding

- . Accruing 120 pts will allow estimated of true depression rate +/- 9% (95% CI)
- After start up of 6 months, the study will accrue ~7 pts/mo
 - If the study does not accrue >50% pts by end quarter 6, the rate will be deemed inadequate to support a phase III study





Assessing the Older Adult with Cancer: Predicting Treatment Tolerability and Outcomes

Grant R. Williams, MD MSPH Assistant Professor, Dept of Medicine September 24th, 2020

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0:43:00

- Would provide background in geriatric oncology
- Focus on geriatric assessment
 - o How to use it personalize and manage treatment of older adults
- Also on barriers to using it

Roadmap



- Provide an overview of the field of Geriatric Oncology
- Examine the role of and barriers to geriatric assessment in the management of older adults with cancer

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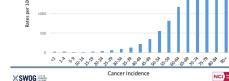
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Age at diagnosis of cancer

- Williams asked why this is an important area
- Cancer predominantly a disease of aging
 - SEER data in slide
- Incidence starts to increase in 4th and 5th decades
 - o Peaks in 8th decade
- For those aged 50–70, number one cause of death in US
- Vast majority of cancer deaths occur in those over 65
- Median age of diagnosis in US is 67
 - But given aging of population, it is estimated that by 2030 about 70% of all new cancer diagnoses will be in those over 65
- Kind of a niche field, but represents majority of patients we're seeing and treating

Age at diagnosis of cancer in general population Age-Specific Incidence Rates

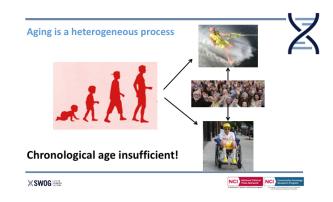




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Age

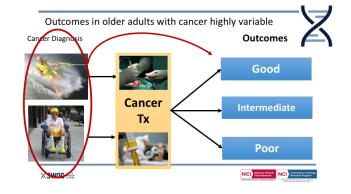
- Unlike developmental process, which is fairly linear and predictable, aging process is very heterogeneous
 - Depends on lifestyle and genetic factors
- Pace of aging unique from individual to individual
- These differences not very noticeable in early decades of life
 - But by 6th or 7th decade, significant difference in pace or accumulation of aging-related phenomena
- Some individuals in 7th decade of life are functionally independent and have few comorbid conditions
- Others same chronological age but have severe functional impairments and face significant health barriers daily
- If everyone walked into clinic in one of these two categories, would be simple field
- But these are extremes of spectrum
- All those patients in between
 - o It's how to assess spectrum of health that makes this challenging



0:46:15

Older adults with cancer

- Chronological age is insufficient assessment of aging process
- Example: Two individuals at left in slide
 - Both treated for cancer
 - o Outcomes are heterogeneous
- Know some older adults have outcomes similar to those of younger patients with aggressive cancer patients
 - o E.g., resection, chemo, or radiation
- See this in phase 2 and 3 trials
 - Older population enrolled in those trials are usually super fit, healthy selection of population
- On flip side, know older adults at higher risk of adverse outcomes



- o E.g., chemo toxicity, surgical complications, tolerating radiation
- Aging itself can put people at higher risk
- What is best predictor of outcomes?
 - o Health status of individual at time of diagnosis

0:47:54

Assessing older adults

- Assessing older patients is conundrum for clinicians
- Age and PS are insufficient
 - o These two are always part of eligibility criteria
 - o But those alone don't predict outcomes or assess aging
- Trying to find better ways to assess older adults to personalize care
- This is goal of field of geriatric oncology
- Come a long way, but how this is done in practice is still vague

Assessing Older Adults with Cancer



- · Remains a clinical challenge
- Chronological age and performance status alone insufficient



 Better ways to assess older adults are needed

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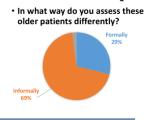
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Evaluating older adults

- Do have data on how older adults are assessed within oncology
- ASCO older adult task force did international survey of >1,000 cancer care providers globally to look at how they assess older adults
 - Asked them "Do you assess older patients differently than your younger patients?"
 - o Seems older patients are assessed differently
 - About 90% of older patients are assessed differently some, most, or all the time
- Overwhelming recognition that we need to assess these patients differently
- Question is how are we doing that?
 - o 70% of time informal
 - o 30% of time formal
- The 70% is the eyeball test

How are Older Adults Evaluated?

Do you assess older patients differently than your younger patients?
 In voold



SWOG INTERNATION ASCO Older Adults Tasking
JCO Oncology Practice. In



- Physician tries to get sense in informal, subjective way how patient is doing
- Some inherent recognition they need to be assessed differently

0:50:46 Iceberg

- Part of routine oncology care assesses
 - o Age
 - o PS
 - Stage of cancer
 - Via CT scan, bloodwork, molecular characterization
 - Mutation markers
 - Have good guidelines based on these
 - Organ function assessments to judge whether patient can tolerate treatment
- Oncologist comfortable doing these steps
- But with older patients, those are the tip of the iceberg

Age Organ function The Geriatric Oncology Iceberg

0:51:47

- Issues under the surface
 - Polypharmacy
 - o Comorbidities and falls
 - o Psychosocial dysfunction
 - Social support
 - o Sarcopenia
 - o Functional cognitive impairments
 - Nutritional deficits
- These issues underneath are as important or even more important in determining how patients deal with treatment and how we can improve and personalize their care
- Unfortunately, these are often missed in routine oncology assessments



0:52:20

• Which gets us to concept of geriatric assessment



Geriatric Assessment...

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0:52:27

What is geriatric assessment?

- Multidimensional interdisciplinary diagnostic process that focuses on determining an older person's medical, psychosocial, and functional capabilities
- A comprehensive global assessment of health
- Consists of specific domains that must be assessed
 - o Different ways to assess each
 - o But important that each is assessed
- An evaluation component to this to help us understand their status and be prognostic
- But also many of these deficits have interventions, so a management side to this
- Challenges of geriatric assessment
- Requires
 - o Time
 - Specialized personnel
 - Expertise
- Typically done in specialty clinic
- Often takes 1–2 hours to complete in-person assessment
- Inherently a challenge, given how many older adults are diagnosed

What is a Geriatric Assessment?



Definition: A multidimensional, interdisciplinary diagnostic process focusing on determining an older person's medical, psychosocial, and functional capabilities

- Requires evaluation of multiple issues and domains
- · Involves both evaluation and management

Challenges

 Requires time, specialized personnel, and expertise



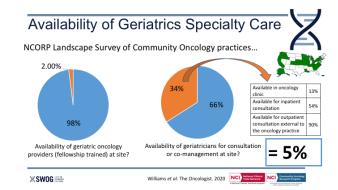




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Geriatric specialists

- Williams's team recently published a study looking at availability of geriatric specialty care
 - o Particularly geriatricians within community oncology sites
- Used NCORP Landscape Survey of Community Oncology practices
 - Wake Forest NCORP base does survey of entire NCORP research base
 - o Get better sense of what is available
 - Also to understand what kind of trials are realistic
- Williams's team used this survey
 - o Embedded questions on geriatric specialty care and access to it
- First question
 - o What is availability of trained geriatric oncologists at site?
 - 2% of all sites
 - Thinks this 2% is Mark O'Rourke
 - Would have been 0% without him
 - What is availability of geriatricians for consultation or co-management at site?
 - 34% of sites had availability
 - Dove deeper
 - Where do they get them?
 - 54% were available within hospital on inpatient side
 - Only 13% had geriatrician available to see patient in their own clinic
 - Most of these, 90%, were external to oncology practice
- Thus when we think about models of care on a nationwide level in US, involving geriatrician with care of every older adult is not realistic
 - o As with palliative care docs: not enough of them
 - Need to think of other models
 - Patient reported measures
 - Advanced practice practitioners
 - Same is true in geriatric oncology

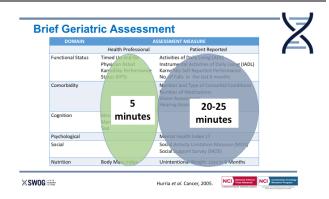


 Overall, only about 5% of oncology practices had geriatrician available within oncology practice

0:57:09

Brief geriatric assessment

- Well recognized we don't have enough geriatricians to see all these patients
- Can't speak of geriatric oncology without mentioning work of Arti Hurria
 - o True leader who blazed a path to develop field to what it is today
 - Unfortunately, passed away two years ago
- Some of her early work was recognition that we should perform geriatric assessment but don't have resources
- She developed Cancer and Aging Research Group Geriatric Assessment
 - Covers core domains as shown in slide
 - Predominantly a patient-reported assessment (85% 90%)
 - Includes assessments of falls, comorbidities, etc.
 - Some parts performed by health professionals
 - Provider assesses performance status, timed get up and go,
 Blessed Orientation and Memory Concentration, and height,
 weight, and weight loss
- Hurria took a 1–2 hour assessment by geriatrician and distilled to a 25–30 minute assessment
 - Only 5 minutes of health care provider's time
 - Rest by patient
- Finally moved geriatric assessment into prime time of oncology



0:58:58

Stages of aging

- Often unclear how what we talk about with geriatric assessment can be used in practice
- So incorporated this slide
 - o Borrowed from William Dale
- Williams said we're good at staging cancer but need to stage the aging
- Geriatric assessment can separate patients into 3 groups:
 - o Fit
- No functional impairments
- No significant morbid conditions
- No geriatric syndromes
- Overall fit regardless of age
- Should be treated similarly to younger counterparts
- Generally deemed fit for chemo, surgery, and should be treated like everyone else
- o Frail
 - Dependence in their ADLs
 - Significant comorbidities
 - Even one that's life threatening
 - Also have clinically significant geriatric syndromes
 - These are patients we recognize probably don't benefit from traditional oncology care
 - Care needs to be more adapted, supportive, palliative care measures
 - Absence potentially of doing any cancer directed therapies
- Above two groups are ones we are better at assessing.
- o It's the in-between group the vulnerable group where biggest challenge lies
- o Vulnerable
 - May have dependence on IADLs but not ADLs
 - Potential comorbid conditions and number of medications, none of which are severe or life-threatening

"Stages of aging" using Geriatric Assessment





- Fit (Excellent, Good)
- No functional impairmentNo significant comorbidity
- No geriatric syndromes



- Vulnerable (Good, Fair)
- Dependence in an IADL but not ADL
- Comorbidities but not severe or life-threatening

 No garietric syndromes other than mild memory described the severe of the
- No geriatric syndromes other than mild memory disorder or mild depression



Frail (Poor)

- Dependence in an ADL
- 3 or more comorbidities or one life-threatening
- A clinically significant geriatric syndrome

× SWOG



- No significant geriatric syndromes
- We must proceed with caution
- We recognize they're at risk
- Not sure how to modify their oncology care
- Trying to find ways to improve their outcomes; really a focus of a lot of research

1:01:27

Value of geriatric assessment

- Uncovers problems not found by routine oncology care
 - o Williams said they looked at study of falls
 - o About 25% 30% of older adults with cancer report falls in last 6 months
 - o Completely overlooked in standard oncology evaluations
 - Even though 3x greater incidence of grade 3 toxicities in patients who fall
- Can help accurately assess life expectancy
 - Particularly important in adjuvant setting
 - o Balancing long-term benefits of therapy
 - Competing comorbidities may mean patient experiences none of those benefits
- Can predict treatment related toxicity and other outcomes
 - o Mortality
 - o Hospitalization
 - Nursing home placement
- Some recent work through NCORP base indicating that geriatric assessment can improve communication
- Widely known that many of issues identified do have interventions
 - $\circ\quad$ For functional impairments, PT and OT can improve function
 - Evidence that interventions can reduce falls
- These are mostly based on general geriatric data that we've applied to oncology space

The Value of Geriatric Assessment in Oncolog



- Uncovers problems not found routinely
- Allows for accurate life-expectancy estimate
- Can predict treatment-related toxicity and other outcomes
- Improves communication
- Many problems have beneficial interventions
- Improve function
- · Reduce chemotherapy toxicities
- · Quality of life
- Survival

× SWOG

Wildiers et al. J Clin Oncol, 2014.

Mohile et al. J Clin Oncol, 2018.





- But in palliative care we now have good data showing improvements in outcomes
- Have lacked that in geriatric oncology space

1:03:32

ASCO 2020 data

- Lack of data was true up until this year's ASCO
- ASCO 2020 a banner year
- Had four oral presentations looking at geriatric assessment-based interventions, showing variety of improved outcomes
- One was Mohile abstract looking at how geriatric assessment can reduce the presence of severe chemo toxicities
 - Was also shown at City of Hope
 - o Also improved completion of advanced directives
- Another study in Australia that showed reduced hospitalizations
- Another study demonstrated that geriatric consultations in peri-operative space seemed to reduce length of stay
 - o Also reduced post-surgical ICU use
- None of these have yet been published
 - o Some are currently embargoed
- Exciting time in geriatric oncology
 - $\circ \quad \text{Now have four studies starting to show these benefits} \\$
 - Even more studies in Europe on large scale



1:05:22

Use of geriatric assessment (GA)

- Can't assume everyone is doing GAs in practice
- Seems like a good idea but many challenges
- ASCO task force asked multiple questions, including
 - How often do you perform a GA in management and care of older adults, particularly before chemo?
 - o About 50% of time, never or rarely perform GA
 - Only about 20% of time do older adults undergo a GA either always or most of the time
 - Williams said he thought this was probably skewed to higher numbers, as people sharing survey via Twitter are those more interested in the field
 - So clearly have a long way to go

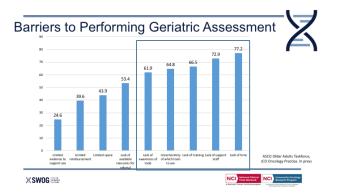
The Use of Geriatric Assessment in Oncology How often do you perform a geriatric assessment?



1:06:39

Barriers

- What are the barriers to performing GA in routine oncology care?
- In ranked list, greatest barriers were lack of training, lack of time, and lack of support staff
- Then lack of awareness and uncertainty of tools to use
 - Williams said this is not surprising, based on his conversations with oncologists
 - They say GA sounds great, but they have no idea what that means or which tool to use
 - Don't have enough time or training
- Piece of good news was only 24% thought there was limited evidence to support its use
 - o And this was before the 4 abstracts at ASCO
- Inherent recognition this makes sense
- So it's not an issue of limited evidence.



1:08:10

Williams's research

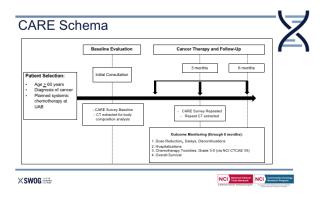
- Said group at UAB developed Cancer and Aging Resilience Evaluation (CARE)
- Took Hurria's GA and recognized that the 5 minutes of health care professional's time it included kept it from being integrated into routine care
- So Williams's team got rid of timed up and go, memory and concentration test, and nutrition measure
- Changed to patient-reported nutrition and cognitive function measures
- Streamlined
- Williams recognized objective testing of cognitive and physical functioning are important, but not so important they should lead to foregoing the whole GA



1:09:23

CARE schema

- Have a CARE registry at UAB
- Patients >60 with cancer eligible for registry, particularly GI cancer
- When they come to clinic, handed 6-page geriatric assessment
- Complete it before seeing provider
- Do have patient's consent retrospectively allowing UAB to keep the questionnaire responses for research
 - o Also allows team access to patient's medical records
 - o They do a lot of sarcopenia and body composition, so they extract that
 - o Also includes cancer type, stage, treatment, and outcomes
 - Outcomes include
 - Mortality
 - Dose reductions
 - Dose delays
 - Dose discontinuations
 - Chemo toxicities
 - Hospitalizations
- Patients treated at UAB get survey up front
 - o UAB tries to repeat it after 3 months of therapy to see changes



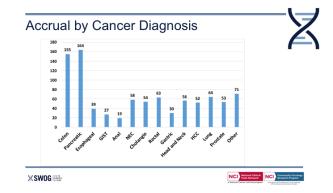
1:10:47

Bakitas relayed question from Chat:

- Are there any apps that will give feedback to the provider if brief GA is inputted, assuming it's done?
- Williams said benefit of doing it electronically is bringing it into a dashboard for providers
 - Makes it easier to integrate as far as the actual scoring of these assessments
- Challenge is it lowers scalability
 - When doing this in all cancer patients, can't hand out lots and lots of iPads
 - o Even their short assessment is 10 pages and about 6 minutes
- Could do it that way but haven't
- Looking at ways to push these questionnaires out to patients via text before appointment would be ideal
 - o They would have more time to complete
- So yes, it can be done, but hard to do in routine care; may be easier in a trial

Williams finished up his slides

Some recent accrual numbers



1:12:27

- Publication about how they're integrating this
- Takes about 10 minutes to complete
- Over 90% of GI patients can complete



Integrating geriatric assessment into routine gastrointestinal (GI) consultation: The Cancer and Aging Resilience Evaluation (CARE)

Grant R. Williams ^{a.b.}*, Kelly M. Kenzik ^{a.b}, Mariel Parman ^a, Mustafa Al-Obaidi ^a, Liton Francisco ^a, Gabrielle B. Rocque ^b, Andrew McDonadé ^a, Ravi Paluri ^b, Rudolph M. Navani ^a, Lalshmin Nandagopal ^b, Olumide Cobolann ^b, Crystal Young-Smith ^a, Matthew Robertson ^b, Smita Bhatia ^a.

- · Completely patient-reported Geriatric Assessment
- 92% of all new GI patients recruited since September of 2017





1:12:46

- Identifying many impairments, which is not surprising
- GI cancer population, so very sick

Table 1 Total and activation and implementation creabs. Total patients N = 232 And patients N = 232 And patients Make 1175 (54.2) Make 1275 (74.2) Make 227 (74.8) Make 227 (74.8) Table 3 (75.64) Table 4 (75.64) Table 5 (75.64) Table 6 (75.64) Table 7 (75.64) Table 7 (75.64) Table 9 (75.64) Ta

1:13:07

Goals with GA

- Need to develop better models to increase its use
- Focus on barriers
- Don't absolutely need extra staff and time
 - o Do need more training
- Do have some tools to predict toxicity and outcomes
 - o But for general oncology populations
 - Need to be refined to be more clinically useful
- Looking at changes in GA
 - o Functional decline

Our goals with Geriatric Assessment



- Develop models to increase the use of GA
- Refine prediction of treatment-related toxicity and other outcomes within GI malignancies populations
- Better understand changes in GA domains in older adults undergoing systemic chemotherapy (i.e. functional and HRQOL decline)
- Design and implement GA-based intervention studies

× swog



- Reductions in HRQoL
- Incidence of falls
- These need to be looked at more longitudinally
- How to implement these GA interventions on broader scale

1:14:22

Williams acknowledge mentors, co-investigators, and collaborators.

Bakitas said later in meeting Rajiv Agarwal would present Pal-Pack Geri-Pal-PRO package that he had presented to GI oncology group.

• Asked Williams to stay for questions around that

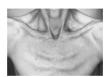


1:14:52

Williams said no time for sarcopenia slides.



Sarcopenia...



XSWOG ■

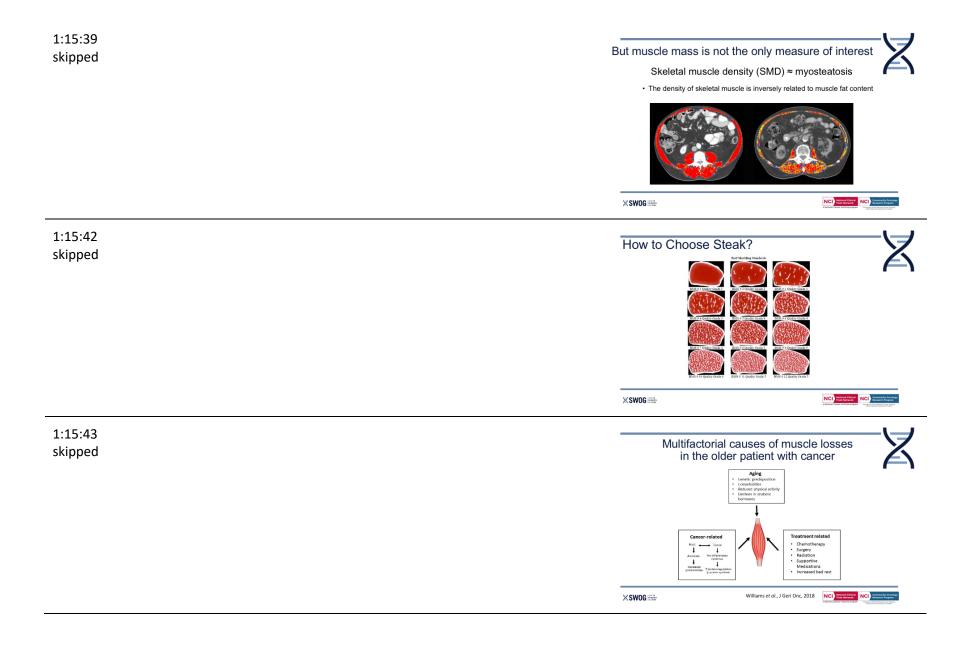


1:15:27 Background skipped · Losses in muscle mass and muscle strength occur as part of the agi Tzankoff, Norris. J. Appl. Physiol., 1997. Morley. Family Practice, 2012. XSWOG ■ 1:15:36 skipped "there is probably no decline in structure and function more dramatic than the decline in lean body mass or muscle mass over the decades of life." - Rosenberg, 1997 ×swog 1:15:37 Measuring body composition skipped Skeletal muscle Subcutaneous adipose tissue Visceral adipose tissue

Skeletal muscle index [SMI]

[SMI]= [red area]/(height(m)²)

Sarcopenia = low SMI



1:15:44 skipped

1:15:48

skipped

Sarcopenia in Oncology

Chemotherapy-induced toxicity

- · Significant association with increased incidence of dose limiting toxicity or severe toxicity
- True regardless of cancer site or type of systemic therapy

Post-operative complications/LOS

- Association with either post-operative infection and LOS Survival/Prognosis
- · Strong predictor of survival independent of age, sex, stage, disease site, and performance status

×swog ===

Kazemi-Biestani et al. Semin Cell Dev Biol. 2





What underlies the association of sarcopenia and adverse outcomes?



- Related to underlying impaired functional status?
- Frailty?
- · Comorbidities?
- · Cachexia and inflammation?
- Driven by tumor biology?
- Altered pharmacokinetics?
- · Or is the effect of muscle independent?



×swog ===



1:15:53

Agarwal discussed the Pal-Pack

- Package of assessments for geriatric measures, palliative care measures, and **PROs**
- Goal is to integrate this package into clinical trials

"Pal-Pack": A Geri-Pal-PRO package of patient assessment measures

Rajiv Agarwal, MD Assistant Professor of Medicine – Division of Hematology/Oncology Vanderbilt Ingram Cancer Center, Nashville, Tennessee

Mark A. O'Rourke, MD Prisma Health Cancer Institute, Greenville, South Carolina Co-Chair, Palliative and End-of-Life Care Committee

× SWOG



1:16:32

The need and the purpose

- Agarwal said that in large oncology trials there has been a cultural shift in recognizing importance of developing combined treatments or modalities that focus on survival benefit but also focus on QoL and PROs
- Said palliative and end of life care committee endorses a consistent, uniform assessment of these metrics to incorporate into SWOG disease-specific trials
- They want to identify QoL and symptom issues typically found in specific diseases to predict favorable end of life care outcomes
 - o E.g., fewer days in hospital at end of life
 - More hospice use towards end of life
 - Less chemo or other cancer treatment in last 2 weeks before death
- Also to identify which patients on investigational treatment would benefit from advanced care planning
- To identify geriatric and caregiver issues
- Agarwal said they want to be able to achieve these goals while patient is still getting investigational treatment

The Need for a Geri-Pal-PRO package of measures



- · Geri-Pal PRO metrics can:
- Identify quality of life & symptom issues that are associated with cancer treatment and survival outcomes, for example, QOL (improved survival) and fatique (decreased survival)
- Predict favorable end-of-life care outcomes, for example, fewer days in hospital in last month of life, more hospice use greater than three days, and less chemotherapy in the two weeks prior to death
- · Aid in advance care planning
- Identify geriatric issues known to impact treatment outcomes and patient experience
- · Identify caregiver issues

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1:17:59

Advantages

- Package will be reviewed in advance by our committee and any disease-specific community committee
- Will provide a menu of options for off the shelf use by investigators developing trials
- Will allow development of rich database for secondary analyses involving geriatric palliative care issues
- Key advantage is to change the culture and language in SWOG trials so they seek not only survival benefit but also a patient experience benefit

Advantages of a Geri-Pal-PRO package of measures



- · Be reviewed in advance by the appropriate committees
- Be available for "off of the shelf" use by investigators writing treatment trials
- Allow the development of a rich database for secondary analyses involving geriatric, palliative care and EOL issues
- Become familiar to clinicians so that metrics become part of the oncology provider language and culture, especially in clinical trials
- SWOG Trials: Survival Benefit + Patient Experience Benefit

× SWOG



1:18:44

Key features

- Completely voluntary
- Reduce the workload for investigators developing treatment trials
- No or very little cost to trial or research base
- Hope over time it can inform disease-specific treatment trials
- Agarwal noted he had presented this idea to GI Committee and asked
 - o What could we do for patients with borderline PS enrolling on a trial
 - What could we do for patients already progressed on 2nd or 3rd line standard of care
 - How can we incorporate geriatric, palliative care, and end of life metrics into trials to both study survival benefit and prepare patients and families for end of life care

Key Features of a Geri-Pal-PRO package of measures



- Reduced workload for investigators developing treatment trials
- · No or very little cost to an individual trial or the research base
- With time and experience, the metrics from the Geri-Pal-PRO package can inform disease-specific treatment trials:
- Design
- · Geriatric, palliative care & EOL interventions
- · Symptom control and QOL interventions

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1:19:50

Examples of measures that could be included

- Agarwal noted they have not yet developed the package
- This list is examples of what could be used
- PROMIS 29
 - Addresses domains of palliative care
 - Assesses fatigue and hope
- Up and go test
 - o Common tool to assess geriatric functionality
- Advance care planning readiness screens
 - Particularly important in trial setting

Examples of Geri-Pal-PRO package of measures



- PROMIS 29, 29 questions, seven domains: physical function, anxiety, depression, fatigue, sleep disturbance, social roles and activities, pain interference, pain intensity. This includes single questions about fatigue and hope.
- Up and Go test: started seated in a chair, stand, walk ten feel forward, turn around, walk back and sit down. Time > 14 seconds, risk for falls.
- Advance care planning readiness screens

XSWOG ■



1:20:31

Next steps

- Continuing to work in and outside of SWOG to develop list of metrics that can be used
- After achieving consensus, will provide
 - Descriptions
 - Language to use for cancer trials
 - References investigators developing trials can take off the shelf to get metrics to put in their protocol
- Agarwal anticipated he would have an update on this for next SWOG meeting in the spring

Dawn Hershman said SWOG has long history of using PROs in trials and doing secondary outcomes.

- So not quite fair for Agarwal to say he's changing the culture
- Advised Agarwal to be sensitive to language he was using
- Agarwal said it was less changing the culture than trying to make it more standard
- Said if SWOG is using lot of PROs, one of the benefits would be trying to create a more uniform approach and standardizing integration
- Hershman said there is a PRO core that helps centralize much of this
- Said it was great to have a focus on trials that are focused on geriatrics
 - She definitely encouraged that
 - Great to have measures specific for that
 - But everything is at a cost
 - Are complex issues with these things
 - Strongly encouraged Agarwal to work with committees
 - Symptom Control and QoL Committee
 - PRO core
 - So part of task is trying to figure out who is responsible for what
 - Hershman said she was more than enthusiastic, but do have to do it in coordinated fashion
- Agarwal said he completely agreed

Next Steps for Geri-Pal-PRO package of measures



- The P&EOL Care Committee working group will confer with stakeholders within SWOG and outside SWOG
- The working group will prepare candidate packages of measures for review and discussion
- When a consensus is achieved, and approval are obtained, the packages along with the needed descriptions, references, and language to use the measures will be made available to investigators developing treatment trials
- Anticipate update by Spring 2021

× SWOG



- Bakitas said to learn more about what PRO package would fit this bill, they are working with the palliative care research cooperative group
 - o It has an instrument library
 - Good for determining state of science before going to PRO group
- Bakitas said it might be bit premature to present here before going to other groups, but was already quite a bit of excitement
 - o Especially from the GI group that had invited Agarwal to speak
- Bakitas asked Agarwal to talk about response he got from GI group
- Agarwal said that, as he's both a GI oncologist and a palliative care doctor, was valuable being able to present in GI group
 - o Both cochairs of GI Committee were highly enthusiastic
 - Noted many patients in GI oncology have many palliative care needs
 - o GI Cmte encouraged Agarwal to present again in the spring
 - Heavily endorsed by leaders of GI
- Bakitas asked Grant Williams for his thoughts about the Pal-Pack concept
 - How would his care instruments support it?
- Williams did not respond, and Bakitas noted he had told her he needed to leave early
- Bakitas thanked Agarwal and thanked Hershman for her comments

1:26:26

Bakitas turned the program over to Mark O'Rourke to review proposed concepts.

Extra Slide: Databases of Geri-Pal-PRO package of measures



- Palliative Care Research Consortium (PCRC) has a library of instruments assessing patient experience and caregiver experience
- National Cancer Institute has the Grid-Enabled Measures (GEM) database of measures
- PROMIS® (Patient-Reported Outcomes Measurement Information System) is a set of person-centered measures

1:26:30

O'Rourke introduced Kerryn Reding to present concept on monitoring toxicities from oral targeted agents.

 Reding said they were developing a feasibility study investigating this research question Monitoring of Toxicities from Oral Targeted Agents and Immunotherapy in Patients with Advanced Renal Cell Carcinoma Using Carevive Software: A Single-Arm Phase II Feasibility Study

> Chunkit Fung, MD, MSCE University of Rochester Kerryn Reding, PhD, MPH, RN University of Washington



WILMOT

1:27:28

Overview

- Patients with metastatic renal cell carcinoma receiving oral targeted agents and immunotherapy agents
- Know that these agents improve survival
 - o Can often double survival time
- But also associated with substantial toxicities
- Goal of study is to manage symptoms
 - o Reduce grade 3+ toxicities
 - o Monitor them using Carevive software
- Single-arm phase 2 feasibility study

Overview

- Goal: Manage symptoms to reduce grade 3+ toxicities
- Monitor toxicities from oral targeted agents and immunotherapy in patients with advanced renal cell carcinoma using Carevive software
- Single-Arm Phase II Feasibility Study



WILMOT CANCER CENTER

1:28:12

Carevive software

- In study, Carevive sends weekly survey to patients that drives automatically generated care plan with strategies for self-managing toxicities
- Healthcare team also has access to data from these surveys

Carevive Software

- Carevive will deliver a web link for subjects to complete an online survey that monitors treatment-related toxicities, drug compliance and health care utilization.
- After completion of the online survey, the subjects will be given an auto-generated online care plan with at home self-management options for drug-related toxicities.
- The health care team will be able to access these online surveys after completion.

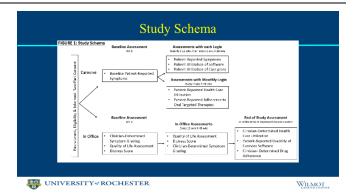


WILMOT

1:28:31

Schema

- Not a randomized design
- Carevive portion with surveys and generated care plans
 - o Will be generating data weekly
 - Can get information on patient, reported symptoms, and patient use of both software and the care plan
 - Every 4 weeks get healthcare use data and patients' reports on their adherence to their oral agents
- Separately in office will get additional data
 - o Clinician-determined grading of symptoms
 - And QoL and distress scores
 - Baseline and 12 weeks x 4
- At end of study will look at how clinician determines the healthcare use plan for each patient
 - o Also interested in how well patients do with Carevive software
 - So collecting patient-reported usability assessment
 - Also interested in how well Carevive software and care plans helped with medication adherence and dosage
 - o So collecting clinician-determined drug adherence report



1:30:11

Accrual

- Started July 2019
- Closed due to COVID
 - Weren't able to conduct in-clinic visits
- Has accrued 3 patients
- Now back up and running
- Testing feasibility includes testing patient accrual
- Now screening patients and hope to ramp back up so they can estimate feasibility

O'Rourke asked how much experience is there with Carevive – number of sites and patients? Also asked if Reding anticipated further barriers in accruing to pilot study.

- Reding said sites nationwide use Carevive but she didn't know how many
- Said a goal of the study is to determine its use in single sites
 - o If able to show feasibility here, then roll out to other sites
 - o Goal would be to open through SWOG as multisite trial
 - O Didn't know number of sites that could be accrual sites for this
- Bakitas said they use it at her institution and Carevive has been forthcoming in indicating how many sites and where they're getting data from

O'Rourke asked about accrual

- Anticipate barriers?
- What to expect?
- Reding replied that it's now a single site study, so there might be individual clinical barriers as they progress
- But they are collecting reasons why people decline to participate
- So will estimate that as they go through data

Accrual Updates

- Study start date: July 24, 2019
- March 2020 to July 2020: Closed to accrual due to Covid-19 pandemic
- Accrual to date: 3 Subjects



WILMOT

1:33:05

O'Rourke introduced Ishwaria Subbiah to present on development and validation of a measurement tool for provider confidence in communication on serious illness.

• O'Rourke announced that the Hope Foundation grant for which the PIs had applied with this concept had just been awarded.

Subbiah presented.

- Said they wanted to identify communications curriculums that are practical for the practicing provider
- Several concepts fit under this umbrella
- This was a feasibility study on integrating a remote learning virtual curriculum for high-quality serious illness conversations
- That was scope of this particular intervention they are studying



Development and validation of measurement tool for provider confidence in communication on serious illness.

Study PI and Collaborators: Ishwaria Subbiah MD, Dave Feldman PhD, Ben Corn MD, Matt Hudson PhD, Valerie Fraser, Mark O'Rourke MD

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1:34:42

Study intervention

- Subbiah emphasized the course they are testing
 - o Delivering Serious News, a course by VITALtalk
- Important because different available curriculums have different objectives
 - Fact that they fall under communications umbrella doesn't mean they are all the same thing
- This particular course is online, self-paced, interactive
- Broken down in way that practicing clinician can do it at their own pace and in their own time
 - o Task oriented
- They are looking at oncologists and advance practice providers at NCORP sites

Study Intervention



- Target population: Oncologists, physician assistants, and nurse practitioners at NCORP sites.
- · Intervention: Complete Delivering Serious News
 - A VITALtalk course, entirely online, self-paced, highly interactive course.
 - · Divided into 15 tasks completed in sequential order.
 - 15-20 minutes per task, or 4-5 hours total.

× SWOG



1:35:33

Design

- They are obtaining baseline and post-course assessments
- They have obtained baseline assessment
- For it they have developed and are validating the Self-Efficacy in Medical Communication (SEMC) instrument
- They will measure baseline SEMC
- Will also measure other metrics such as Adult Hope Scale
- They give participants access to course and 2 weeks to complete it
- Will then repeat assessment after that and at 4 week and 12 week intervals
- Done entirely online
- Subbiah thanked Hope Foundation for grant funding
- Said this is a feasibility study
 - o They want to measure completion rate of this curriculum
 - Target is >=60%
- Secondary aims to be measured include
 - Acceptability/satisfaction with program
 - o Individual clinician's level of engagement with course
 - Will get backend user metrics from VITALtalk
 - o Estimate ability of SEMC to measure self-efficacy in communication
 - Estimate the effect size for the subsequent studies
- Also will measure baseline hopefulness and burnout among participating providers
- An exploratory variable measures interval of change in patient's perception of provider communication using existing provider experience surveys that their practices already send out
 - Not interacting with patient directly
 - Practice survey that goes out anyway includes questions on patient satisfaction with communication
 - o They will compare results to figures from previous quarter
- Will inform future larger scale studies
- In planning stages of rolling this out through NCORP
- Subbiah encouraged members to watch for emails about it

Study Design and Measures



- Single arm study of online VITALtalk course with administration of the newly developed survey, SEMC.
 - Pre: Adult Hope Scale (AHS) and Self-Efficacy in Medical Communication (SEMC)
 - · Post: SEMC, immediately after, 4 weeks, and 12 weeks later.
- · Current Status:
 - · Grant under review at the Hope Foundation.



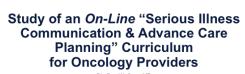
- Also incentives for participants
- Looking to enroll 100 providers

O'Rourke said idea is to improve care of patients by improving communications skills of providers.

• Said a second concept in that vein would be presented by Ben Corn

1:38:41

Corn said the course they were looking at an alternative communications strategy that complements some of the elements of VITALtalk.



Pl: Ben W. Corn. MD
Investigators: Ishwaria Subbiah, MD, David B. Feldman, PhD, Matthew Hudson, PhD
SWOG Cancer Research Network Palliative and End-of-Life Committee Co-chairs:
Mark A. O'Rourke, MD and Marie Bakitas, DNSc, NP-C
Patient advocate: Valerie Fraser

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1:39:40

- Corn said the organization they want to work with is Center to Advance Palliative Care (CAPC)
- Center has operated >2 decades
- Have an array of products



1:40:00

- They have large number of courses taken
 - o >One-half million
- They've told Corn there has been dramatic spike in interest among providers in becoming educated in COVID era





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1:40:27

- They have a communications curriculum
 - o 5 courses (see slide)
 - Represent bread and butter issues many grapple with in palliative care
- Corn said beauty of tool is that each course requires about 20 minutes
 - o Includes post-test
 - Iterative process: get feedback in real time
 - User gets a grade on the website

CAPC Communication Curriculum



- The five courses are:
- Delivering Serious News
- Discussing Prognosis
- · Clarifying Goals of Care
- · Conducting a Family Meeting
- Advance Care Planning Conversations
- Each course requires ~20 mins &includes a brief post-course test
- · The courses are completed online
- · Scoring via CAPC website

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1:41:09

- Corn said O'Rourke set up meeting for him with leadership of CAPC
- They said they've been collecting data informally over 2 decades but haven't been formally assessing effectiveness of their products
- They were enthusiastic about SWOG investigators bringing rigor to this
- Slide shows some examples of homegrown data
- Examples show they're interested in comfort-zone issues about sharing prognosis
- In bottom 2 rows, also interested in professional persona and whether on a collegial level we would recommend products to others

Curriculum Impact (Clinician Self-Report



Evaluation Item	% Agree: Pre-training	% Agree: Post-training
"I am comfortable communicating w pts about Dx, Px & Dz- Trajectory"	75%	96%
"I am comfortable responding to emotional reactions from pts & caregivers."	81%	97%
"I am comfortable eliciting what is most important to pts"	75%	96%
"I am comfortable initiating conversation about advance care planning"	67%	95%
"I have made practice improvements as a result of achieving CAPC Communication Designation."	NA	93%
"I would recommend CAPC Communication training to colleagues" (WIWI)	NA	99%



1:42:09

Design

- Corn said design is work in progress
- Corn's team wants to get parameters from before enrollment
 - Satisfaction with Life scale
 - Adult Hope Scale
 - Main indicator of trade hope
 - Abbreviated version of Maslach Burnout Inventory
- Pre and post parameters
 - SEMC
 - Common tool for empathy, the IRI
 - Also interest in was it worth it (WIWI) test

Study Design and Measures



- · Waitlist control study of online CAPC communication courses · Pre:
 - · Satisfaction With Life Scale (SWLS)

 - Adult Hope Scale
 Abbreviated Maslach Burnout Inventory (aMBI)
 - Pre & Post:
 - Self-Efficacy in Medical Communication (SEMC)
 Empathy: Interpersonal Reactivity Index (IRI)

 - Was It Worth It (WIWI)
 - · Pre- and post- 90-day average CG-CAHPS scores (Consumer Assessment of Healthcare Providers and Systems, Clinician & Group Survey Database)
- · Current Status:
 - In development

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1:42:59

Aims

- Primary aim is to compare self-efficacy of those who take the course to a waitlist control
- Secondary aims
 - o Correlate baseline SEMC with markers like hope, empathy, and burnout

Primary Aims



- **Primary Aim**: Compare to the waitlist control the effect of the five CAPC courses on the change from pre- to post in the SEMC.
- Primary Hypothesis: The delta SEMC in the intervention arm will be greater than that of the waitlist control.
- Secondary Aim 1: Correlate baseline SEMC with (baseline) satisfaction, hope, empathy and burnout among participating
- Secondary Hypothesis 1: Baseline SEMC will correlate directly with baseline QOL, hope, and cognitive empathy and inversely with distress empathy and burnout



1:43:21

- Compare IRI empathy score between waitlist controls and those who take the course
- Exploratory objective related to CG-CAHPS

Secondary Aims

- Secondary Aim 2: Compare to the waitlist control the effect of the five CAPC courses on the change from pre- to post in the IRI empathy score.
- Secondary Hypothesis 2: The delta IRI empathy score in the intervention arm will be greater than that of the waitlist control.
- Exploratory Aim: To correlate SEMC with pre-90-day average CG-CAHPS scores (Consumer Assessment of Healthcare Providers and Systems, Clinician & Group Survey Database) and with provider
- Exploratory Hypothesis 1: Baseline SEMC will correlate directly with pre CG-CAHPS communication domain scores.
- Exploratory Hypothesis 2: The Baseline IRI empathy score will correlate directly with the pre CG-CAHPS communication domain scores.

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1:43:39

- Corn said it may look similar to what Subbiah just presented
- He identified areas that don't represent overlap
 - Small doses
 - Lends itself to our lifestyles
 - Based on heuristic model for learning

Upside: CAPC Protocol



- · Small doses
- · Heuristic model
- · Data repository of CAPC
- · Willingness of CAPC to analyze
- · Affirms SWOG commitment to P-P communication
- · Establishes leadership role for SWOG

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1:44:09

- From Kahneman
- Idea of iterative self-educating learning processes with autocorrect mode is very effective
- Remarkable how well computer learns who you are and helps you get in sync with precepts they're trying to communicate





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1:44:30

- o Another point of attraction is CAPC's data repository
 - Can ask it various questions for secondary analysis
 - CAPC leadership supports analyses we'd like to do
 - Reflects this committee's commitment to provider—patient communication
- If someone said there's only one therapeutic intervention for colorectal cancer, it would sound absurd
- Similarly, should be multiple ways to overcome a communication hurdle

Upside: CAPC Protocol



- Small doses
- Heuristic model
- · Data repository of CAPC
- · Willingness of CAPC to analyze
- Affirms SWOG commitment to P-P communication
- · Establishes leadership role for SWOG

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1:45:35

 Corn said course takers do get a designation from CAPC, which appeals to those who thrive on positive reinforcement

O'Rourke said to continue theme of doing things to help providers improve patient experience, he would introduce David Feldman.



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1:46:24

- O'Rourke said Feldman would present on concept of improving hope with a hope workshop
- They had intended to do this in person at SWOG's spring meeting

Online Hope Workshops for Patients/Caregivers/Providers

Verbal update by David B. Feldman and Benjamin W. Corn
No slides to present



1:46:49

Feldman noted he has 2 talks back to back:

- To present a concept
- To present on continuing research
- Both fall under category of enhancing hopefulness for providers and patients
- Would start with providers

Enhancing Hopefulness for Providers and Patients

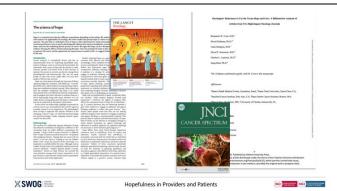
David B. Feldman, Santa Clara University
Mark A. O'Rounce, Prisma Health Update Cancer Institute
Marie A. Bakitas, University of Alabama at Birmingham
Robert S. Kouse, University of Pennyivania
Jay G. Hull, Dartmouth College
Heidl E. Delninger, St., Loseph Mercy Health System-Ann Arbo
Matthew H. Huddon, Pitran Health Update Cancer Institute

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Feldman highlighted two publications

- "The Science of Hope" published in September in *Lancet Oncology*
 - It's a literature review of 30+ years of scientific research on hope in the social sciences
 - Also reviews growing research field in cancer space
 - Hypothesizes about and cites research on possible mediators of the effects of hopefulness on cancer endpoints
 - o Also contains sort of manifesto or research plan for future studies
 - Feldman encouraged anyone interested in the work he was presenting to review this
- Article by Corn, Feldman, et al. on oncologists' reluctance to use the term "hope" in JNCI Cancer Spectrum
 - o In press
 - Contains a bibliometric analysis
 - Quantitative analysis of patterns in literature
 - o Analyzed 20 years' worth of all articles in JCO and JAMA Oncology
 - o Analyzed trends in use of words related to hope and hopefulness
 - Would expect to find, given the improvement in cancer outcomes over past 25 years, an increase in use of terms related to hope.
 - They observed the opposite: a decrease in the use of most of those terms



- Said seems to be growing reluctance of investigators to use the terms in writing
- o They also bibliometrically analyzed narrative sections in both journals
 - Most articles are primary research
 - But small number of narratives
 - 1st-person perspective
 - Generally from physicians and other providers
- They did not see a decrease in use of hope terms in those narrative sections
- Hints that providers value hope but increasingly tend not to use it in scientific research
- Hope can be investigated quantitatively

1:51:07

• Feldman presented some of the hope research he has been engaged in

SWOG Hope Survey

- Feldman presented on this in plenary address in PC&EoL Cmte session at spring meeting
- Invited 1,000 SWOG members to complete a survey
- 226 did; response rate right on par with other surveys of professional orgs
- Submitted to journal for review
- Inspiration was literature on burnout
- All know of high rates of burnout in cancer care professionals
- Some research shows providers have low levels of things like psychological wellbeing and life satisfaction
- Can think of burnout as opposite of hopefulness
- They wanted to investigate relationship between hope and burnout
- Also life satisfaction
 - Lots of calls in literature to attend more to general well-being of providers
- Feldman said they found that

Ongoing Hope Research

- SWOG Hope Survey: 226 SWOG members. Submitted for journal review.
- Hope mediated the relationships of job stress and burnout with life satisfaction.
- Hopefulness associated with lower burnout (-.23, p = .005) and greater life satisfaction (.50, p < .001).
- Online Hope-Enhancement Workshop for Providers:
 - · Scheduled to take place in mid-November.
 - Pilot project offered to SWOG members (space limited to approximately 30 total).
 - · Pre- and Post-workshop surveys.
- Secondary Data Analysis: ENABLE data sets (NCT00253383; NCT01245621).
- Hopefulness and survival in patients with advanced cancers.



Hopefulness in Providers and Patients



- Hope mediated the relationship between job stress and burnout on the one hand
- And life satisfaction on the other hand
- Feldman speculated that results are consistent with idea that job stress and job burnout are not directly predicting or impacting life satisfaction
 - Instead, they erode hopefulness of providers
 - This erosion leads to lower satisfaction
- Feldman noted that hopefulness was not measured as hope about any one thing in life but as general attitude of hopefulness toward life
- Feldman suggested thinking about interventions to help provider well-being by enhancing hopefulness
 - o May prevent things like job stress and burnout from becoming too much
- Feldman said this leads to second bullet point in slide
 - o Online hope enhancement workshop for providers
- Two interventions already in the literature for enhancing hope
 - o Single-session 2-hour interventions
 - One is known as the hope workshop
 - Developed by Feldman and Diane Dreher
 - Already applied to various populations (non-provider)
 - Increased hope and life satisfaction
 - Decreased depression and anxiety
- Seems reasonable to ask if we can generalize this and apply to providers
- Feldman and collaborators have been tweaking workshop for use with SWOG members
- Got the go-ahead
- Were ready to do this at spring group meeting before COVID
- Feldman said they've been working to put workshop into online format so it can be delivered via videoconferencing
- They're also about to roll out a hope-based intervention app
- Said those interested in this should watch for it in their email inbox
 - May get invite in next month to participate
- Will emphasize science of hope, applying to patients, and nurturing and enhancing it in oneself

- Space limited to about 30 providers total
- Is a study, so includes pre and post surveys

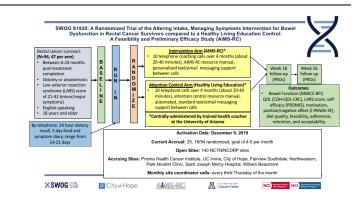
1:57:39

O'Rourke introduce Robert Krouse for a brief update on \$1820

- Study this committee has put much energy into
- O'Rourke noted there would be no time for new business and apologized

Krouse asked Virginia Sun for update on accrual

- Sun said accrual is about 25 registered to step 1, 22 randomized to step 2
- **Activated December 2019**
- Just about at 20% of target
- Many sites still opening
- Do have one protocol paper that has already been approved and that she will submit soon



1:59:39

Co-Chairs: Cynthia A. Thomson, PhD, RDN – University of Arizona Tracy Crane, PhD, RDN - University of Arizona Robert S. Krouse, MD - University of Pennsylvania

Biostatisticians and Data Operations: Katherine Guthrie, PhD Kathryn Arnold, MS Roxanne Topacio, CCRP SWOG Statistics and Data Management Center Fred Hutchinson Cancer Research Center,

Protocol Development/Coordination: Christy Klepetko Vanessa Benavidez

SWOG Operations Office, San Antonio, TX

Study Personnel

Nurse Coordinator: Christa Braun-Inglis, APRN, FNP-BC, AOCNP – University of Hawaii

Patient Advocates: Lee Jones, MBA Florence Kurttila, MA

 GI Committee Champions: Mazin Al-kasspooles, MD - University of Kansas (Surgical Oncology) Stacey Cohen, MD - University of Washington (Medical Oncology)

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Seattle, WA









1:59:50

Krouse said S1316 (malignant bowel obstruction study) was still following 3 people. Hoping to have update with findings at spring meeting.

Krouse encouraged participation in monthly meeting. Also new ideas and new members.

• Asked members to please come to cochairs or other members to bring forward ideas for consideration

2:01:20

Meeting was adjourned.

PALLIATIVE AND END OF LIFE CARE COMMIT

- . New Business: now is the time to speak up
- · P&EOL Care monthly conference calls: third Thursday, 5:00 pm Eastern time
- · Other regular calls for individual studies and concepts in development
- · We strive to improve oncology palliative and end-of-life care through research and scholarship. We welcome new members:
 - · Provider clinicians interested in palliative and end-of-life care
 - · Nurse clinicians interested in palliative and end-of-life care
 - · People from various healthcare, industry, and life experience backgrounds
 - · Investigators with interests and/or ideas for P&EOL care research
- · Contact Christy Klepetko at cklepetko@SWOG.org

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Chat Box Comments

(Chat timestamps are aligned with video recording timestamps; chat entries from before meeting start are not included)

0:01 from Courtney Wille (privately): Do we have slides? from C Blanke (privately): Jara is presenting but I need to be available for questions 0:06

from Ashley Milford to all panelists: 0:06 Hear you great

from Courtney Wille (privately): Can you move C Blanke to panelist? 0:07

from Vincent Chung to host (privately): 0:08 My presentation is coming up.

0:13 from Courtney Wille to host (privately): Please move Frank Meyskens to panel

from Jeff Rains to Courtney Wille 0:13 (privately):

done

0:14 from Courtney Wille to host (privately):

Bernard Parker too please.

0:20	from Courtney Wille to host (privately):	He is in the audience.
0:20	from Jeff Rains to Courtney Wille (privately):	he's live
0:22	from Courtney Wille to host (privately):	Thank you. A few others are in audience. Not sure if they will speak but if you can move them please. Carole seigel, Kathy Crew,
0:27	from Jeff Rains to Courtney Wille (privately):	done and done!
0:27	from Courtney Wille to host (privately):	Thanks so much!
0:28	from Courtney Wille to host (privately):	They are asking if it is okay if they go over a little since they started late. Okay with me if okay with you.
0:28	from Mark O'Rourke to everyone:	Marie, Excellent discussion around the syndemic.
0:29	from Yara Salman to host (privately):	I'm here I need to be unmuted
0:30	from Yara Salman to host (privately):	I can hear everyhting I need to be unmuted
0:30	from Carole Seigel to all panelists:	Marie, I agree! It is good to recognize the impact the syndemic has on everyone! Carole
0:37	from Gina Cravey to host (privately):	What is this study number?
0:39	from Matthew Hudson to all panelists:	Question for Dr. Salman-is capacity screening dependent upon depression diagnosis (that is, patients not depressed do not get assessed for capacity?
0:46	from Banu Symington to host (privately):	life in the virtual syndemic. Quest is at my doorthjey are putting up a telephone pole for adjacent neighborhoodwill be taking me off line in a few minutes
1:08	from Jeff Berenberg to all panelists:	Are there any computer or APPS that will give feedback to the provider if a brief GA is inputted assuming it is done like the information Supriya provided

1:17	from Marie Bakitas to host & presenter:	wonder about your thoughts related to the geri pal pack, dr. agarwal is mentioning wonder how CARE would fit in
1:19	from Jeff Berenberg to all panelists:	Part of the difficulty is even getting older adults onto our trials they are really under accrued
1:21	from Kathy Crew to host (privately):	I know that there are ongoing trials of established treatments in elderly patients which incorporate geriatric assessments and specifically assess toxicities in older adults
1:24	from Carole Seigel to all panelists:	It was very well received!
1:40	from Marie Bakitas to host & presenter:	Ishwariah, you are a total star! so proud of you for moving our agenda forward with your grant!
1:46	from Nanette Robinson to all panelists:	Both these studies very interesting and what I might choose to participate in! How do you make sure that there isn't bias in the MDs who choose to participate and may be already "better at" these skills?
2:00	from Valerie Fraser to all panelists:	Thanks everyone!
2:00	from Chrissie Baker to host (privately):	Thank you very much for an excellent presentation.