

Going High and Going Low with Health Literacy in Adolescents' with Cancer: Does It Matter?

Family-**C**entered Advance Care Planning
for **T**eens with **C**ancer (FACE-TC)

Maureen E. Lyon, PhD,
FABPP
Principal Investigator
Conway Chair
Conversation:
April 16, 2019

Type 2 Renewal Application for Parent R01 “Building Evidence for Effective Palliative/End of Life Care for Teens with Cancer” (FACE-TC)

- Continuation of funding past year 5
- Competes for funding with all other peer reviewed applications
- Must be developed as fully as a first time application
- Submitted in June cycle, in place of Final Progress report
- Due to Grants & Contracts May 28th
- Currently in Year 4 of 5 year Award



Parent Trial – 4 study sites



- **Children's National Health System, Washington D.C. - Coordinating study site**
- **Akron Children's Hospital- Akron, OH - Study site**
- **University of Minnesota's Masonic Children's Hospital - Minneapolis, MN- Study site**
- **St. Jude Children's Research Hospital – Memphis, TN - Study site**
- **Funding Sources**
 - National Institutes of Health/National Institute of Nursing Research (NIH/NINR), R01 NR15458-04.
 - NIH Center for Advancing Translational Sciences Institute at Children's National (CTSI-CN) UL1TR001876.
 - *The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Overarching Purpose of Parent Study

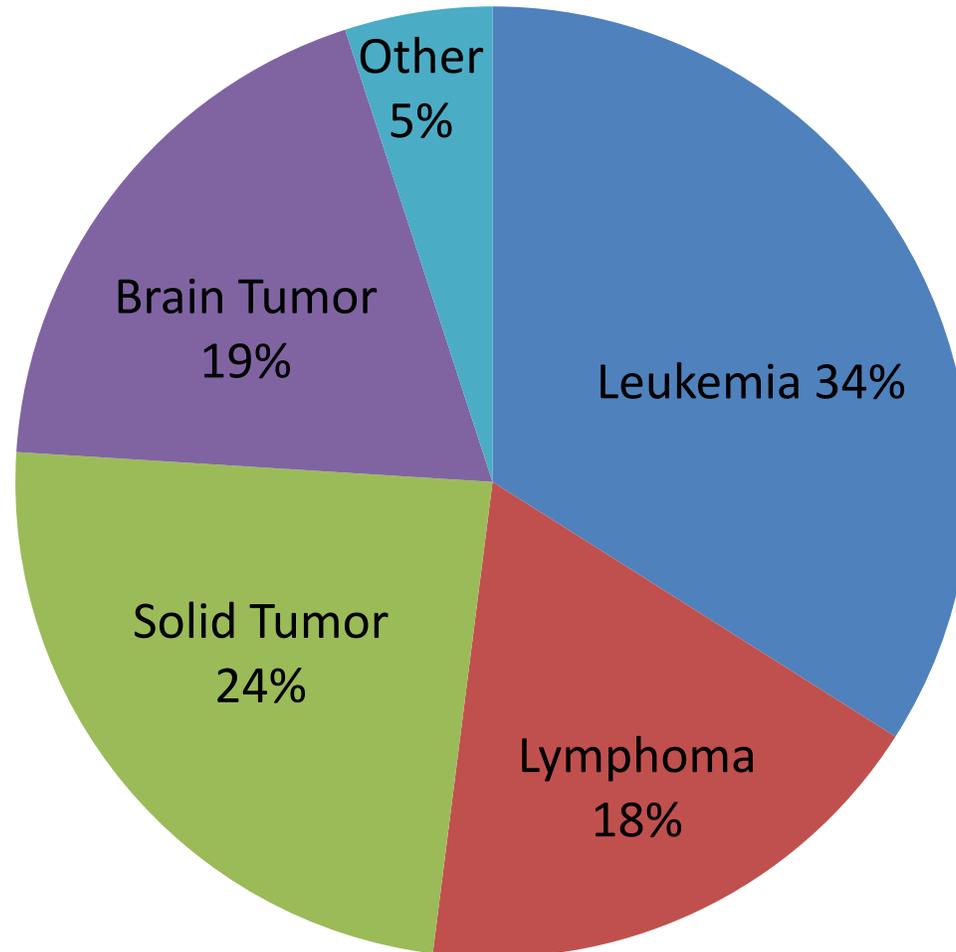
- AIM 1:
 - To evaluate the effect of FACE-TC on patient-family congruence in treatment preferences.
- AIM 2:
 - To evaluate the effect of FACE-TC on AYA patient quality of life [pain interference, fatigue, psychological (anxiety, depressive symptoms) spiritual/existential (meaning/purpose, peace)].
- AIM 3:
 - To evaluate the effect of FACE-TC on early completion of pACP goals of care and advance directives, i.e. advanced planning for EOL care. (Does care received at EOL reflect care desired?)
- Continue longitudinal study of current specific aims – 5 years?



Background

- The Family Centered (FACE) ACP for Teens with Cancer (FACE-TC) pilot study demonstrated:
 - Planning enabled families to understand their adolescents' treatment preferences
 - Planning also enabled adolescents to receive palliative care significantly earlier than controls.
 - Satisfaction and worthwhile ratings were very high for participating teens and their surrogates
 - Intervention adolescent/family dyads were more likely than controls to agree to limit treatments.

Cancer Diagnosis at Baseline, N=130



Inclusion Criteria

- AYA: all malignancies, at any stages of illness, with all prognoses
 - ≥ 14 years, <21 years at time of enrollment
 - Not developmentally delayed
 - Not depressed, homicidal, suicidal or psychotic (actively)
 - English-speaking
 - Aware of diagnosis
 - Not in foster care
- Surrogate: All of above plus/except:
 - ≥ 18 yo, knows patient's diagnosis
 - Legal guardian if patient is assenting (under 18)
 - Adolescent willing to discuss diagnosis with surrogate (has chosen him/her)



Palliative/End of Life Care for Teens with Cancer

This study has
8 study visits

- 1  **Meet the Team:** Enrollment/Secondary Screening and Randomization
- 2  **Session 1: 60 minute Intervention Group - Lyon FACE-TC Advance Care Planning Survey / Treatment as usual: Control**
- 3  **Session 2:** 60-minute Intervention Group - Respecting Choices Interview
Treatment as usual: Control
- 4  **Session 3:** 60 minute conversation (Five Wishes: Intervention Group)
- 5  **3-month Follow Up Visit**
- 6  **6-month Follow Up Visit**
- 7  **12-month Follow Up Visit**
- 8  **18-month Follow Up Visit & Close Out**

Methods: *FACE-TC Intervention*

- Longitudinal, prospective, 2-arm study design
- Computer randomization of adolescent/family dyads after baseline assessments completed
 - Randomization at 2:1 intervention:control [pilot showed treatment benefit]
- Single, blinded intent-to-treat design

	FACE-pACP Intervention	Treatment as Usual Control
Session 1/ Week 1	Lyon FACE Advance Care Planning Survey ©	
Session 2/ Week 2	Respecting Choices Next Steps Interview®	Assessment Only
Session 3/ Week 3	Five Wishes ©	

Background –Health Literacy

- AYAs with cancer are called upon to make complex decisions regarding treatment at an emotionally distressing time.
- Survivors need to manage long-term health care
 - Health Literacy among AYAs with cancer in Germany (n=206) is associated with
 - HRQoL (mental health, vitality & social functioning, depression)
 - Fewer depressive symptoms
 - Gender & education were confounders
- Found $\frac{3}{4}$ of survivors (ages 15-39 years and 80% female) had low Health Literacy
- Interventions are needed for improving Health Literacy

Richter D et al., Health Literacy in adolescent and young adult cancer patients and its association with health outcomes. J Adolescent & Young Adult Oncology 2019; DOI 10.1089/jayao.2018.0118

Going High and Going Low with Health Literacy in Adolescents' with Cancer: Does it Matter?

- Health Literacy in the current sample or new sample or both?
 - Exposure to FACE pACP may improve Health Literacy
 - To implement a longitudinal study with a large sample and balanced educational levels and gender distribution to examine underlying variables that predict higher Health Literacy and how Health Literacy can be significantly improved during the survivorship phase.
 - Ultimate goal: to determine how health literacy can be best achieved and to develop suitable interventions and materials (e.g. tools with avatars?) for all participants interacting in the health care system to improve health literacy.

Confounding variables: in palliative care or not, education, gender

Measures – if did replication study –sample size?

- European Health Literacy Survey (HLS-EU-Q16)
- Short Form Health Survey SF-12v2 or measures HRQoL
- PROMIS PHQ-9 to measure depression? Or PROMIS measures
- Looks at understanding of choices? Concerns teens & families did not understand implications of following at end-of-life
 - Tube feeding
 - CPR
 - Mechanical ventilation

Research Goals

- pACP process can be standardized to make it available across the board as a **standard of care** intervention
- Answer the question: **Is improved Health Literacy another benefit of pACP?**
- Alternatively: **Or is Health Literacy irrelevant to pACP outcomes?**
- **Are teens living with cancer able to achieve agreement with their families about EOL treatment preferences, regardless of level of Health Literacy?**

Questions? Feedback? Ask for 4 or 5 years of funding?

Aims, if use the same sample:

1. At 24 months post-baseline provide all study dyads with FACE pACP (so some will have had this once before, and for other dyads it will be first time). Booster sessions (Session 2-goals of care conversation & 3-Five Wishes) at 36, 48, 60 months.
2. For those AYAs who do not survive, is the care desired the care received? (Bereavement outcomes for families? Moral distress or resiliency for HCP? Need to compare to a standard of care control?)
3. Is AYA or family Health Literacy related to study outcomes: HRQoL (physical, psychological, spiritual), congruence in treatment preferences, care desired is care received at the end-of-life?



Significance

- AYA cancer survivors are medically underserved as they transition to adult health care settings, a problem for all AYAs living with a chronic illness
- Enhanced Health Literacy through pACP may optimize management of HRQoL outcomes for cancer survivors transitioning to follow-up care
- Enhanced Health Literacy through pACP may improve transitioning to an adult PCP during this critical period
- Examine the relationship of health literacy with the physical, psychological, and social effects of cancer and its treatment
- To empower AYA survivors to best engage in follow-up care
- To optimize patient outcomes

“If you were very ill and knew that you would not get better, who would you want to be involved in decisions about your end-of-life care?”

Myself	My family	My doctor	Someone else
0	0	0	0

- Responded wanting:
- 96% (43/45) My family
- ___% (/) My doctor



“Being able to complete an advance directive that would let loved ones know your wishes, if you were unable to speak for yourself”

Very important	Somewhat important	Neither important nor unimportant	Not very important	Not at all important	Do not know
0	0	0	0	0	0

- Adolescents that indicated either Very Important or Somewhat Important
 - 91% (41/45)



“Do you think your doctor or the hospital will respect your wishes, that is, do what you want about medical care?”

Yes, definitely	Very probably	Probably	Probably not	Do not know
<input type="radio"/>				

- Doctors that said probably, very probably, or definitely
 - 93% (42/45)



“Do you think your parent/guardian/surrogate will respect your wishes, that is, do what you want about your medical care?”

Yes, definitely	Very probably	Probably	Probably not	Do not know
<input type="radio"/>				

- Family members that said probably, very probably, or definitely
 - 91% (41/45)



“Whether you have completed any advance directives/pre-plans or not, have you talked about your wishes for care at the end of life with anyone?”

Spouse or Partner	Parents	Siblings	Friends	Boyfriend or Girlfriend	Lawyer	Primary Physician	Clergy	Other	Have not talked with anyone	Do not know
○	○	○	○	○	○	○	○	○	○	○

- Adolescents who have never discussed EOL care wishes with anyone
 - 56% (25/45)



“Who are the best people/best person on the treatment team to bring it up with you?”

Physician	Nurse Practitioner	Nurse	Social Worker	Psychologist	Case Manager	Chaplain	Patient Advocate	Other	Do not know
0	0	0	0	0	0	0	0	0	0

- Adolescents think physician should be the person to bring up the topic of end-of-life care
 - 62% (28/45)



“How comfortable are you talking about death?”

Very comfortable	Somewhat Comfortable	Neither comfortable or uncomfortable	Not very comfortable	Not at all comfortable	Not sure	No Response
0	0	0	0	0	0	0

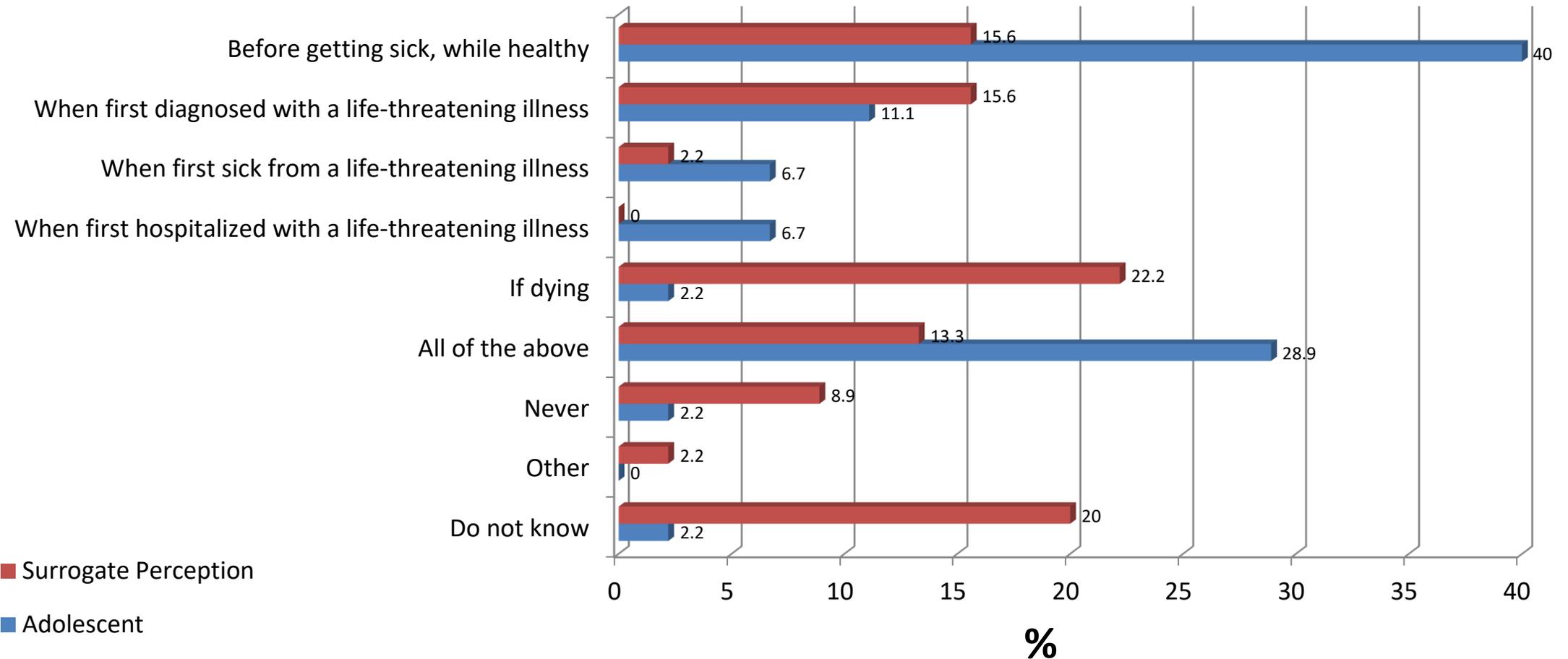
- Adolescents that feel very or somewhat comfortable talking about death
 - 62% (28/45)



How important would each of the following be to you, if you were dealing with your own dying?

- Honest answers from physicians: 100%
- Saying everything they want to say to family: 98%
- Understanding treatment choices: 97%
- Being at peace spiritually: 94%
- Physical comfort: 91%
- Knowing how to say goodbye: 87%
- Not being a burden to loved ones: 86%
- Being able to stay in own home: 77%
 - 55% want to die at home with or without hospice; 10% in hospital
- Being off machines: 62%

When do you think is the best time to bring up end-of-life decisions?



“Which do you think are worse than death?”

- Not being able to communicate my wishes for care to family members: 58% (26/45)
- Living with great pain: 42% (19/45)
- Total physical dependency on others: 22% (10/45)
- Nothing is worse than death: 31% (14/45)



Adolescent Feedback

- “The first time I met you, I thought, this lady wants me to do a research study and meet with me several times to ask me questions...how boring! But, I must say, I really enjoyed it. Like today, I didn’t even realize I was going to get money for coming and I was really looking forward to it!”
- **He also said that he would be interested in doing any other research studies that he would be eligible to do.**

Adolescent Feedback

“Actually, I expected the study to be more morbid. I did not think it was hurtful or unhealthy in any way. I do think this is a very important conversation and I think other teens should consider taking part in the study and take it seriously. Teens want to be independent and they should have a say in their medical care. They need to be made aware of these problems and take part in decision making. I would have never thought about these things if it weren’t for this study.”

Strengths & Limitations

- Strengths:
 - Randomized Clinical Trial
 - Multi-site, single blinded
 - Rigorous training protocol
 - Reproducible
- Limitations:
 - Interim data analysis from Session 1 only
 - Potential gate-keeper bias by Oncology staff
 - Wide variety of oncology diagnoses, prognoses, levels of acuity (newly diagnosed to years off treatment), treatments & effects

Conclusions

- Teens with cancer feel it is very important to communicate their treatment preferences and EOL wishes to family
- Input from teens themselves about advance directives and EOL wishes is crucial to gain
- This intervention can be generalized to adolescents with other life-limiting conditions
- Conversations matter: structured, adolescent/family-centered, evidence-based ACP conversations are likely a helpful intervention to facilitate open communication and give teens with cancer a voice in their care

Acknowledgments



- We give deep thanks to our study families for helping us
- We are thankful for our funders:
National Institutes of Health
National Institute of Nursing Research Award Number R01 NR15458-04.
NIH National Center for Advancing Translational Sciences Clinical Training Science Institute at Children's National Award Number UL1TR001876
- We also thank the following people for their work on this study:
 - Staff from all participating research sites
 - Linda Briggs, MSN, MA, RN, Respecting Choices® a Division of CTAC Innovations

FACE-Teens with Cancer Study Team



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<http://www.ninr.nih.gov/newsandinformation/conversationsmatter#.U3-htPldV8E>

Contact Information

- Maureen Lyon, PhD – mlyon@childrensnational.org
 - Lyon Advance Care Planning Survey – Adolescent & Parent version are available upon request from Dr. Lyon without a fee
- Sarah Friebert, MD – sfriebert@akronchildrens.org