Pre-Application Webinar

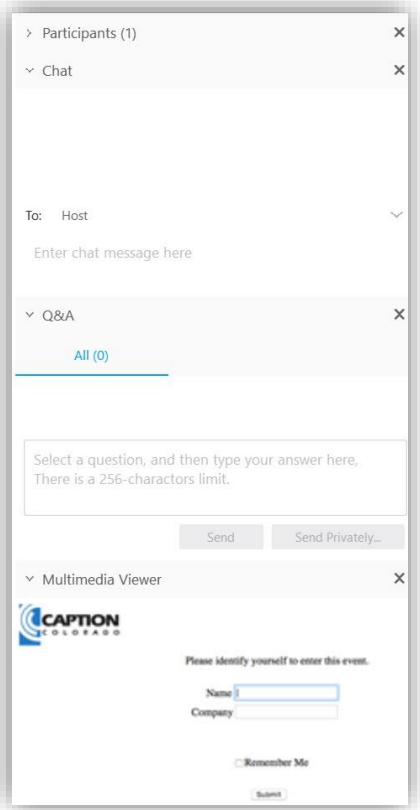
Optimizing the Management and Outcomes for Cancer Survivors Transitioning to Follow-up Care
RFA-CA-19-035
(R01 Clinical Trial Required)

Michelle Mollica, PhD, MPH, RN, OCN

NIH NATIONAL CANCER INSTITUTE

May 3, 2019

Using WebEx and Webinar Logistics



- All lines will be in listen-only mode
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Webinar Presenter

Michelle Mollica, PhD, MPH, RN, OCN
Healthcare Delivery Research Program

RFA concept developed in collaboration with:

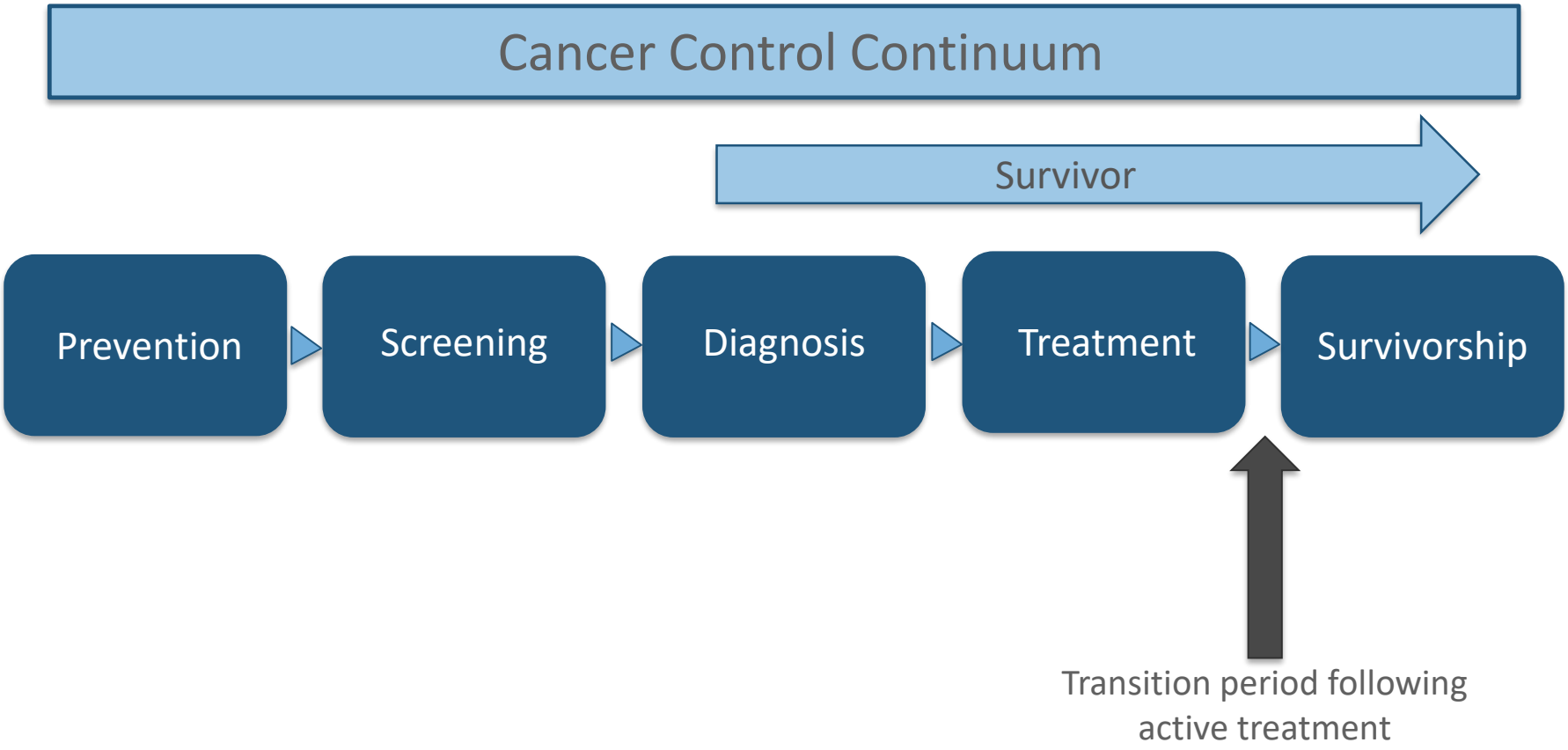
- *Margaret Farrell, MPH, RD*
- *Andrew Freedman, PhD*
- *Lisa Gallicchio, PhD*
- *Paige Green, PhD; MPH, FABMR*
- *Li Zhu, PhD*
- *Paul Jacobsen, PhD*
- *Ashley Wilder Smith, PhD, MPH*

Overview

1. *Background*
2. *Goals of the Request for Applications (RFA)*
3. *Application Requirements*
4. *Questions*

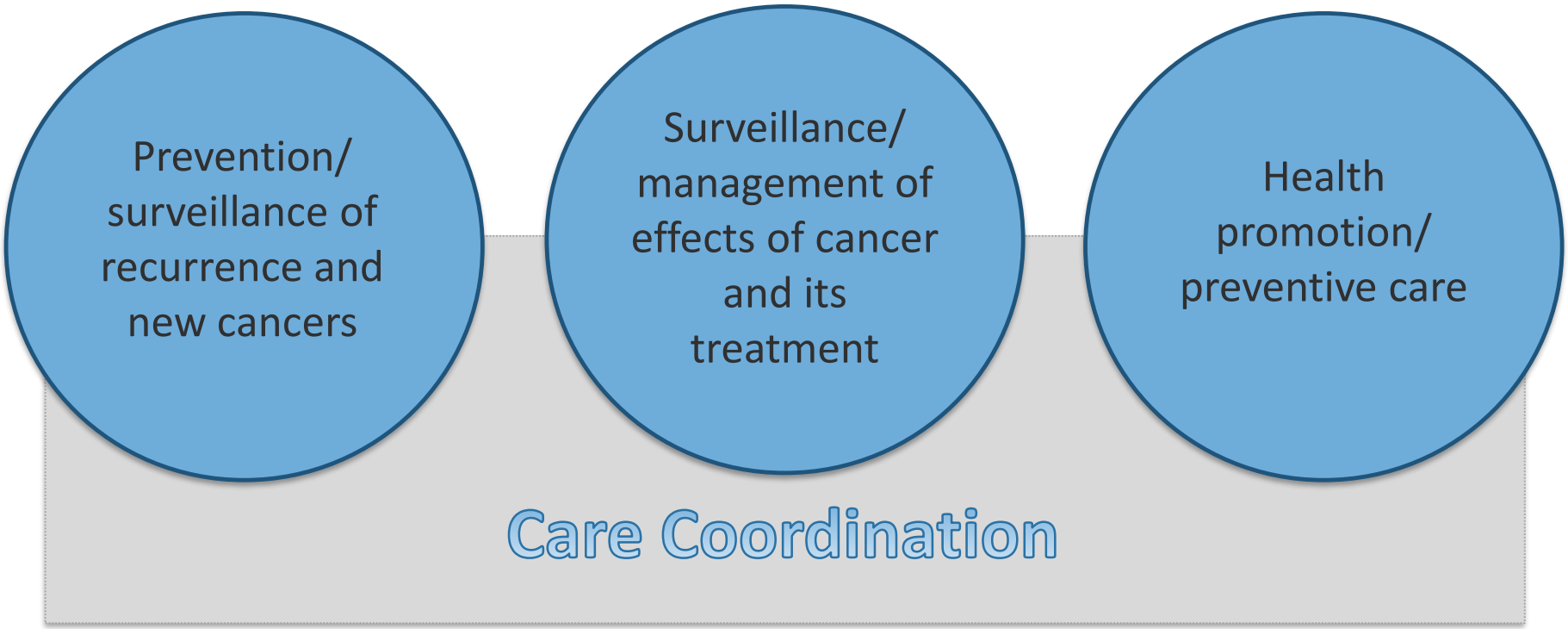
Background

Lost in Transition



Institute of Medicine. *From cancer patient to cancer survivor: Lost in transition.* Washington, DC: Institute of Medicine; 2005.

Survivorship Care After Active Treatment



Institute of Medicine. *From cancer patient to cancer survivor: Lost in transition.* Washington, DC: Institute of Medicine; 2005.

Models of Post-Treatment Survivorship Care

Challenges to Successful Follow-up Care for Survivors

- Unclear who is responsible for specific components of care
- Lack of communication and coordination between providers
- Ongoing provider education on new treatments needed
- Limited evidence that survivorship care plans improve survivor outcomes

Jacobs L, Shulman L. Follow-up care of cancer survivors: Challenges and solutions. *The Lancet Oncology.* 2017;18(1):e19-e29.
Jacobsen P, DeRosa A, Henderson T, et al. Systematic review of the impact of cancer survivorship care plans on health outcomes and health care delivery. *J Clin Oncol.* 2018;(epub).

Goals of the RFA

Purpose of RFA-CA-19-035

- Solicit applications that develop and test models of care for adult survivors of cancer who are transitioning from active treatment to follow-up care
- Focus on enhancing communication, collaboration, and coordination among oncology and non-oncology providers to improve cancer survivor outcomes

NIH Research Project Grant (R01)

- Supports a discrete, specified, and circumscribed research project
- Most commonly used grant program
- 3-5 years of funding
- PIs strongly encouraged to present preliminary data to support proposed aims

Applications Considered Responsive

- Adult-onset cancers post active cancer treatment
- Patients whose follow-up care (at least in part) can be transitioned to providers other than those who provided active treatment
- Collaboration among oncology and non-oncology providers
- More than one domain of follow-up care:
  - Recurrence and second cancers
  - Physical and psychological effects
  - Health promotion/prevention
- Multi-level intervention: at least 2 levels; patient, provider, practice/org

Applications Considered Responsive (continued)

- Period following completion of active treatment
- Address scalability and sustainability
- Investigator team including oncology and non-oncology providers
- Include meaningful endpoints:
  - Patient-centered outcomes
  - Healthcare utilization
  - Care quality
  - Cost of care

Additional Considerations

Applications strongly encouraged (but not required) to focus on:

- Needs of minority or medically underserved survivors
- Survivors receiving care in community settings
- Samples of survivors that include more than one cancer type

Applications Considered Non-Responsive

- Observational research only
- Interventions focused only on patient/survivor
- Cancer patients on chronic/long-term therapies
- Advanced cancer patients or those with metastatic disease
- Program evaluations of existing models of care
- Survivorship care plan provision only
- Pediatric cancer survivor populations (please see RFA-CA-19-033)

Application Requirements

- Receipt date: June 28, 2019
- Letter of intent to Michelle Mollica (michelle.mollica@nih.gov) due May 28, 2019
- Applications reviewed by Special Emphasis Panel
- Please note and address special review criteria:
  - How strong is the team in terms of representation of oncology specialty providers and other health care professionals (e.g., PCP, NP, PA, other specialist provider)?
  - How well has the applicant addressed the potential for scalability and sustainability in the development, design, and testing of the proposed intervention?

Application Requirements: Clinical Trials

- NIH requirements for clinical trials research applications were updated in January 2018. Please note the following policies:
  - Application form now consolidates all Human Subjects and Clinical Trial related information into one place and also expands information required for clinical trials applications (FORMS-E)
  - Investigators and staff must receive training in Good Clinical Practice
  - All sites participating in multi-site studies research will use a single IRB
  - All NIH-funded clinical trials are expected to register and submit results to Clinicaltrials.gov
- Information about the NIH Clinical Trial Requirements: https://grants.nih.gov/policy/clinical-trials.htm

Application Requirements: Budget

- Budget should reflect the actual needs of the proposed project
- May not exceed $500K in direct costs per year
- Awardees are asked to budget funds for at least two investigators to attend an annual investigator meeting

Resources

- Read the RFA carefully: https://grants.nih.gov/grants/guide/rfa-files/RFA-CA-19-035.html
- Access and data sharing plans required for projects funded as part of the Cancer Moonshot: https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/funding/public-access-policy
- Webinar and FAQ will be posted on our website: https://healthcaredelivery.cancer.gov/media
- Connect with us early:
  Scientific contact: Michelle Mollica; michelle.mollica@nih.gov

Questions?

Please type your questions in the Q & A section on WebEx

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