Understanding and Addressing Barriers to Adolescent and Young Adult (AYA) Enrollment

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Disclosures

- None

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Overview

1 DISPARITIES IN AYA ENROLLMENT & OUTCOMES

2 BARRIERS TO AYA ENROLLMENT ONTO CANCER CLINICAL TRIALS

3 ONGOING EFFORTS TO IDENTIFY AND TARGET BARRIERS AND FACILITATORS TO ENROLLMENT

4 OVERCOMING DISPARITIES IN AYA ENROLLMENT: THE PATH FORWARD

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Disparities in AYA Enrollment and Outcomes

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The Problem

Under-enrollment of AYAs onto cancer clinical trials limits the ability to determine the most effective treatments to improve survival and health-related quality of life.

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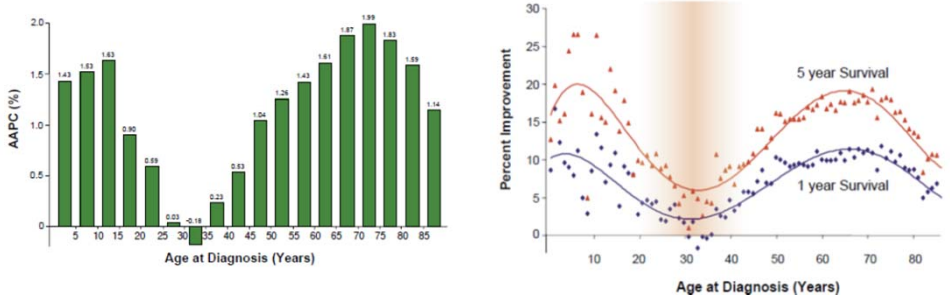
Change in 5-Year Relative Survival All Invasive Cancer, SEER 1975-97



SEER 1975-97

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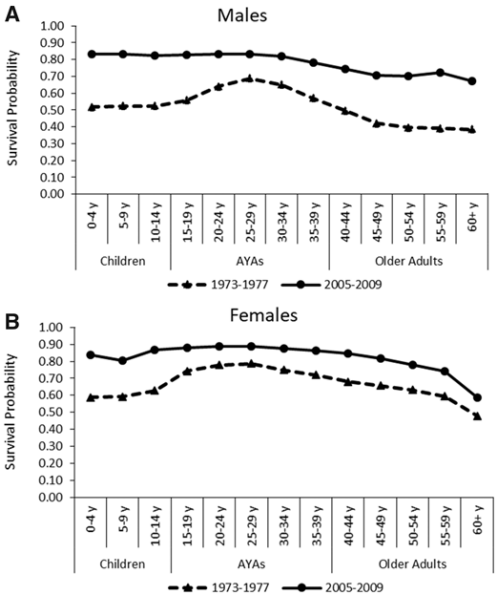
AYA Survival is Improving: Can we do better?



Liu JNCI 2018

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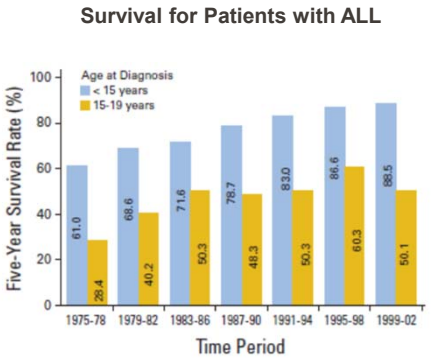
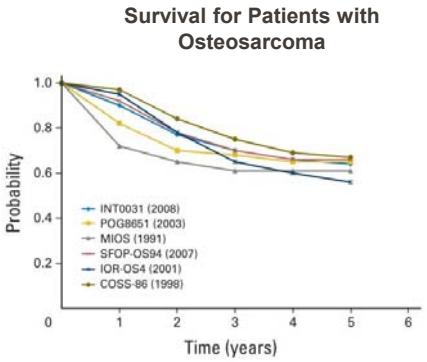
Survival for Many AYA Cancers has been Stagnant



Smith JCO 2010



Isakoff JCO 2015

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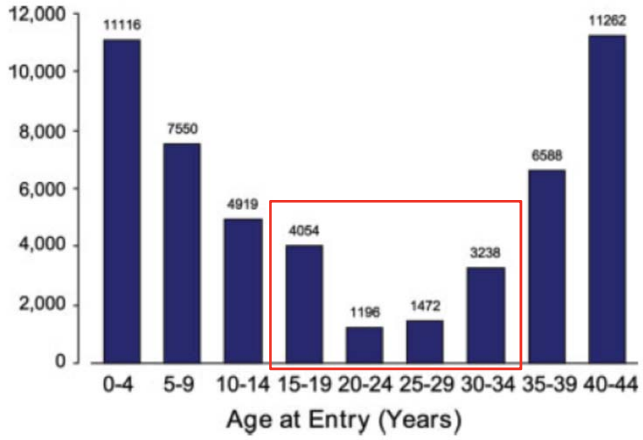
MD Anderson | Disparities in AYA Enrollment

AYA Enrollment onto Cancer Clinical Trials



Bleyer Cancer 2006

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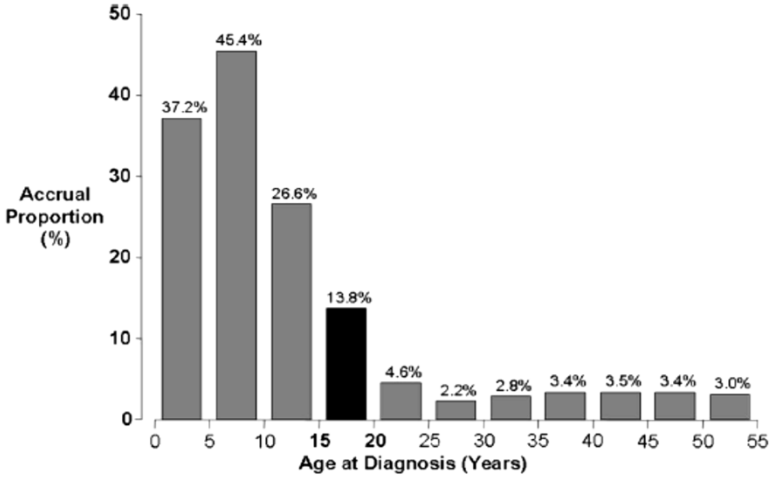
Estimated AYA Enrollment on NCI Sponsored Trials 1997 - 2005



Bleyer Cancer 2006

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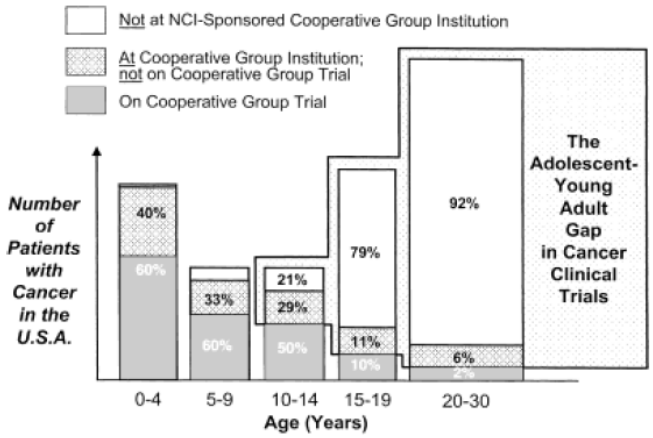
AYA Enrollment on Cooperative Group Trials



Bleyer Ped Hem Onc 2007

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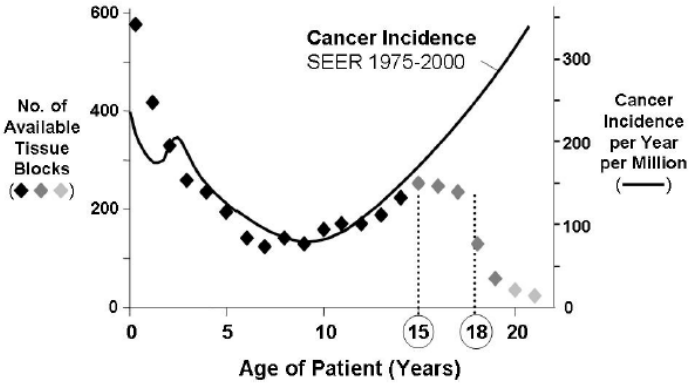
Limited Available AYA Specimens



Bleyer Ped Hem Onc 2007

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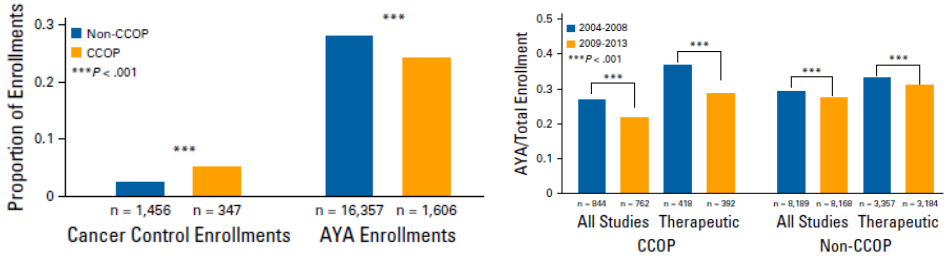
AYA Enrollment on Children's Oncology Group Clinical Trials



Roth M. J Oncology Practice 2016

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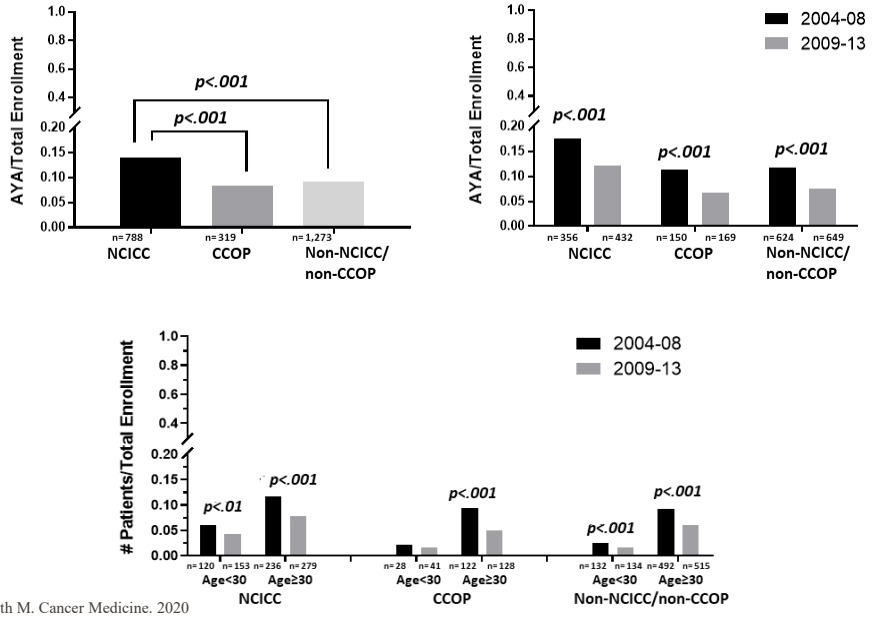
AYA Enrollment on SWOG Trials 2004-2013



Roth M. Cancer Medicine. 2020

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Barriers to AYA Enrollment onto Cancer Clinical Trials

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Suggested Barriers to AYA Enrollment

Community

- Lack of awareness and trust in trials

Societal

- Access to trials: location, insurance, transportation
- Availability of trials

Communication

- Cultural and language barriers

Provider

- Time, resources, incentives, institutional barriers

*Limited evidence documenting barriers for AYAs

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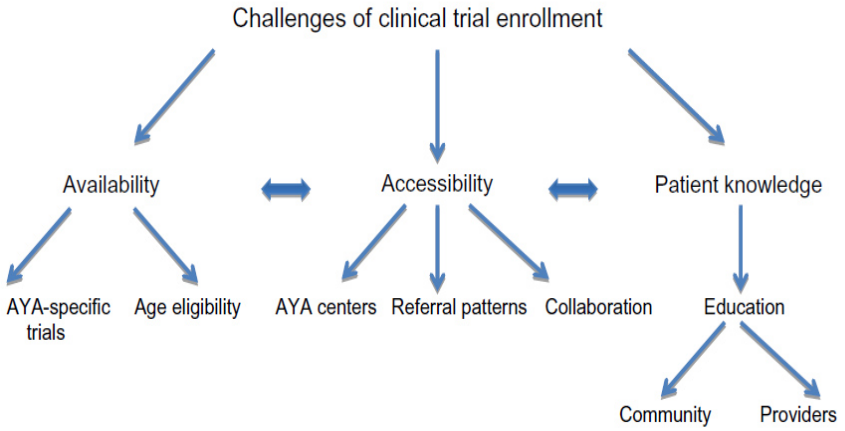
Suggested Barriers to AYA Enrollment



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Trial Access and Availability

- AYAs are less likely to receive treatment at NCI Designated Cancer Centers
- Community sites have limited access to research resources and clinical trials
- Geography impacts location of treatment

	15 Years	16 Years	17 Years	18 Years	19 Years
Pediatric (%)	76.3	78.9	46.2	23.1	7.1
Adult academic (%)	13.2	10.5	30.8	38.5	32.1
Local/Community (%)	10.5	10.5	23.1	38.5	60.7

Yeager Ped Hem Onc 2006 Albritton J. Clin Onc. 2007

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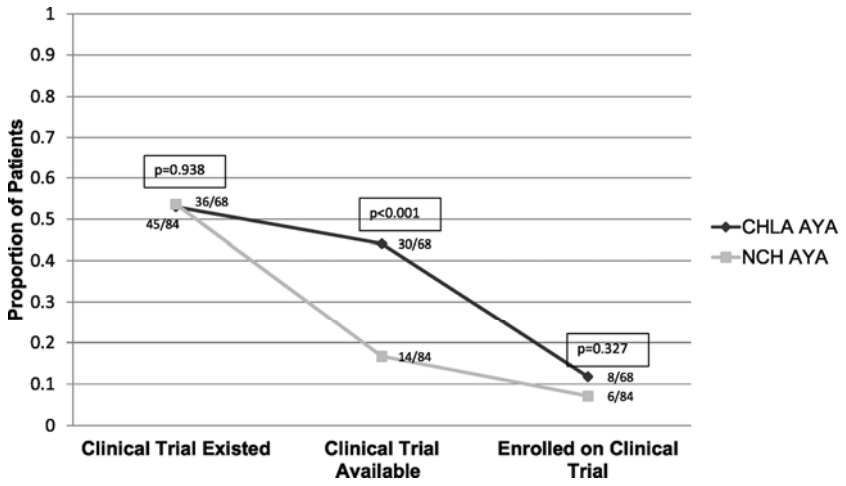
Trial Availability, Access, and Enrollment: One Size Does Not Fit All



Thomas Cancer 2018

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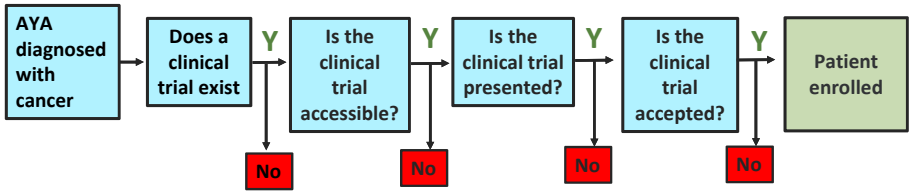
Steps Required for Successful Enrollment



If one step is unsuccessful, enrollment does not occur!

Freyer Current Ped Reports 2015

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Ongoing Efforts to Identify and Target Barriers and Facilitators to Enrollment

COG AYA Responsible Investigator Initiative

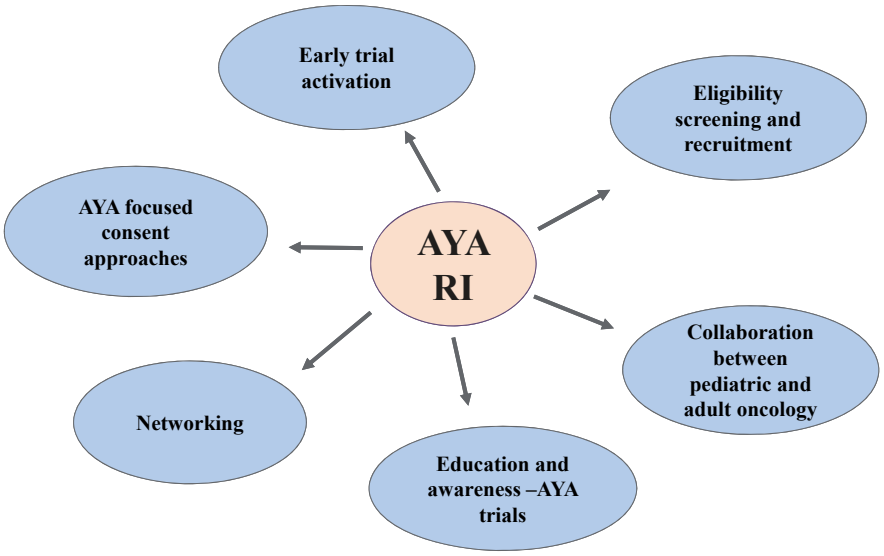
Mission: To optimize AYA enrollment onto COG clinical trials through the development of a network of "AYA champions" charged with enhancing local trial enrollment.

Approach

- COG centers identify an AYA "Responsible Investigator" who is highly involved in the enrollment of AYAs to represent site
- On monthly webinars sites present:
  - Institutional make-up, IRB structure, interactions with med onc
  - Local barriers and facilitators to AYA enrollment
  - Strategies and resources used to enhance enrollment
- AYA enrollment workshops held at COG meetings addressing shared barriers identified on the RI Network webinars
- Utilize shared resources and approaches to develop and implement local initiatives to overcome enrollment barriers

Officially launched in 2018

Institutional Goals of the RI Network



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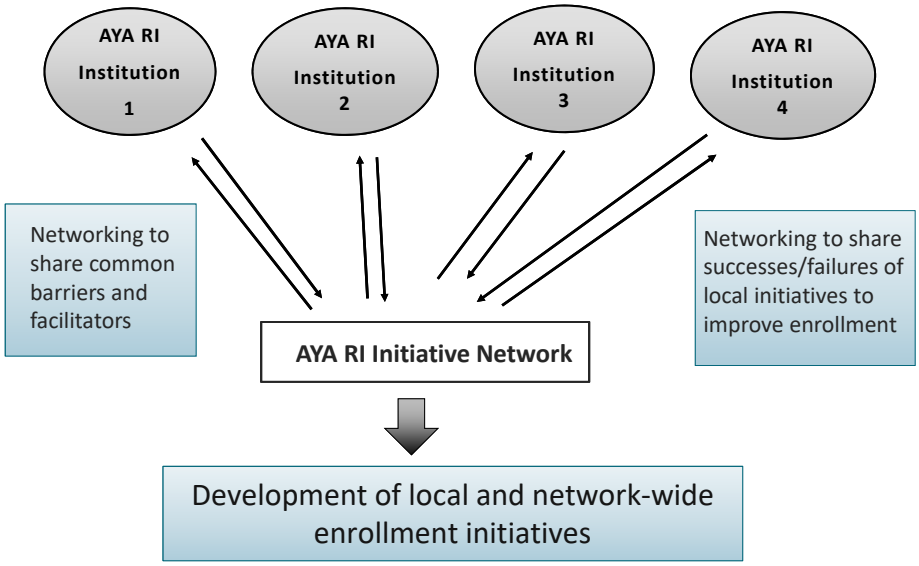
Key to Success: RIs Learn from Each Other



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COG AYA Responsible Investigator Initiative

AYA RI Network includes >150 members from:

- Large, medium, and small institutions
- Urban and community centers
- Free standing children's hospitals, pediatric programs within adult hospital, pediatric programs separated from affiliated adult programs
- Sites with and sites without AYA programs, sites developing AYA programs
- 14 international sites including 6 sites from Australia and New Zealand
- Members include physicians, research associates and nurses, administrators…

To date, the AYA RI Network has conducted:

- 14 AYA RI Network webinars
- >25 site presentations from sites with varied institutional demographics
- 3 COG workshops and 2 additional AYA enrollment breakout sessions

Roth M. JAYAO. 2020

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Barriers and Facilitators to Enrollment

Major Themes	Barriers	Facilitators
Lack of AYA relevant available clinical trials	- Limited number of AYA eligible trials available via NCTN	- Ensure that existing trials are activated at the site
Poor communication between pediatric and medical oncology	- Limited opportunities for communication between pediatric oncology and medical oncology - Lack of awareness of AYA trials available across NCTN cooperative groups - Lack of cross-service screening procedures to identify eligible AYAs	- SOPs for identifying eligible patients across pediatric and medical oncology for newly diagnosed and relapsed patients - Joint tumor boards - Increased communication between pediatric oncology and medical oncology research offices - Presence of an AYA champion focused on increasing AYA enrollment
Logistical constraints to accessing clinical trials	- Ability to open AYA relevant trials often dependent on institutional resources - Lack of consideration of clinical trial availability in institutional algorithms for assignment of primary oncology team - Challenges to medical oncologists enrolling patients onto COG trials open at affiliated sites - Separate IRBs - Confusion surrounding who is required to obtain consent when enrolling medical oncology patients onto COG trials - Lack of clarity regarding which research office is responsible for study reporting and audits	- SOPs for designation of primary oncologist (pediatric vs medical oncology) based on clinical trial availability - Increased communication between pediatric and medical oncology research teams
Need for leadership support, sufficient resources, and appropriate policies	- Lack of support from institutional leadership for AYA initiatives - Institutional upper age limits preventing treatment of older AYAs in pediatric setting - Limited allocation of AYA space - Limited research resources to open AYA relevant trials that will likely only enroll a few patients	- Executive and departmental leadership in support of AYA initiatives - Development and funding of an AYA program - Expansion of the age limit permitting young adults to be treated in the pediatric setting

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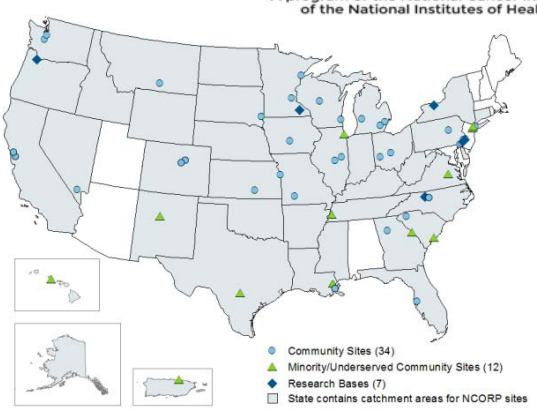
Understanding and Addressing Barriers to AYA Enrollment at NCORP Sites

NCI Community Oncology Research Program

A program of the National Cancer Institute of the National Institutes of Health



Profile*

- 46 NCORP institutions
  - 34 Community
  - 12 Minority/Under-served
  - 873 participating sites
- 5 NCORP are NCI-CCC
- 23 affiliated with COG
  - 20 mixed pediatric/adult
  - 3 pediatric-only
  - 317 affiliated sites, but only 45 enroll with COG
- Population defined as rural in NCORP-containing states: 5.1 – 50.7%

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Understanding and Addressing Barriers to AYA Enrollment at NCORP Sites

STAGE 1

Primary Objective:

Describe barriers and facilitators to enrollment of adolescents and young adults (AYAs) onto therapeutic and supportive care cancer clinical trials at NCORP sites, from the perspective of the provider and the institution.

STAGE 2

Primary Objective:

Develop targeted interventions designed to overcome to reduce identified barriers and improve AYA enrollment onto cancer clinical trials.

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Defining Barriers and Facilitators to AYA Enrollment: Stage 1 NCORP Research Plan

Step 1
- Identify diverse group of NCORP Sites
- Identify key stakeholders in the enrollment process

Step 2
- Develop interview guide: Barriers to enrollment
- Conduct phone interviews with stakeholders at selected institutions

Step 3
- Code and analyze data from one-on-one stakeholder interviews
- Summarize key barriers and facilitators to AYA enrollment across NCORP sites

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NCI Community Oncology Research Program

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Defining Barriers and Facilitators to AYA Enrollment: Stage 2 Research Plan

Step 1
- Share summary data on enrollment barriers with stakeholders
- Identify key stakeholders in the development and implementation of changes to the enrollment process across institutions in Stage 1

Step 2
- Conduct inter-institutional focus group to determine targetable barriers
  - Identify shared, high-yield barriers to address
  - Discuss potential approaches to enhance enrollment

Step 3
- Feedback summary data on selected high yield barriers to AYA enrollment
- Conduct monthly calls to identify strategies to overcome barriers
- Apply for additional funding to study interventions across NCORP sites

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Stakeholder and Site Selection

Site Selection

- Diverse group of NCORPs
  - Community Based and Minority Underserved
- Include high and low AYA enrolling sites
- Include sites with Med Onc/Ped Onc and Med Onc only

Stake Holder Selection

- NCORP PI and NCORP lead administrator
- Lead CRA or Research Nurse
- Physician heavily involved in enrollment process
- Nurse or Patient Navigator
- Regulatory Research Associate
- Patient Advocate (if available)

Includes 5 NCORPs with 2 sites from each NCORP- Up to 60 one-on-one interviews

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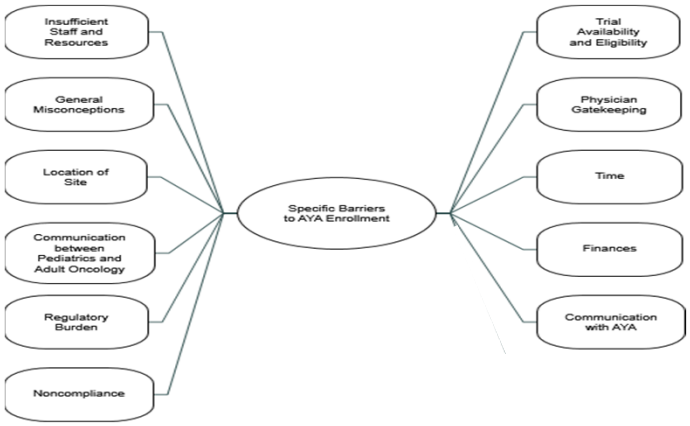
Study Progress, Next Steps, Early Results

- 100% of sites selected → 43 interviews completed
- Completing analysis
- Plan: Identify and review key targetable barriers with NCORP core study team → Develop stage II intervention(s)



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Study Progress, Next Steps, Early Results

- Stakeholder views on enrollment barriers centered on 5 main themes:
  1) Lack of site-level prioritization or discussion of AYA enrollment
  2) Limited number of clinical trials for AYAs available nationally, few trials opened locally
  3) Insufficient resources and research staff
  4) Concerns about the cost effectiveness of opening AYA trials due to low numbers of eligible patients
  5) Patient misconceptions about CCTs
- Stakeholder views on enrollment facilitators centered on 3 main themes:
  1) Presence of an AYA program focused on increasing enrollment
  2) Having a designated site AYA "champion"
  3) Having site leadership identify AYA enrollment as a priority
- Stakeholders agreed that incentivizing AYA enrollments via increased reimbursement and/or study credits could potentially lead to increased enrollment.

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Cross-Enrollment FAQs

- Many sites have questions about the requirements to enroll medical oncology patients onto COG studies and pediatric oncology patients onto adult NCTN group trials
- Lack of clarity on cross-enrollment procedures may be a significant barrier to enrolling AYAs
- To date, few medical oncology patients and pediatric oncology patients have been cross enrolled

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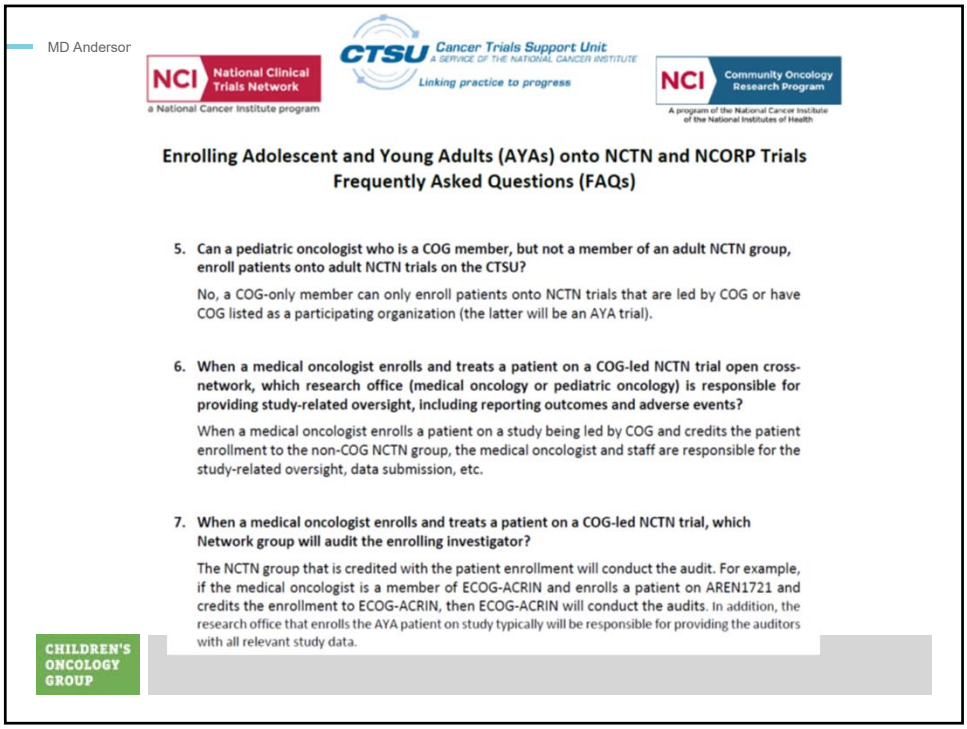

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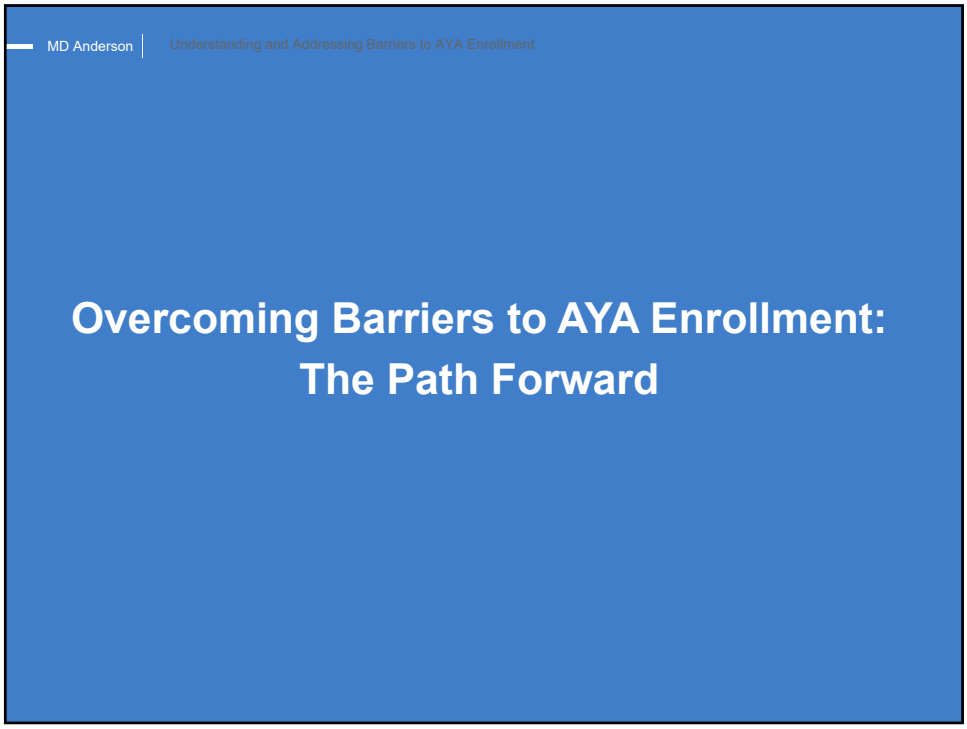

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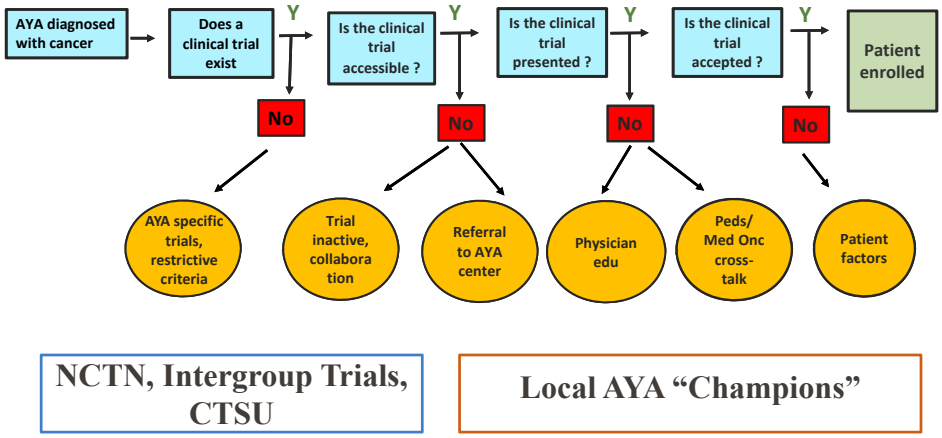
Overcoming Barriers to Enrollment



NCTN, Intergroup Trials, CTSU

Local AYA "Champions"

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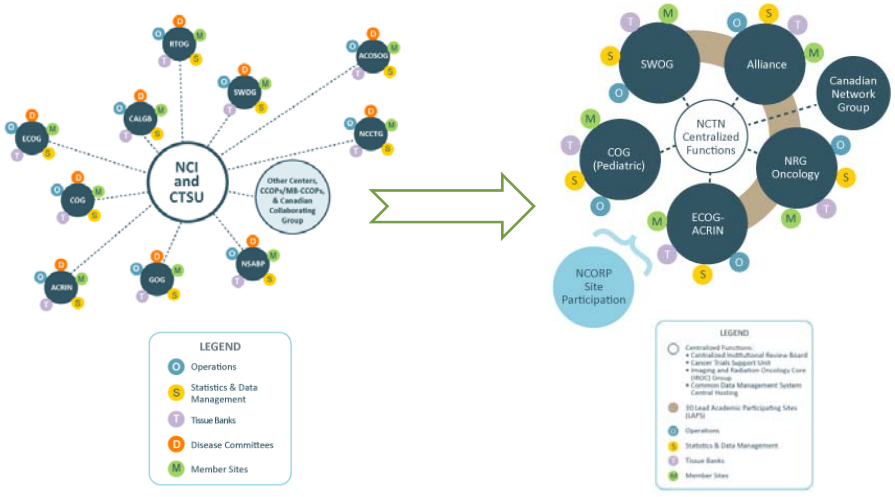
Bringing NCI Cooperative Groups Closer Together



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Development of Intergroup AYA Trials

AYA Cancer Classification	Examples	Primary Study Population	Contributing Study Population	Potential Coordinating Group
"Pediatric type"	Acute lymphoblastic leukemia, osteosarcoma, Ewing sarcoma	Pediatric	Adult	COG
"Adult type"	Colorectal carcinoma, breast cancer, melanoma, thyroid cancer	Adult	Pediatric	Adult Group
"AYA type"	Acute myeloid leukemia, Hodgkin lymphoma, germ cell tumor	Both	Not Applicable	Inter-Group

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SWOG

ECOG-ACRIN cancer research group
Reshaping the future of patient care

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

Weiss Semin Oncol 2015

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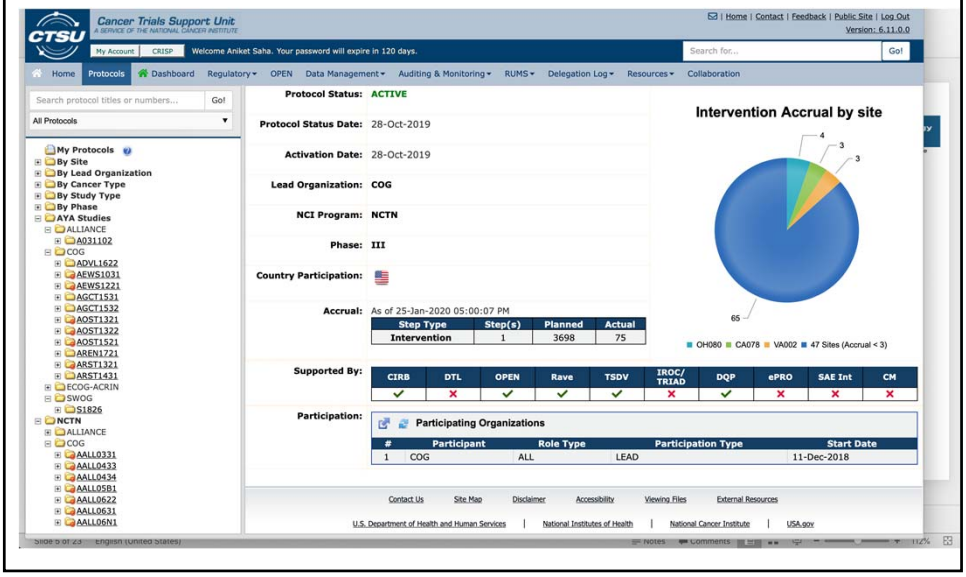
Cancer Trials Support Unit: Cross Enrollment



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Tackling AYA Enrollment Across your Site

- Designate “AYA Champions” at your site and at affiliated sites
  - The champion can be from any discipline closely involved in the clinical trial enrollment process
- Identify key barriers to AYA enrollment across your site
- Select initial barrier(s) to address
- Provide feedback on # of AYA enrollments across your site

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Select Barrier(s) to Enrollment to Address at your Site and Across your Network

- Lack of prioritization of opening AYA trials
- Lack of patient awareness of clinical trials
- Lack of provider awareness of eligible AYA patients
- Lack of knowledge of current AYA research portfolio
- Limited site awareness of current AYA enrollment
- Lack of prioritization of enrolling AYAs onto trials
- Regulatory barriers to opening AYA trials

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Consider Starting with "Low-Hanging Fruit"

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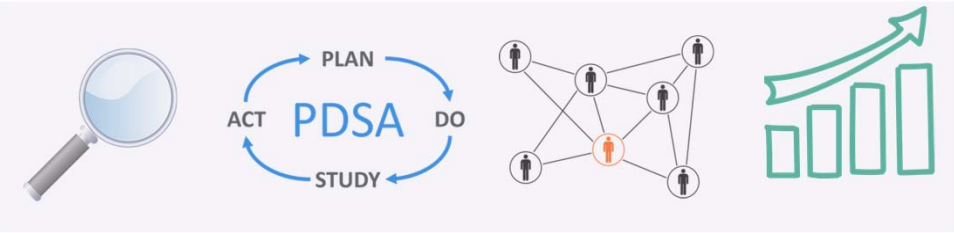
Opportunities to Increase Enrollment Through AYA "Champion" Networks

Identifying shared opportunities to increase enrollments

Development of Quality Improvement Enrollment Initiatives

Changes across institutions through enrollment working groups

Improvements in AYA Enrollment



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Summary and Next Steps

- AYA enrollment onto cancer clinical trials is sub-optimal at many sites and addressing this disparity needs to be a priority
- A number of barriers exist to enrolling AYAs onto trials
- Targeted interventions aimed at increasing enrollment for populations facing enrollment disparities have been successful
- Work with your site and hospital network to understand current barriers to enrollment and plan and implement strategies to increase enrollment.

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Thank you!

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