

The Children's Oncology Group Adolescent and Young Adult Responsible Investigator Network: A New Model for Addressing Site-Level Factors Impacting Clinical Trial Enrollment

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Purpose: In the Children's Oncology Group (COG), there is precedent for scientific committees designating institutional Responsible Investigators (RIs) to promote clinical trial enrollment and coordinate related research activities. In response to low enrollment of adolescents and young adults (AYAs) on COG clinical trials, the COG AYA RI Network was established. Leveraging this network, we undertook an initiative to identify site-level factors influencing AYA enrollment.

Methods: The overarching goal of the AYA RI Network is to increase AYA enrollment onto COG trials. At each site, RIs highlight AYA disparities, facilitate activation of relevant trials, improve recruitment processes, and expand interactions with medical oncologists. Through a series of monthly national webinars and workshops, participating RIs reported local barriers and facilitators enrolling AYAs. A mixed-methods approach was utilized to determine major themes of factors affecting site-level enrollment.

Results: For this report, there were 145 participating RIs representing 122 demographically and geographically diverse sites. There were 13 interactive webinars and 3 symposia involving 25 speakers focused on addressing enrollment barriers. Major thematic categories for site-level barriers were (1) Lack of available trials; (2) Poor communication between pediatric and medical oncology; (3) Logistical constraints to accessing trials; and (4) Need for leadership support, sufficient resources and appropriate policies.

Conclusion: The COG AYA RI Network has identified multiple site-level barriers impeding AYA clinical trial enrollment and represents a novel model for developing and implementing appropriate solutions through a nationally coordinated strategy.

Keywords: cancer clinical trial, enrollment, disparity

Introduction

ALTHOUGH SURVIVAL FOR ADOLESCENTS and young adults (AYAs, 15–39 years old) has generally improved over the last three decades, outcomes for certain cancer types and patient subsets have not.^{1–6} Compared with children <15 years old, a much lower proportion of AYAs, especially those age 21–39 years, participate in United States National Cancer Institute (NCI)-funded clinical trials, and this may be an important factor limiting progress.^{1,6–11} In addition to being associated with improved survival, participation of AYAs in NCI-sponsored clinical trials enables gaining access to investigational therapies, accessioning of biology specimens

essential for basic and translational research, and conducting cancer control, epidemiology, and supportive care studies aimed at reducing treatment-related toxicity and improving health outcomes in this unique population.^{7,12} Low enrollment of AYAs onto cancer clinical trials has been prioritized internationally as a problem in urgent need of innovative clinical and research initiatives.^{6,13–16}

The cause of low AYA participation in clinical trials is likely multifactorial. Although national-level factors such as limited existence of relevant clinical trials may contribute, several site-level barriers likely play a crucial role. These include the regulatory burden of opening trials, ineffective eligibility screening and recruitment procedures, poor

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communication between medical and pediatric oncologists, limited time and resources supporting clinical research by medical oncologists, and psychosocial challenges.^{6,17-22} Among medical oncologists, a lack of familiarity with pediatric trials may serve as an additional enrollment barrier for younger AYA patients.

Although research documenting strategies for improving AYA trial enrollment is limited, such efforts have been effective among other cancer populations burdened by disparities, such as ethnic minorities and the elderly.^{16,23,24} Limited reports suggest that building institutional AYA programs to increase collaboration between pediatric and medical oncology teams may result in improved clinical trial enrollment of AYAs.²⁵⁻²⁷ In many successful AYA programs, a key component is a designated “AYA champion” whose purpose is to ensure the distinctive clinical needs of this population are met, including increasing their participation in cancer clinical trials.^{25,26} Similarly, improved clinical trial enrollment may result from identifying individuals responsible for specific research tasks, such as clinical research associates (CRAs), research nurses, and physicians.²⁸⁻³¹ Building on this approach, the Children’s Oncology Group (COG) has successfully utilized designated Responsible Investigators (RIs), or site “champions,” for several disciplines, including cancer control and supportive care, nursing, radiation oncology, pathology and surgery, to foster clinical trial enrollment and other site-level research activities.³²

Based on those observations, in 2018, the COG AYA Oncology Discipline Committee formed the AYA RI Network as a group-wide strategy for improving institutional AYA clinical trial enrollment onto COG trials.³³ Formation of the COG AYA RI Network was based on the premise that designation and ongoing engagement of AYA RIs would constitute a key structural change within COG institutions capable of enhancing multiple aspects of the clinical trial enrollment process. The objective of this report is to describe (1) development and implementation of the COG AYA RI Network; and (2) site-level AYA enrollment barriers encountered by AYA RIs. This information will help inform development of a nationally coordinated strategy involving site-level interventions to improve AYA clinical trial enrollment, potentially involving other United States National Cancer Institute National Clinical Trials Network (NCTN) and international cooperative oncology study groups using similar AYA-focused networks in partnership with COG.

Methods

Composition of the AYA RI Network

The AYA RI Network is an activity of the COG AYA Oncology Discipline Committee. The Network is led by the Associate Vice Chair for Clinical Trials and Therapeutics assisted by two COG AYA Committee members, who coordinate all network activities, including recruitment of new network members, hosting of all webinars, and development of workshops and presentations at COG meetings. In January 2018, COG institutional Principal Investigators were invited to nominate one RI at each of their sites who has meaningful AYA patient contact, familiarity with local barriers to AYA enrollment, a strong interest in AYA cancer

clinical trial enrollment, and active COG membership. RIs could represent any discipline, including pediatric oncology, medical oncology, nursing, clinical research associate, or behavioral health.

The COG AYA RI Network was launched in February 2018. At the time of this report, there were 145 COG RIs, including physicians, nurses, CRAs, and psychologists, representing 122 demographically and geographically diverse COG institutions. Institutions included free-standing children’s hospitals, sites with pediatric and medical oncology on shared or separate campuses, and sites located in community and urban settings. Within the network, ~50% were children’s hospitals within a larger medical center, 40% were pediatric oncology departments within a larger medical center, 10% were stand-alone children’s hospitals, and <3% were designated cancer centers. Many participating sites had medical school affiliations that included both pediatric and medical oncology programs, but the level of interaction between those programs varied greatly by site. There were eight sites from Canada and 6 from Australia and New Zealand. Some institutions designated more than one AYA RI.

Purpose and function of the AYA RI

The primary purpose of the AYA RIs is to optimize AYA enrollment onto COG-led trials, and other NCTN trials in which COG is participating, at their sites. AYA RI responsibilities are focused on implementing steps to facilitate clinical trial enrollment of AYAs treated within their institution (Table 1).

Network activities

The primary mechanism through which the AYA RI Network supports enrollment is providing education and peer support to institutional AYA RIs. To achieve its goal, the AYA RI Network hosts monthly national webinars and interactive workshops at the semiannual COG meetings for AYA RIs to share best practices and leverage site-level experience. Through these venues, AYA RIs present practical information, including their program characteristics, Institutional Review Board (IRB) structure, and interactions with medical oncology, followed by a detailed description of their local barriers and facilitators to enrollment. From April 2018 through July 2019, there were 13 webinars with 25 speakers from varied institutions, with between 40 and 100 RIs attending each webinar. Importantly, there were three webinars dedicated to forming intrainstitutional collaborations between the pediatric and medical oncology AYA teams; those presenters were a pediatric oncologist representing COG and a medical oncologist representing SWOG Cancer Research Network from the same institution. In addition to the monthly webinars, AYA Committee sessions focused on enrollments were held at the semiannual COG meetings (Spring 2018, Fall 2018, and Spring 2019). Through these ongoing opportunities, RIs may share resources and adopt approaches for developing their own local initiatives.

Data analysis

A mixed methods approach was utilized to identify commonly shared barriers and facilitators to AYA enrollment across a diverse group of institutions. All 25 AYA RI

TABLE 1. ROLES OF THE ADOLESCENT AND YOUNG ADULT RESPONSIBLE INVESTIGATOR

<i>Role</i>	<i>Examples</i>
1. Address regulatory issues	Work with research office and IRB to advocate for opening AYA trials Assist medical oncology research offices with navigating cross-enrollment process Ensure adherence with study procedures and reporting of adverse events for AYA cross-enrollments
2. Enhance screening and recruitment processes	Utilize systematic screening processes to identify and target AYA patients for recruitment to front-line, retrieval, and non-therapeutic studies Establish cross-service screening processes with medical oncology to address full AYA age spectrum Designate consistent clinical or research staff member to lead screening efforts (e.g., nurse or clinical research associate) Initiate cross-service email notifications of newly diagnosed AYAs and potentially applicable studies
3. Facilitate collaboration between pediatric and medical oncology	Address common barriers to collaboration Identify and open available AYA eligible trials Form partnerships to identify and recruit AYAs eligible for COG and other NCTN trials Ensure adherence with protocol requirements Facilitate COG membership for medical oncology Form COG-SWOG dyad for COG AYA RI Network, if applicable Establish joint tumor boards, where applicable
4. Serve as the institutional AYA-focused communication link with COG, including the AYA RI Network	Provide site-level feedback for active and proposed COG studies Serve as the recipient of COG accrual updates, newsletters, and surveys Share site-level information on local enrollment challenges and solutions Participate in COG AYA RI Network webinars
5. Raise local awareness and educate regarding AYA clinical trial enrollment disparities	Track local AYA enrollments Share local AYA enrollment figures with medical oncology, nursing, CRAs Present at grand rounds, seminars, tumor boards Educate staff on strategies to overcome barriers to enrollment Disseminate information from AYA RI Network webinars

AYA, adolescents and young adult; COG, Children's Oncology Group; CRAs, clinical research associates; IRB, Institutional Review Board; NCTN, National Clinical Trials Network; RI, Responsible Investigator; SWOG, SWOG Cancer Research Network.

presentations detailing site-specific enrollment barriers and facilitators were independently reviewed by the study team. Barriers and facilitators cited were rank-ordered by frequency and organized into thematic categories by group consensus. Notes taken during the presentations were used for narrative enrichment within each thematic category.

Results

The COG AYA RI Network webinars and symposia conducted between April 2018 and July 2019 yielded numerous insights into site-level barriers and facilitators to AYA clinical trial enrollment. In this study, these are grouped thematically and discussed, beginning with the most commonly mentioned factors (Table 2).

Theme 1: lack of available clinical trials

An enrollment barrier identified by all participating sites is the perceived lack of available, AYA-relevant clinical trials. Many RIs stated that their sites had numerous AYAs whom they wanted to enroll on trials, however, COG studies or

other NCTN cooperative group studies were not available for many cancer types. Many RIs specifically noted that there have been a very limited number of sarcoma trials available for AYAs. It was noted that the existence of cancer clinical trials varies over time and is largely determined by COG and NCTN scientific priorities and funding. For trials that exist, however, their local availability is more dependent upon institutional research resources and priorities.

Theme 2: poor communication between pediatric and medical oncology

All RI Network presenters noted that limited, often minimal, communication between pediatric oncology and medical oncology services significantly hindered their ability to enroll patients. Few sites had procedures in place to identify AYAs diagnosed with new or relapsed cancer outside their department. Sites noted that it was easier to identify and screen newly diagnosed AYAs presenting to their institution compared with patients who relapsed while already under the care of the institution. A few RIs noted that their sites are

TABLE 2. COMMON SITE-LEVEL ADOLESCENT AND YOUNG ADULT ENROLLMENT BARRIERS AND FACILITATORS

<i>Major Themes</i>	<i>Barriers</i>	<i>Facilitators</i>
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	Established standardized procedures 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	Designation of primary oncologist (pediatric vs. medical oncology) based on clinical trial availability Improved 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 young adults 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

Barriers and facilitators to AYA enrollment as reported by site AYA RIs during AYA RI Network webinars. The most commonly noted barriers and facilitators are included. See Table 1 for abbreviations.

developing standardized processes for prospectively identifying eligible AYAs. Sites implementing these initiatives were mostly smaller in size and utilized email lists that included pediatric and medical oncologists and their respective clinical research teams. Most RIs noted that pediatric and medical oncologists within their institutions were frequently unaware of each other’s available trials. Joint tumor boards were frequently noted as a strong facilitator to both identifying AYAs who may be eligible for clinical trials, as well as sharing information about available trials. However, tumor boards were often limited to specific malignancies and joint tumor boards were not standard for most cancer types. Another enrollment facilitator strongly endorsed by almost all sites was the presence of AYA champions at their institution who serve as communication links between pediatric and medical oncologists.

Theme 3: logistical constraints to accessing clinical trials

Difficulty opening existing trials at the institution was identified by many RIs as a major obstacle. This was attrib-

uted to both logistical constraints and physician practice patterns. Larger pediatric centers expressed a greater ability to open more AYA-relevant studies, often the result of having more research resources. Many RIs noted that while AYA relevant trials may be activated at their children’s hospital, medical oncologists practicing at an institution that is affiliated but has a separate IRB rarely have access to the same trials. Thus, the availability of clinical trials for AYAs often depended on where they were treated, which was frequently determined by the referring providers, insurance contracts, or hospital guidelines stipulating age limits for care. Few institutions considered availability of clinical trials in their algorithms for determining where AYAs should be treated.

Even at institutions encompassing both pediatric and medical oncology with a single IRB, additional challenges to enrolling AYAs onto COG trials were identified. Most RIs noted that none of their medical oncology colleagues was a member of the COG, giving rise to uncertainty about whether permission is needed from COG to enroll medical oncology patients onto a COG trial, who should obtain informed consent, and which research team is responsible for study monitoring and audits. Unfamiliarity of medical oncologists with

COG protocols was also noted as a common barrier. Some RIs noted that on occasion, patients would be transferred to pediatric oncology to allow for study enrollment. However, this was infrequent and many RIs perceived concerns from medical oncology providers about “losing patients” if trial enrollment was determinative. In general, RIs stated that few medical oncologists were enrolling AYAs onto COG protocols, and few pediatric oncologists were enrolling AYAs onto adult NCTN trials.

Theme 4: need for leadership support, sufficient resources, and appropriate policies

AYA RIs identified the importance of receiving support from institutional leadership for enhancing AYA enrollment and prioritizing improvement of AYA care. Support from executive and departmental leadership promoted collaboration and closer communication between pediatric and medical oncology surrounding AYA programmatic efforts. Some RIs noted that development of an AYA program facilitated enrollment onto clinical trials, specifically when the AYA program was disease-focused, for example, hematologic malignancies. RIs stated that launching of new institutional AYA programs required significant support from institutional and divisional leadership. Increasing upper age limits for treatment in the inpatient and outpatient settings, and allocation of space, were also perceived to be helpful.

Conclusions and Future Directions

The COG AYA RI Network constitutes a network of “AYA champions” focused on improving AYA clinical trial enrollment at their sites. As reported here, the AYA RI Network has already yielded meaningful insights into prevalent enrollment barriers and facilitators at COG institutions, which may now serve as potential targets for focused interventions. Informed by this study and other insights gained through the AYA RI Network, the COG AYA Oncology Discipline Committee is currently conducting a stakeholder survey study at COG sites that are part of the NCI Community Oncology Research Program (NCORP) to determine more directly what potentially modifiable, site-level factors influence AYA enrollment. A formal survey of COG AYA RIs is in development to obtain more quantitative data and greater detail on AYA enrollment barriers and facilitators across COG institutions.

Although this COG-based network has successfully incorporated the pediatric oncology perspective on AYA enrollment, it is crucial to acknowledge that the majority of AYAs aged 21–39 are treated by medical oncologists. Early in the development of the RI Network, it was recognized that collaboration with medical oncology could significantly increase its impact, which led to a pilot collaboration with the SWOG Cancer Research Network whereby three webinars on AYA enrollment challenges and solutions were presented by an institutional “COG-SWOG dyad” (i.e., a pediatric oncologist from COG and a medical oncologist from the SWOG Cancer Research Network at the same institution). As a result of these presentations, the COG AYA RI Network is now partnering with the SWOG Cancer Research Network AYA Committee to recruit “COG-SWOG institutional dyads” at other sites, and eventually involve other NCTN groups in similar manner.

The AYA RI Network has grown significantly over its first year, and this report describes the most common shared barriers and facilitators to enrollment. Several initiatives have been launched because of this Network, including (1) distribution of a survey to all AYA RIs to elucidate further shared enrollment barriers and facilitators; (2) development of a “Frequently Asked Questions” document addressing common questions about cross-group enrollment of AYAs onto NCTN trials, which will be distributed within COG and the other NCTN groups; (3) expansion of the network to include more medical oncologists; and (4) sharing of AYA enrollment resources across the AYA RI Network and NCTN. Additional plans include the development of smaller working groups within the RI Network to pilot the implementation of standard operating procedures for identifying and enrolling eligible AYAs on study. Longer term studies evaluating the impact of the COG AYA RI Network on clinical trial enrollment and related outcomes are also planned.

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