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## Barriers and Facilitators to Adolescent and Young Adult Cancer Trial Enrollment: NCORP Site Perspectives

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### Abstract

**Background:** Although it is well documented that adolescents and young adults (AYAs) with cancer have low participation in cancer clinical trials (CCTs), the underlying reasons are not well understood. We used the National Cancer Institute Community Oncology Research Program (NCORP) network to identify barriers and facilitators to AYA CCT enrollment, and strategies to improve enrollment at community-based and minority and/or underserved sites. **Methods:** We performed one-on-one semistructured qualitative interviews with stakeholders (NCORP site principle investigators, NCORP administrators, physicians involved in enrollment, lead clinical research associates or clinical research nurses, nurse navigators, regulatory research associates, patient advocates) in the AYA CCT enrollment process. NCORP sites that included high and low AYA-enrolling affiliate sites and were diverse in geography and department representation (eg, pediatrics, medical oncology) were invited to participate. All interviews were recorded and transcribed. Themes related to barriers and facilitators and strategies to improve enrollment were identified. **Results:** We conducted 43 interviews across 10 NCORP sites. Eleven barriers and 13 facilitators to AYA enrollment were identified. Main barriers included perceived limited trial availability and eligibility, physician gatekeeping, lack of provider and research staff time, and financial constraints. Main facilitators and strategies to improve AYA enrollment included having a patient screening process, physician endorsement of trials, an “AYA champion” on site, and strong communication between medical and pediatric oncology. **Conclusions:** Stakeholders identified several opportunities to address barriers contributing to low AYA CCT enrollment at community-based and minority and/or underserved sites. Results of this study will inform development and implementation of targeted interventions to increase AYA CCT enrollment.

More than 80 000 adolescents and young adults (AYAs, ages 15-39 years) are diagnosed annually with cancer in the United States (1), but relatively few enroll on cancer clinical trials (CCTs) compared with children (2-9). AYA participation on CCTs remains critical to further improve survival in high-risk subgroups, provide access to novel therapies, optimize supportive care, and study host biology. Limited AYA participation on studies may hinder the ability to further improve AYA cancer care and outcomes (8,10).

Few studies have assessed the underlying reasons for the enrollment disparity (4,11,12). A recent systematic review suggests that limited physician awareness of current AYA trials, patient access to trials, and trial availability may contribute to low AYA enrollment (6,13-24). Suggested facilitators to AYA enrollment include frequent communication between medical and pediatric oncology teams, presence of a research infrastructure conducive to enrolling AYAs on trials, and efforts aimed at increasing physician awareness of AYA studies. Most of these

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**Table 1.** Selected NCORP affiliate site characteristics<sup>a</sup>

NCORP site No.	Site type	Presence of medical and pediatric oncology	High vs low AYA enroller	Region
1a	Minority and/or Underserved	Med/Ped Onc	High	East
1b	Minority and/or Underserved	Med Onc	Low	East
2a	Community-based	Med/Ped Onc	High	Midwest
2b	Community-based	Med Onc	Low	Midwest
3a	Community-based	Med Onc	High	Midwest
3b	Community-based	Med Onc	Low	Midwest
4a	Community-based	Med/Ped Onc	High	Midwest
4b	Community-based	Med/Ped Onc	Low	Midwest
5a	Community-based	Med/Ped Onc	High	West
5b	Community-based	Med Onc	Low	West

<sup>a</sup>AYA = adolescent and young adult; NCORP = National Cancer Institute Community Oncology Research Program.

findings were published from single institution studies, and multicenter studies are needed.

The National Cancer Institute (NCI) Community Oncology Research Program (NCORP) was created in part to improve CCT enrollment within community-based oncology and minority-serving sites in the United States. The NCORP includes 46 sites (32 community sites, 14 minority and/or underserved sites) consisting of more than 1000 participating affiliate sites and has expanded patient access to NCI-funded supportive care and therapeutic trials. However, AYA enrollment at NCORP sites is limited, and, despite being the primary treatment setting for AYAs, lags behind that at academic sites (5,9). To our knowledge, no studies have assessed barriers or facilitators for AYA enrollment in community sites. Our goal was to identify perceived barriers and facilitators to the enrollment of AYAs onto CCTs among a representative sample of CCT enrollment stakeholders at NCORP sites.

## Methods

### Site Selection

We purposefully selected NCORP sites to ensure adequate diversity of characteristics that could influence CCT enrollment (see Table 1) by using the following requirements for each NCORP affiliate site: 1) a minimum of 50 total enrollments for patients 15 years or older over the past 2 years, 2) at least 1 AYA enrolled over the past 2 years, 3) at least 1 enrollment for patients 40 years or older over the past 2 years, and 4) at least 1 affiliate with more than 10% AYA proportional enrollment (high enrolling) and at least 1 affiliate with less than 3% AYA proportional enrollment (low enrolling). Eighteen NCORP sites (13 community, 5 minority and/or underserved) met study eligibility criteria. We contacted 15 of these sites, and the first 5 to return complete stakeholder contact information were selected for participation. Within each NCORP, stakeholders were interviewed from 2 affiliate sites (high- and low-AYA enrolling). All National Clinical Trials Network research bases were represented in the study. Enrollment data were obtained from the NCORP enrollment database.

### Stakeholder Recruitment

The NCORP site principal investigator (PI) and NCORP administrator were recruited via email. PIs and administrators were

given an online survey link that was used to provide contact information for the lead research nurse at the affiliate sites. The study coordinator contacted the research nurse via email and requested he or she distribute a recruitment email, which included a brief description of the study, to individuals who fit the defined stakeholder categories. Individuals who expressed interest were sent an online survey link for screening and consent. If the respondent agreed to participate, contact information was collected to schedule an interview. Consent and participant screening was conducted via REDCap (Vanderbilt University, Nashville, TN).

### Instrument Development

The interview guide for each stakeholder was informed by a systematic review (13), drafted by the study investigators (EJS, HLK, MR, ITM) and reviewed by the study team for relevance. The interview guides were slightly modified for each stakeholder group to ensure relevance to the stakeholder's role in enrollment. For example, NCORP PIs were asked about the prioritization of AYA enrollment across their affiliate sites, and lead clinical research associates (CRAs) were asked about local screening processes.

### Stakeholder Interviews

Individual interviews were conducted with the NCORP Site PI and administrator, and up to 5 interviews were conducted with key stakeholders at each affiliate site. These stakeholders included the lead clinical research associates or lead clinical research nurse; the physician involved in the enrollment process; the nurse navigator, if available; the regulatory research associate; and the patient advocate, if available. After obtaining electronic consent, individual interviews were scheduled and conducted (<60 minutes) through the video-conferencing software Zoom (Zoom Video Communications, Inc, San Jose, CA). The interviews were moderated by MR, EJS, or HLK, who received training on conducting qualitative interviews by ITM. A note taker was present to ensure consistency between the interviews and transcripts. Interviews were recorded, transcribed verbatim, and de-identified for analysis. Interviews began in May 2019 and continued until data saturation was reached (September 2019).

All research materials were confidential, password protected, and accessed only by the study team. The data

underlying this article will be shared on reasonable request to the corresponding author. The institutional review boards at MD Anderson Cancer Center (PA18-0957) and the National Institutes of Health (P194541) approved the study design.

## Statistical Analysis

Sociodemographic characteristics of participants were described with univariate statistics. Adept Word Management Inc transcribed the recorded interviews, independently coded the transcripts, and used a structured approach to content analysis (25). Coding was completed after each round of 10 interviews to incorporate findings into future interviews and identify when data saturation had been achieved (defined as no new identified themes). Each transcript was read, all potential codes identified, and a final framework of themes and/or subthemes was created. Members of the research team (EJS, HLK) cross-checked the data and coding framework and made minor modifications to the themes and/or subthemes, creating the final codebook. The codebook included each theme, subtheme, definitions, and example quotes. We compared participating and nonparticipating NCORP sites on 3 characteristics (proportion of medical and pediatric oncology at each site; mean AYA yearly enrollment; mean total yearly enrollment) using the Fisher exact test. All tests were 2-sided, and the *P* value was set at .05 for statistical significance.

## Results

### Study Population Overview

We contacted 15 of the 18 eligible sites (11 community based, 4 minority and/or underserved) and 6 community-based (54.5%) and 2 minority and/or underserved (50.0%) NCORPs that expressed interest in participating, with 4 community-based and 1 minority and/or underserved NCORPs included in the study. Participating NCORPs were similar to the nonparticipating NCORPs (eg, proportion of medical and pediatric oncology at site: 0.50 vs 0.31, *P* = .44; mean AYA yearly enrollment: 6 vs 5, *P* = .71; mean total yearly enrollments: 69 vs 62, *P* = .69). Theme saturation was reached after 43 interviews (Table 2). Below, we outline the barriers and facilitators to AYA CCT enrollment that emerged. We also discuss the 2 main strategies that had been implemented to improve AYA enrollment.

### Barriers to AYA Enrollment

Eleven barriers to enrollment were identified. Subthemes and example quotes are presented in Table 3 and summarized below.

**Insufficient staff and resources.** Dedicated staff and resource limitations were believed to impact the total number of open trials. According to 1 study participant, “we are really small staff, and (...) we [the site study staff members] don’t even really necessarily have the resources to approach different groups” (CRA, female, 35-44 years).

**Trial availability and eligibility.** Stakeholders perceived a limited number of trials available, both nationally and locally, directed toward AYA patients or diseases commonly diagnosed in this population. Additionally, they reported a trend toward restrictive eligibility criteria, limiting AYA eligibility. For example, 1 physician (female, 55-64 years) stated “only about five percent

**Table 2.** Stakeholder type and number of interviews completed during the study

Stakeholder	No. of interviews
NCORP site PI	5
NCORP Administrator	4
Lead CRA or research nurse <sup>a</sup>	11
Physician involved in enrollment	7
Nurse navigator	6
Regulatory research nurse	5
Patient advocate	5

<sup>a</sup>1 site included 2 clinical research associates. CRA = clinical research associate; NCORP = National Cancer Institute Community Oncology Research Program; PI = principal investigator.

to six percent of our patients are actually candidates for the clinical trials that are currently available.”

**Physician gatekeeping.** Stakeholders believed AYAs usually learn about CCTs through conversations with their physician. However, physicians may be unaware of available trials, do not support trials, or wish to treat AYAs with more aggressive and/or timely treatments.

**Uncertainty regarding the CCT enrollment process.** Stakeholders believed that younger patients were more likely to be concerned about not getting the best treatment and preferred standard of care. However, this view was not universal, and a few stakeholders reported that young patients were more open to CCTs or had similar concerns about trial enrollment as other patients.

**Location of trial site.** Stakeholders perceived that younger patients were more likely to obtain cancer care at an academic institution rather than a community cancer center. Additionally, AYAs were considered less likely to enroll in CCTs if they had to travel substantial distances (eg, >2 hours driving) for extra appointments.

**Time.** AYA patients were viewed as being busier than other demographic groups, and these time pressures may prevent them from taking on the additional appointments, tests, and so forth required for CCT participation. Stakeholders felt that the window for trial enrollment decision making was a barrier; some believed AYAs felt the window was too short, whereas others believed it was too long.

**Communication between pediatric and adult oncology.** Stakeholders found that lack of communication between pediatric and adult oncology teams was a barrier to AYA enrollment, likely due to lack of knowledge of available trials and being unaware of eligible AYAs treated in a different department.

**Finances.** Possible financial concerns believed to hinder AYA enrollment included insufficient health insurance coverage, uncertainty of coverage status, concerns that the trial will impact the patient’s employment, and the financial burden incurred by participation.

**Regulatory burden.** A few stakeholders identified regulatory burden as a barrier to AYA enrollment, specifically among smaller research offices. Stakeholders reported that increased paperwork, navigation of red tape to start trials, and the risk of multiple audits for joint trials were all potentially limiting AYA enrollment. As one NCORP site PI said, “We limit the number of studies that can be opened because there’s a huge regulatory burden” (male, 55-64 years).

**Adherence.** Stakeholders stated that AYA patients were less likely to adhere to the requirements of their treatment protocols compared with others, which led to AYAs being removed from trials.

Table 3. Stakeholder-reported barriers to cancer clinical trial enrollment<sup>a</sup>

Barrier	Subtheme	Example quotes	No. of times referenced
Insufficient staff and resources	Limited staff size and resources affect the number of trials that can be open and the time people can commit to advocating for AYA enrollment	“First of all, we have limited staff. The CRA that I work with is responsible not only for oncology, but also for a fairly active cardiology and rheumatology research program.” (Female, 55-64 years, physician involved in enrollment)	36
	Lack of specialized equipment and individuals trained in specific subspecialties	“Not all of our sites have, for example, radiation doctors. So they’re not going to open a study that would have radiation as part of the research.” (Female, 35-44 years, NCORP Administrator)	
	AYA cancer diagnoses are rare, and the resource and staff costs to open a trial for a rare cancer type are too high	“Well, it probably means that we’re going to be less likely to open, say a sarcoma trial, than we might otherwise. Because again we have to justify cost and every time we open a clinical trial it costs us money and if we can’t get enough money back to justify the cost of the trial and we has to justify that to our bosses.” (Female, 65-74 years, NCORP Site PI)	
Trial availability and eligibility	Limited number of trials available for AYA patients because they are a small population often diagnosed with rare cancer types	“They’re probably opening more for the adult population . . . I think their main focus has been on adults in community sites . . . they probably aren’t as likely to enroll or to activate those types of trials specifically for adolescents and young adults.” (Female, 35-44 years, RRA)	37
	AYA patients are ineligible for many trials due to age (eg, younger than 18 years), the presence of comorbidities, and other factors	“What I’m seeing with clinical trials is that so much of it is focused on patients with a specific molecular profile of their tumor and that’s relatively uncommon, and therefore the majority of my patients simply are not eligible.” (Female, 55-64 years, Physician involved with enrollment)	
Physician gatekeeping	AYAs most often learn of trials through their physicians, and when physicians are unaware of trials, do not support trials, wish to treat AYAs with more aggressive/timely treatments, they won’t present the trials	“There are some doctors that would spend the time, doing all that [discussing clinical trials] and having those conversations. And there’s other doctors, not really.” (Female, 35-44 years, Nurse Navigator)	21
	AYAs patients are scared, fearful, and uncertain about what it means to be part of trial and how it will affect their outcomes and are overwhelmed by the enrollment decision-making process	“So most of the hesitation is the word clin—you know, a trial in itself, knowing that—you know, they feel like they’re almost like the test dummy, to figure out if it’s going to work or not.” (Female, 35-44 years, Patient Advocate)	
Uncertainty regarding the clinical trial enrollment process	AYA patients prefer to go to more specialized hospitals than local cancer centers		30
	Misunderstandings and/or misconceptions of how clinical trials work		
Location of trial site	Community sites lose younger patients to larger hospitals when they were geographically close	“Other than losing some of that population too, I mean, just geographically speaking [Town Name] is very close to the [State University] and so I just—I think that would be a barrier that we’re going to lose those patients to the [State University].” (Female, NCORP Administrator, 35-44 years)	19
	AYA patients less likely to enroll if they had to travel substantial distances for trial tests or appointments	“There are certainly some barriers that we have here, that might preclude a patient from participating and that come to mind since this is a rather rural area, distance, and time and travel can be real barriers.” (Female, 55-64 years, CRA/CRN)	

(continued)

Table 3. (continued)

Barrier	Subtheme	Example quotes	No. of times referenced
Time	<p>AYA patients seem to be busier than other demographics and may feel that they don't have time to take on another treatment</p> <p>Many patients start treatment immediately upon diagnosis and do not want to wait to be enrolled in a trial</p>	<p>"A lot of these AYAs are still living independently, and when you're living independently, you often have outside—you have to work, you have to provide for yourself, or sometimes they're also providing for their elders." (Male, 25-34 years, Patient Advocate)</p> <p>"We had one instance where just the delay of getting a patient enrolled and randomized, and then drug available, was more than what they wanted to wait for it. They very much, if they have cancer, want to start treatment the next day." (Male, 35-44 years, NCORP Administrator)</p> <p>"I'll go back to the disconnect between the service lines, where they fall and who's responsible for them." (Male 35-44 years, NCORP Administrator)</p>	18
Communicate between ped/adult oncology	<p>Gap in communication between pediatrics and adult oncology with pediatrics unsure of how to handle AYAs above age 18 years and adult oncology unsure of how to handle AYAs younger than 18 years</p> <p>Insurance companies do not know how to treat billing for AYAs on clinical trials that begin on the pediatric side but transition to the adult side due to age limits</p>	<p>"Let's say we have a twenty-year-old . . . going to be seen as a pediatric therapy . . . if you process it through the adult clinic and they look at the NCCN guidelines, they're not seen for an adult. . . going to be on this [pediatric] therapy, it's standard of care and should be billed to the patient. . . no that's approved for pediatrics [not adult]. Insurance doesn't know what to do with AYA." (Female, 45-54 years, CRA/CRN)</p> <p>"Because I think in the beginning, the AYA, if it's a working adult, their biggest concern is how is this going to financially impact their job, their family, and forth." (Female, 45-54 years, Nurse Navigator)</p> <p>"So the only problems that we've had in doing that actually has more to do with insurance coverage. So in the pediatric clinic, a lot more is covered a lot. It's a very different process for insurance for adults." (Female, 45-54 years, CRA/CRN)</p>	14
Regulatory burden	Increasingly more paperwork and navigation of red tape to get research trials started, and joint trials come with increased risk of audits	"We limit the number of studies that can be opened because there's a huge regulatory burden . . . let's not use our slot to open that study because we probably won't accrue to it." (Male, 65-74 years, NCORP Site PI)	8
Adherence	AYAs are less likely to adhere to the study protocol than younger and older participants	"Probably the biggest barrier has been noncompliance with quite a number of AYA patients, especially for those who have been on the COG protocol in the past. We have had to take a number of them off protocol, because they weren't following the standard recommendations or doing things that were required by the protocol." (Male, 45-54 years, Physician involved with enrollment)	4
Contacting AYAs	Reaching AYAs by telephone is more difficult than with older patients, and AYA patients may require more attempts	"We had a hard time reaching these patients. They often didn't answer their phone and some of them didn't have voicemail set up and if they did have voicemail set up, they didn't always return our calls." (Female, 35-44 years, NCORP Administrator)	3

<sup>a</sup>AYA = adolescent and young adult; COG = Children's Oncology Group; CRA/CRN = clinical research associate/clinical research nurse; NCCN = National Comprehensive Cancer Network; NCORP = National Cancer Institute Community Oncology Research Program; PI = principal investigator.



**Contacting AYAs.** Stakeholders reported that challenges in contacting AYA patients was a barrier to enrollment. They discussed that AYAs are difficult to reach via telephone, often do not have voicemail, and usually require multiple follow-up calls before response.

### Facilitators to AYA Enrollment

Thirteen themes were identified as facilitators to AYA CCT enrollment. Definitions and example quotes are presented in Table 4 and summarized below.

**Use of a screening process.** The stakeholders believed that increasing awareness of available AYA-eligible trials and targeting the AYA population during screening would improve enrollment. This could be accomplished through development of specific patient screening systems, designating an individual to identify AYA patients, or having a list of open trials available for providers.

**Community and staff education.** Stakeholders believed that it was important to include efforts to educate staff about the AYA enrollment disparity and the importance of the AYA population and to inform patients and staff about available CCTs. They also stated that cross-training staff in pediatric and medical oncology processes would improve enrollment, as AYA patients often straddle these departments.

**Physician endorsement.** Stakeholders believed that patients were more likely to enroll in a CCT when endorsed as the best treatment option by their physician. Improving physician awareness of available AYA trials, investment in research, and physician-patient communication were suggested strategies for increasing physician CCT endorsement.

**Incentivize enrollment.** Stakeholders reported that enrollment could improve if sites received incentives for prioritizing AYA enrollment, such as additional funding, reimbursements, and/or NCORP credits. To improve patients' likelihood of enrolling in trials, stakeholders also suggested providing resources to help AYAs navigate the enrollment process (eg, insurance coverage information, gas cards).

**Departmental collaboration.** Stakeholders stated that improving the relationship between pediatric and medical oncology departments, such as undertaking collaborative research, would increase AYA enrollment. A few sites had multidisciplinary tumor boards that included both pediatric and medical oncologists and noted that creating AYA-specific clinics and/or tumor boards could improve trial awareness.

**Updated communication methods.** Stakeholders felt that providing AYAs with more autonomy and involvement in the decision-making process and tailoring communication as peer to peer may improve enrollment. Moreover, communication about trials using AYA-preferred methods (eg, use of email or texting, online materials) may aid in this process.

**More AYA trials.** Stakeholders reported that developing trials targeted to AYAs or common AYA cancers and making more AYA trials available would improve enrollment. Additionally, expanding age eligibility for pediatric- or adult-oriented trials would increase AYA participation.

**Simplified interaction with the Children's Oncology Group.** Stakeholders stated that simplifying the interactions between providers and Children's Oncology Group (COG)-led trials may improve AYA enrollment. Several stakeholders suggested that allowing providers not involved in COG to participate in COG studies or have easier access to COG studies would increase AYA enrollment.

**AYA coordinators and navigators.** Stakeholders reported that having AYA navigators with strong rapport with AYA patients and providers is critical to improve enrollment.

**Advocates and mentors.** Several stakeholders encouraged the utilization of AYA advocates (eg, AYA cancer survivors, community members) in the clinical setting.

**AYA working groups.** Stakeholders said that the formation of institutional AYA working groups focused on raising awareness to AYA enrollment challenges at the site level and within NCORP institutions may improve enrollment efforts.

**Increasing awareness.** Stakeholders mentioned that expanding advertising across sites, outside oncology departments and across social media platforms may improve AYA enrollment.

**Delineation among doctors.** Stakeholders mentioned the potential importance of specialization among oncologists. For instance, general oncologists may not know of or recall trials pertaining to a specific disease site, whereas oncologists with a specific disease focus may be aware of relevant trials for AYAs within their area of expertise.

### Strategies to Improve AYA Enrollment

**Institute a process aimed to enhance AYA enrollment.** In the current study, stakeholders indicated site-specific strategies to enhance AYA enrollment, such as lists identifying AYA-eligible trials, flagging potential AYA participants, and creating an AYA program (Table 5). For example, an NCORP administrator (female, 35-44 years) described, "we have a separate AYA list that goes out monthly that talks about the active AYA trials that we have."

**Designate an on-site individual for enhancing AYA enrollment.** Identifying an on-site "AYA champion" to prioritize AYA trial opening and interactions with and the involvement of the AYA population in the CCT process was noted to advance enrollment. The "AYA champion" works directly with the staff to determine a feasible workflow to integrate AYAs into the CCT process. A patient advocate (female, 35-44 years) described one example, "I have a nurse coordinator that's over with pediatric and adult who is my research coordinator ... she follows both on the adult side and the pediatric side."

### Discussion

This study identified several barriers to AYA CCT enrollment across NCORPs, including insufficient staff and resources, limited local trial availability and eligibility, and financial barriers. Stakeholders also identified key facilitators that may improve AYA CCT enrollment, such as incentivizing enrollment, creating AYA-specific screening processes, and identifying an AYA champion. These findings identified multilevel barriers and numerous opportunities to meaningfully increase AYA enrollment across the NCORP.

Stakeholders discussed that the lower frequency of some AYA tumors (eg, osteosarcoma) is a universal and multifaceted barrier to enrollment (26). Some participants discussed this issue regarding prioritizing staffing and resources, and others discussed this issue in terms of trial availability. However, previous research suggests that many AYA trials are available at the national level, but sites are not opening these trials locally and struggle to enroll eligible AYAs (23,27). A recently completed systematic review found this to be a consistently reported barrier across studies (13). Stakeholders also noted that only COG members could enroll on COG-led trials.

Table 4. Stakeholder-reported facilitators of cancer clinical trial enrollment\*

Facilitator	Subtheme	Example quotes	No. of times referenced
Institute a screening process	<p>Provide streamlined care for the patients, such as between pediatric and medical oncologist or physicians in different subspecialties</p> <p>Improve communication and collaboration between providers and departments</p> <p>Develop a system or have a designated individual to identify or flag potentially eligible AYAs</p> <p>Have a prepared list of available, open studies</p>	<p>"But actually their care is fragmented and they are not getting in trials is kind of a symptom of a bigger problem and we need to work on figuring out how we're going to do care for AYAs better and whatever we figure out to do that then is where you introduce your clinical research." (Male, 55-64 years, NCORP Site P1)</p> <p>"That depends on the site you're at and the physicians you're dealing with. Some sites have a weekly huddles with the physicians to discuss open trials and what's available. They may also look at the upcoming week of schedules and see what patients are coming in and what might be available for them." (Female, 55-64 years, NCORP Administrator)</p> <p>"We talked to almost every new referral from a clinical trials perspective right when they were diagnosed. ... That was a lot of information for patients, but I think that was pretty successful, but I don't know that you see that number of staff and a lot of facilities anymore." (Female, 45-54 years, Nurse Navigator)</p> <p>"If we could come up with a listing of our studies that kind of have the gap, meaning, some of our studies go up to like twenty-six or twenty-three type of thing. Where we could then make a listing maybe and supply that to the research coordinators and the nurses who do the screening on the adult side just to kind of keep it in their mind." (Female, 45-54 years, CRA/CRN)</p> <p>"If our EMR was a little bit better, and it's theoretically supposed to be working towards doing this to be able to flag for us potentially relevant clinical trials, I think that would be good." (Female, 35-44 years, Physician involved with enrollment)</p> <p>"The optimal step would be to say hey here's what we've created by working together with our oncologist, pediatric community, and we would be happy to make this available to help you guys develop a similar mechanism in your community with you." (Male, 55-64 years, NCORP Site P1)</p> <p>"Just keeping, maybe, informed with the research department, having them keep me up-to-date. Maybe go to research meetings to make sure I'm aware of what's available because then I might be able to point out to a patient to them that might be eligible for an open clinical trial." (Female, 45-54 years, Nurse Navigator)</p> <p>"I think we will here in the near future if we can get our adult area of staff, more and I can work with one of the nurses to cross train, and we definitely think that will be a possibility to capturing more of that age group from 21. ... maybe all of us should learn a little bit of everything, like all the protocols, but then there is so many that it's hard to keep the adults and pediatrics straight. But, yeah, if we just had more training." (Female, 45-54 years, RRA)</p> <p>"Patient education is what I'm trying to promote." (Female, 45-54 years, Nurse Navigator)</p> <p>"I think just further reaching out to the community that even for kind of common diseases like Hodgkin's, there are protocols. ... To make community education and possibly even more at the sites we have." (Female, 55-64 years, Physician involved with enrollment)</p>	35
Community and staff education	<p>Collaborative efforts in developing AYA educational materials</p> <p>Educate staff about the AYA enrollment disparity, the importance of the AYA population and available trials</p> <p>Cross-training nurses and other staff in both the pediatric and medical oncology processes because AYA patients often overlap these departments</p> <p>Direct patient education or communication</p> <p>Provide educational resources for and opportunities to educate the broader community about clinical trials and available protocols</p>	<p>"Leverage existing technology to alert staff and physicians that a patient may be eligible for an AYA trial"</p> <p>"Collaborative efforts in developing AYA educational materials"</p> <p>"Educate staff about the AYA enrollment disparity, the importance of the AYA population and available trials"</p> <p>"Cross-training nurses and other staff in both the pediatric and medical oncology processes because AYA patients often overlap these departments"</p> <p>"Direct patient education or communication"</p> <p>"Provide educational resources for and opportunities to educate the broader community about clinical trials and available protocols"</p>	26

(continued)



Table 4. (continued)

Facilitator	Subtheme	Example quotes	No. of times referenced
Physician endorsement	Patients value their provider's opinions and when physicians feel positively about a clinical trial being the best treatment option, patients are more likely to enroll	"I truly believe that physician endorsement of clinical trials, that that's presented in a positive light from the physician, I think that makes those, those—I just believe that that's the key." (Female, 55-64 years, CRA/CRN)	19
	Making physicians aware of the AYA population and available trials	"I think a lot of it goes back to your oncologist knowing what's available and kind of being very proactive." (Female, 45-54 years, Nurse Navigator)	
	Physicians need to deem that the site has the appropriate AYA population available to enroll in open studies	"Most of the trials that we set up here are ones that are kind of guided by the physicians themselves. We get all kinds of trials that we consider opening here, but the physicians themselves decide which ones are a good fit, which ones we have the population for. . . if you have a population where there's need for it they're the ones that finds them." (Female, 55-64 years, CRA/CRN)	
Incentivize enrollment	AYA enrollment would improve when providers are invested in research	"The best thing about our pediatric oncology providers is that they are all deeply interested in research, and so they understand that patients that are enrolled in clinical trials typically with have [on average] better outcomes." (Female, 35-44 years, CRA/CRN)	21
	Help AYAs navigate the process of being diagnosed with cancer and while undergoing treatment, which may include providing free or low-cost treatment options and resources	"I think it would be great to have someone who's knowledgeable across all insurance aspects. . . but sometimes I think to have somebody that's more knowledgeable about insurance coverage, what financial means are out there. Because a lot of these kids, this young population with their young families, their college debt, they're brand new homeowners, financially how do we advise these patients?" (Female, 45-54 years, Nurse Navigator)	
	Provide NCORP credits for AYA enrollments	"I think credits is probably the thing that would get the most out of it. That seems to be the thing that NCORPs are basically focusing on because that's how we're judged, is the number of credits that you get. So I think credits is the big thing." (Female, 55-64 years, NCORP Administrator)	
Emphasize the benefit of participating in clinical trials to AYAs	Create incentives for specifically enrolling AYAs	"From the NCI, I don't necessarily think there's any incentive to specifically target the AYA population." (Male, 35-44 years, NCORP Administrator)	
	Emphasize the benefit of participating in clinical trials to AYAs	"I think it really gets back to the ability to give back to the oncology community, give back to others who are going through the same thing." (Male, 25-34 years, Patient Advocate)	
	Increase site reimbursement for enrollment	"We do not get enough reimbursement in order to cover the cost of the time for our research associate for the oncology piece One of the things that we've used to incentivize them to keep the program going is our ability to be certified on a higher level from the American College of Surgeons reviews, and so we've managed to do that. We've actually surprisingly enough been able to get accommodations for our research enrollment." (Female, 55-64 years, Physician involved with enrollment)	

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Table 4. (continued)

Facilitator	Subtheme	Example quotes	No. of times referenced
Departmental collaboration	Required participation by NCORP members in studies	“We don’t have very much interaction and they have been serially resistant to joining the NCORP and we have not been able to figure out why . . . I think maybe it’s just a basic inertia that this is working well and we don’t have to change anything and we don’t want to change anything.” (Female, 65-74 years, NCORP Site PI)	15
	Participate in AYA-specific clinics or tumor boards	“We are looking at having an AYA clinic where we have requested that their medical oncologist at least provide us with one or two providers so that we can run a joint clinic, where we will see the AYA patients there.” (Male, 45-54 years, Physician involved with enrollment)	
	Improve relationships between pediatric oncology and medical oncology departments	“I realized that other institutions might not have the setup that we have here, how close peds and adult set. But I say it’s really great if you can form some sort of conversations or even if it’s a panel that you guys meet every few months to showcase what’s available on either side.” (Female, 35-44 years, Patient Advocate)	
Updated communication methods	Communicate to AYAs about clinical trials in a developmentally appropriate manner	“Well, I always think I’m not presenting it as here’s this great option and here’s your other option. It just, here’s what standard is, here’s what you can do. We have this clinical trial that’s available. Here’s the difference and why we want to know about this or what we’ve seen be successful. And AYAs really want that autonomy. They want that—they want to be part of their, their decision making.” (Female, 35-44 years, Patient Advocate)	13
	Tailor communication to AYAs as peer to peer	“Conversation . . . I’m not making the choices for them, but having conversations and having people who really understand these on the provider side and then on the patient side, people who . . . really want to listen and want to be a part of their treatment options and know what’s available. I think the biggest thing that get people to enroll is that conversation, giving them time to talk about it and talk about their fears and talking about what the benefits are and trying to be as objective as possible with that, but just letting them know what’s out there.” (Female, 35-44 years, Patient Advocate)	
	Creating email management lists to better distribute information among providers	“We’ve upgraded all of our AV devices for the meeting, as well as build a pretty big listserv of people who we want to get patient perception on this. . . . We can mass blast based on different demographics, different age, different payer mix, all of those variables are already listed in that serv. . . . We are starting to explore how to further and continually engage people.” (Male, 25-34 years, Patient Advocate)	
More AYA trials	Communicate about trials in ways the AYA population understands and prefers	“We felt like emailing was better or if we could get a cell phone number, we could not even like leaving a message on the cell phone, but if we would like text them or something like that, that seemed to work. So I felt like that was a little bit different than what I had seen before with the general population.” (Female, 35-44 years, CRA/CRN)	11
	Open more trials for diseases commonly affecting AYA population	“Well, I think my first step would be making sure that I had studies open in diseases that are more likely to affect an AYA. . . .” (Female, 45-54 years, NCORP Site PI)	
	Expand study eligibility criteria and develop easier or more feasible study designs for this population	“Availability of decent doable studies. . . . It’s studies that I think are not going to put a young person through more procedures than they would, otherwise,	(continued)

Table 4. (continued)

Facilitator	Subtheme	Example quotes	No. of times referenced
	Design studies specifically with the AYA population in mind	normally have, or try to minimize that as much as possible to still get the answer to a legitimate scientific question." (Female, 45-54 years, NCORP Site PI) "I think we need to continue to be very determined to find the kinds of studies that meet the needs and offer options of care for our patients. . . . It's kind of exciting, we have some younger physicians and they're very excited about the options of research and it's nice to see them step up and really become some leaders in that and that's exciting to see." (Female, 55-64 years, CRA/CRN)	8
Simplify interaction with COG	Allow clinical trial participation by providers not involved in COG, as well as easier access to COG trials	"I'm through COG and other providers need to be registered with COG, and that in of itself is a very cumbersome process. So it's my understanding that if an adult provider wants to participate in the COG study, they have to join COG. . . . So that process is very cumbersome. And so I think that limits us in some aspects because the providers have to take time to do that and then they have to renew it every single year and anyway, so that's a process in [and] of itself. But if the provider is interested in the study, then the provider will be registered with COG there and then their team, CRN will also have a membership to COG." (Female, 35-44 years, CRA/CRN)	
	Simplify the clinical trial process for enrolling participants in COG trials	"I also think that I can't say enough simplifying especially for COG the process of not only being a member of COG but also simplifying the process that you know when you are navigating the COG website and you are typing ALL or you are typing AML and 6000 different studies come up and 6000 different pieces come up. But it's not so easy to look and say okay I have a relapsed patient or refractory patient that has a Philadelphia-like mutation. If you look enough you can find what's available but it's not as easy to navigate. So I think people get frustrated." (Female, 35-44 years, Physician involved in enrollment)	
	Leverage the existing NCORP infrastructure to improve the clinical trial process	"If COG could leverage that NCORP infrastructure instead of giving it to one institutionally on their end that could become a nightmare. I understand that it had to complicate things, but it would also allow us to be able to enroll better, easier." (Female, 45-54 years, CRA/CRN)	
AYA coordinators and navigators	Build strong relationships between the AYA and coordinator/navigator, such as through the investment of time and resources	"But if there was someone who maybe was focused more on that population because I suspect that you need somebody who interacts with younger patients in a different way a little bit than older patients. And so somebody who maybe is younger and might appreciate the barriers and challenges that a younger population has rather than an older population." (Female, 35-44 years, Physician involved in enrollment)	5
	Strengthen communication between AYA coordinators and physicians or other providers	"I really think the major thing that's been helpful is to have a dedicated person on each side that communicates. I think as just in a big institution with no defined people, it's hard." (Female, 55-64 years, Physician involved in enrollment)	
	Have AYA coordinators, navigators, or other AYA champions involved in every step of enrollment process as they are better able to communicate with AYA population	"I think having people that understand this population and are interested in working with them, meeting them where they are. I think that would make a huge difference in the success of these patients." (Female, 45-54 years, CRA/CRN)	

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Table 4. (continued)

Facilitator	Subtheme	Example quotes	No. of times referenced
Advocates and mentors	<p>Have AYA cancer survivors who have completed trials be lay navigators, mentors, and advocates for current patients</p> <p>Promote AYA self-advocacy and autonomy</p> <p>Community advocates can also communicate information with the AYA population</p>	<p>"A lot of times our patients have asked 'How can I give back?' . . . then we offer this program . . . typically, it is a lot of our younger individuals that are so happy to participate in it and really a rewarding experience for the next—to the next cohort to come through. (Male, 25-34 years, Patient Advocate)</p> <p>"We offer the ability to build a complex care binder for any of our oncology patients. . . . So they can take it to any other provider if they're out of state or out of network at the time and immediately present it to that team so that they can actively give the correct course of action." (Male, 25-34 years, Patient Advocate)</p> <p>"People wouldn't even realize what would be available for them. Community advocates are always good as well—to be able to engage. . . ." (Female, 35-44 years, CRA/CRN)</p>	9
AYA working groups	Form AYA committees whose focus it is to improve AYA accrual onto clinical trials and bring awareness and discussion to the enrollment challenges faced by this group	"We started an AYA committee three years ago with the help of [name]. We looked at all of our data and at that point we were only getting about 3.0% of AYA on clinical trials. And so we made a concerted effort to improve our accrual and get it up to 6.7% at the end of our five-year grant period. So it's certainly something that we are cognizant of and aware of. . . . Being the AYA experts you are, it's a difficult group of patients." (Female, 65-74 years, NCCRP Site PI)	3
Increasing awareness	Create AYA-specific advertisements	"Other than trying to talk about like what would the marketing needs be with it and have not gone a whole lot further. . . . When we're advertising, it's including them in that lump they're in the same—they use our same branding, they're in the same broadcasts—well, media area—but I don't know how much of our work benefits them. . . . They do have stuff listed on their website with us, but specifically AYA, I don't know." (Female, 35-44 years, CRA/CRN)	5
	Better evaluate the needs of the AYA population	"If you want to do an AYA marketing campaign, you could evaluate, 'What do I have in my portfolio, what could I add to it to make it stronger to increase our enrollment with it, to be able to help push that information back to our physicians into even the public?'" (Female, 35-44 years, CRA/CRN)	
	Increase advertising efforts across sites and outside of oncology	"How do we even let people know that—of this age group - 'You can come here?' We are about two hours away from a major city that has a children's hospital and they definitely advertise it. . . . But while we do really well with advertising that pediatric hospital within our adult groups, that middle age bracket is like, 'Where do we go? What do we do?'" (Female, 35-44 years, CRA/CRN)	
	Increase social media efforts for clinical trial advertising	"I think one of the challenges that we probably have, or one of the things that we could probably do to improve our AYA enrollments would be to put more effort into marketing our clinical trials program through social media. That's been a big challenge for our healthcare system in terms of trying to embrace social media. We finally have acceptable use policies. Our healthcare system recognizes that people get their news from Facebook. It sucks, but that's where they—that's where they go in the morning, and we're gradually increasing our presence to hopefully—the end goal is to have every patient that comes in the door to our healthcare system—I don't want to say expecting to go on a clinical trial, but really have them understand and expect that they're going to be screened for a	

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Table 4. (continued)

Facilitator	Subtheme	Example quotes	No. of times referenced
Delineation among doctors	Providers with a subspecialty may have better awareness of trials available for specific disease sites	<p>clinical trial and that'll be part of the discussion with their doctor, whether it's on the pediatric side or the adult side. I think we have a ways to go there." (Male, 35-44 years, NCORP Site Administrator)</p> <p>"Currently if a physician's a generalist, it's hard to remember that there's a study open for such and such disease when your institution has 300 studies open. So it really helps to have dedicated physicians that are dedicated to doing clinical research and that are dedicated to a specific disease type. I think that would affect AYA, as well as adult." (Male, 65-74 years, NCORP Site PI)</p>	2

<sup>a</sup>AYA = adolescent and young adult; ALL = acute lymphocytic leukemia; AML = acute myeloid leukemia; AV = audiovisual; COG = Children's Oncology Group; CRA/CRN = clinical research associate/clinical research nurse; EMR = electronic medical record; NCORP = National Cancer Institute Community Oncology Research Program; PI = Principal Investigator; RRA = Regulatory Research Associate.

However, this is not the case under current National Clinical Trials Network procedures. Misinformation about available AYA-eligible trials and unfamiliarity with cross-enrollment procedures limit the number of trial sites perceive to be available to their AYA patients. By uncovering these misperceptions, our results suggest that improving staff awareness of tumor-specific, AYA-eligible trials, the procedures for cross-enrollment, and incentivizing sites for AYA and/or rare cancer enrollment may be targets for potential interventions (26,28).

The presence of an AYA champion was reported to improve AYA enrollment. The AYA champion helps prioritize AYA trial openings and works with research staff to seamlessly integrate AYAs into the CCT process. Previous studies found that creating an AYA-specific clinic or internal infrastructure successfully improves AYA enrollment [see (13) for a summary]. The COG AYA Responsible Investigators Network is currently working with the SWOG Cancer Research Network to develop a comprehensive network of AYA champions, including key stakeholders from pediatric and medical oncology to enhance AYA-focused research (29).

Stakeholders also highlighted the importance of a screening process that alerts staff to potential AYA patients. Both conventional (eg, AYA-focused tumor boards) and digital approaches (eg, alerts within the electronic medical record) could be effective, allowing for tailoring across institutions. However, cost-effective approaches must be identified. The use of targeted screening programs, in conjunction with feedback and internal auditing interventions, may be a possible approach and have previously been used to improve cancer screening and CCT enrollment in other populations (30,31).

Though the current study identified numerous possible interventions for improving AYA CCT enrollment that will likely be useful to both high and low AYA enrolling sites, it is important to note that the right intervention must be implemented at the right level. Broad interventions, such as efforts within the COG NCORP Committee to distribute newsletters and frequently asked questions documents about AYA trials, is one way to improve knowledge of available AYA trials. Interventions at the local level (eg, feedback and/or auditing, identification of AYA champions) will require tailoring to institution-specific needs.

The current study provided a multilevel assessment of barriers and facilitators to enrollment. A key limitation is the lack of AYA patient perspectives. Patient advocates were included to address this limitation, but additional barriers and opportunities would likely be identified through AYA patient interviews. Because of the anonymity of our study design, we were unable to confirm the accuracy of reported barriers and/or facilitators. Finally, our sample included diverse NCORP sites, but participation bias may be present. Therefore, their views may not be fully representative, and additional site-specific challenges may exist.

With the identification of evidence-based barriers to AYA CCT enrollment and opportunities to improve enrollment, there is urgency to develop and evaluate interventions aimed at increasing AYA enrollment. Potential targets include educating stakeholders on nationally available AYA trials, incentivizing AYA enrollments, creating tailored screening processes, providing feedback to sites on AYA enrollment, and formally designating local AYA champions. Rigorous, scientifically sound trials identifying the most efficient and effective strategies to maximize enrollment are needed, and, without them, the minimal inclusion of AYAs on CCTs will remain unchanged and disparities in AYA care and outcomes will persist.



Table 5. The definition(s), example quote(s), and total number of references of each identified AYA enrollment strategy<sup>a</sup>

Facilitator	Subtheme	Example quotes	No. of times referenced
Institute a process aimed to enhance AYA enrollment	Have a program or specific coordinator focused on AYA clinical trial enrollment  Create a list of AYA trials and potential AYA participants  Improve AYA enrollment by having the support of site leadership	<p>"I'm actually the AYA program coordinator. So anytime we get a patient... I'll get a call from either our adult side or our pediatric side and we'll find out what's the best fit for them on either side or what kinds of needs they have. Talk about fertility or whatever they need really from the beginning until the end." (Female, 35-44 years, Patient Advocate)</p> <p>"It's making sure that the rest of the CRA in the adult setting and the PIs have the list of everything that's AYA. ... We just make sure that they have the list of the possible to open or the AYA. So it's a matter of making sure the right switches are on within our electronic CTMS to be able to make sure they have the information." (Female, 45-54 years, CRA/CRN)</p> <p>"I think the leadership will be supportive, because they also recognize that ... there is a deficiency when it comes to AYA enrollment. And I think that our head of research is actually interested in pushing that ahead, just to improve our numbers and make sure that these patients benefit from whatever is available for this patient group." (Male, 45-54 years, Physician involved in enrollment)</p> <p>"Through our AYA program, anything we need in terms of fertility or—you know, they are very quickly to help us get things done." (Female, 35-44 years, Physician involved in enrollment)</p>	15
Designated employee for enhancing AYA enrollment	The availability of resources for AYAs  Utilization of an AYA navigator or nurse navigators or research nurses to facilitate interactions with AYAs  Form AYA committees or tumor boards to facilitate departmental crosstalk	<p>"I have a nurse coordinator that's over with pediatric and adult who is my research coordinator. So she is extremely helpful with the research side of things and explaining what things mean when I don't understand it. And she follows both on the adult side and the pediatric side and kind of goes wherever is needed as well. ... We're lucky that in the adult side and the pediatric side, that the research person I talked about, she keeps me updated on what's available. And she actually emails both sides. So both oncologist practices, what's available in the age bracket. ... So we're lucky that, you know, we're involved in with the project, every child and that is for twenty-five and under, whether it's on the adult side or ped side, where we can really have some good conversations about what is available at our center, AYA wise for research pretty early on." (Female, 35-44 years, Patient Advocate)</p> <p>"One of the things we also do is help to coordinate our tumor board or cancer conference weekly. ... The pathologists, the oncologists will pick the patients, so when they're reviewed a cancer case conference weekly, all those patients, there's a discussion of whether they meet eligibility for clinical trials. And we have clinical trial nurses at that meeting so that they can identify patients as they're being discussed as being eligible." (Female, 45-54 years, Nurse Navigator)</p> <p>"It starts with relationships. We have great relationships and built up that respect with, obviously, our physicians, but also the mid-levels and nurse practitioners. ... So the trust that we've developed within the</p>	11

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Table 5. (continued)

Facilitator	Subtheme	Example quotes	No. of times referenced
	Appointing an AYA champion	chemo nurses, too, if they identify somebody who has questions or—who has emotional needs or has started something of concern to them, they reach out to us. So that's a way to open the door so we can get in. And then, we can further that conversation and identify what patients need. What are they most concerned about?" (Female, 35-44 years, Nurse Navigator)	
		"... In our NCCORP, the champion would be the pediatric oncologist at the pediatric hospital, right. And so I think those people are clearly, clearly going to be your champion for your first A and your AYA." (Female, 45-54 years, NCCORP Site PI)	
	Availability of individuals to help navigate the AYA clinical trial process	"We have a really great group of financial counselors within our main location that will get everybody to make sure that they're going to be sitting okay. I know financial burdens can be an issue because young kids that are in their mid-twenties may not be on their parents' insurance and may have really high deductibles and it's going to be a cost no matter what." (Female, 35-44 years, CRA/CRN)	

<sup>a</sup>AYA = Adolescent and Young Adult; COG = Children's Oncology Group; CRA/CRN = Clinical Research Associate/Clinical Research Nurse; NCCN = National Comprehensive Cancer Network; NCCORP = National Cancer Institute Community Oncology Research Program; PI = Principal Investigator.

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## Data Availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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