Psychosocial Barriers and Facilitators to Clinical Trial Enrollment and Adherence for Adolescents With Cancer

abstract

Adolescents (aged 15–19 years) have not experienced the same survival gains as children and older adults diagnosed with cancer. Poor clinical trial enrollment and adherence rates among adolescents may account for some of this disparity. Although biological, regulatory, systemic, and practice-related challenges to clinical trial enrollment and adherence have been examined, studies of psychosocial factors, which can serve as barriers or facilitators to enrollment and adherence, are limited. To bring attention to these psychological factors, we reviewed existing literature on psychosocial barriers and facilitators that can affect an adolescent's decision to enroll and adhere to a clinical trial. We also provide potential strategies to address psychosocial factors affecting clinical trial accrual and adherence. Pediatrics 2014;133:S123–S130

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KEY WORDS
adherence, adolescent, cancer survivors, clinical trial, enrollment, psychosocial

ABBREVIATIONS
AYA—adolescent and young adult
NCI—National Cancer Institute

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Clinical trial participation has been associated with improved rates of survival among individuals diagnosed with cancer.1,2 However, rates of accrual to potentially life-saving clinical trials are significantly lower among adolescent (15–19 years) and young adult (20–34 years) cancer survivors, compared with children and adults.3 Approximately 20% of 15- to 19-year-olds diagnosed with cancer are treated at institutions that participate in National Cancer Institute (NCI)-sponsored clinical trials and only ∼10% are enrolled in a clinical trial.4 Numerous biological, regulatory, systemic, and practice-related challenges have been noted as reasons for poor clinical trial enrollment among adolescents diagnosed with cancer.5 Some difficulties include lack of age, diagnosis, and stage-specific clinical trials,6 poor physician referral rates,7 and policy and legal regulatory barriers regarding age and access to medical centers where clinical trials are offered.6 Once enrolled, adherence to clinical trials is challenging due to the long-term commitment to adhering to the study protocol and multiple visits to the treatment facilities, which may be burdensome for adolescent patients and their families. Although these factors and other considerations have been well characterized,3–7 less is known about the role psychosocial factors play as barriers or facilitators to an adolescent’s decision to enroll in and adhere to a clinical trial. Although this decision is an important one for all individuals diagnosed with cancer, it may be particularly difficult for adolescent patients, given the cognitive, developmental, legal, and ethical issues unique to this population.

Adolescence is a developmental stage marked by physical and pubertal changes, cognitive maturation, identity formation, development of more complex social relationships, and struggles with autonomy versus dependence8,9 It is also the time when individuals are often expected to begin taking on increased responsibility in contributing to or making their own decisions, including medical decisions. An adolescent’s level of desired autonomy versus dependence in decision-making regarding clinical trial enrollment may vary depending on cognitive and emotional maturity, as well as family dynamics. However, adolescents are not legally able to make clinical trial enrollment decisions without the expressed and written consent of their parents.10 This legal issue becomes a challenge when encouraging adolescents to assume more responsibility in medical decision-making, if and when their feelings and opinions are not shared by their caregivers and/or medical providers. When an adolescent’s desire for independence and autonomy increase, parents and medical providers may witness adverse developmental behavior (eg, challenging authority, provocative behavior, detachment or separation, other personality or behavioral changes) brought about during their increasing maturity.11 This period of “storm and stress”12 can be challenging for caregivers, providers, and adolescent patients when making important decisions (eg, enrolling in a clinical trial) that can affect short- and long-term medical outcomes.

To better understand potential psychological factors affecting decision-making for adolescent patients with cancer and their families regarding clinical trial enrollment and retention, we reviewed current research on both psychosocial barriers and facilitators. We also describe strategies that may address these psychosocial factors, which affect clinical trial accrual and adherence.

PSYCHOSOCIAL BARRIERS AND FACILITATORS AFFECTING ENROLLMENT

Psychological Response to Cancer Diagnosis

Coping with a cancer diagnosis and the potential effects of treatment decisions at a vulnerable developmental stage, such as adolescence, can create a strong psychological burden that may affect an adolescent’s psychological and social well-being. This impact may usher in the development of psychological distress, depression, anxiety, posttraumatic stress disorder, and poor self-image.12–15 Adolescents, more so than children diagnosed with cancer, have the cognitive capacity to process the gravity of their diagnosis. Consequently, adolescents may experience higher rates of distress and anxiety about facing premature mortality and the effects of disease and related treatment, such as changes in appearance (eg, hair loss, weight, scarring, skin coloration) and changes in autonomy (eg, dependence on caregivers, changes in mobility).15–17 Adolescents can feel overwhelmed and shocked, or they may even experience denial, after receiving a cancer diagnosis.18 As with older adults, the development of these psychological symptoms may potentially affect an adolescent’s ability to make complex treatment decisions. Unlike adults aged >25 years, adolescents may not have fully developed goal-oriented behavioral and/or executive functioning skills such as organization, planning, and impulse control19 that assist in making important medical decisions, despite adverse emotional response. Although adverse or negative emotions such as fear, denial, and distress can serve as inherent barriers to decision-making, there is currently little to no research examining the psychological burden resulting from a cancer diagnosis and its related effects on lower levels of enrollment in clinical cancer trials.

Although adverse or negative emotions such as fear, denial, and distress can serve as inherent barriers to decision-making, research has outlined protective qualities such as self-efficacy and resilience that can improve the psychological well-being of adolescents diagnosed with cancer.20 Unfortunately, there is a dearth of published research.
findings that examine whether adolescents who are more resilient or those with higher levels of self-efficacy are more likely to enroll in clinical trials.

**Attitudes, Perceptions, and Beliefs About Clinical Trials**

Adolescent perceptions, attitudes, and beliefs about clinical trials can also affect enrollment decisions. Adolescents diagnosed with cancer who participate in clinical trials may believe that they will experience improved quality in their medical care and receive additional attention from specialized providers.\(^5\) In addition, adolescents electing to participate in clinical trials may do so for altruistic reasons or because they hope for therapeutic benefit over and beyond what their current or proposed treatment course provides.\(^21\)

Few studies have examined perceptions, attitudes, and beliefs that serve as barriers to adolescent cancer clinical trial enrollment. Some adolescents may fear losing control over their bodies or reduced quality of life related to participating in a clinical trial.\(^22\) A larger body of research has examined barriers in adults diagnosed with cancer. Barriers that need further exploration and may be salient for the adolescent population include the following: (1) medical mistrust and feeling like a “guinea pig,” especially among ethnic minority groups;\(^23-25\) (2) concerns about quality of life issues and loss of autonomy as a result of clinical trial participation and related adverse effects;\(^26,27\) (3) the perception that risks of enrollment outweigh the short- and/or long-term benefits;\(^28\); and (4) the belief that the clinical trial investigator is more invested in research than in the patient’s well-being.\(^28\)

Other factors that may serve as barriers and/or facilitators to enrollment, but have not been explored, are adolescents’ beliefs in their provider’s ability to offer effective treatment within and external to the context of the clinical trial and an adolescent’s decision to enroll when there are no other available medication interventions.

**Information, Knowledge, and Awareness About Clinical Trials**

The level of adolescent and provider knowledge concerning clinical trials can contribute to enrollment rates among adolescents.\(^29\) Research examining knowledge about clinical trials among children and adolescents has delineated a lack of understanding of what clinical trials are, the difference between clinical versus nonclinical research treatments, and incorrect assumptions about the level of invasiveness of clinical trial interventions compared with standard treatments.\(^30,31\) Misinformation and a lack of awareness may also be the result of poor readability, understandability, and clarity of consent forms used in child and adolescent cancer research and clinical trials.\(^32,33\) A medical provider’s knowledge of available clinical trials and communication about clinical trial information can also affect an adolescent’s awareness level.\(^3,28\) Lara et al\(^34\) found an association between poor understanding (ie, ability to accurately describe what a clinical trial is) about clinical trials and reduced willingness to participate in clinical trials among adolescents aged <18 years. However, this association was not found among adolescent and young adult (AYA) cancer survivors aged 18 to 24 years. Unfortunately, it is unclear whether increased understanding about trials is associated with improved adolescent participation in clinical trials. Research has also not examined whether clinical trial participation is greater among adolescents who understand that involvement in a clinical trial may help them receive services from leading cancer specialists, cutting-edge care, and increased monitoring.

**Sociodemographic Factors**

Sociodemographic characteristics associated with clinical trial enrollment have been routinely examined among adult cancer survivors; however, these associations are underexplored in adolescents. One such variable is race/ethnicity. Among young adults (aged 20–39 years), research has shown few ethnic differences, with similar declines in clinical trial accrual rates among ethnic minority cancer survivors compared with those who are not ethnic minorities.\(^4,35\) However, in a study looking at clinical trial enrollment of AYA patients identified via the population-based Surveillance, Epidemiology, and End Results program, there were racial/ethnic differences in time to accrual, with non-Hispanic black and Asian/Pacific Islander cancer survivors being treated later than non-Hispanic white subjects.\(^3\) Although survivors who are racial and ethnic minorities have been shown to visit their physician for regular care less than non-Hispanic white cancer survivors, their rates of enrollment in clinical trials may be equal to or higher than those of non-Hispanic white cancer survivors.\(^36\)

Differences in clinical trial accrual rates based on gender have been minimally explored in young adults and have gone unexplored for adolescent survivors. Although poor accrual rates for cancer survivors aged 20 to 39 years have been reported for both male and female subjects, deficits in participation have been more pronounced among male subjects independent of race and ethnicity.\(^5,35\)

Concerns regarding cost and insurance coverage related to clinical trials for adolescent survivors may also be prohibitive to clinical trial enrollment. AYA subjects continue to be the largest population of uninsured or underinsured individuals in the United States.\(^3\) Especially true for uninsured or underinsured adolescents who are aged ≥18 years, lack of insurance coverage may impede access to clinical trials and access to other health care services. Parsons et al\(^5\) reported that the highest
rates of clinical trial enrollment among cancer survivors aged 15 to 39 years of age were among those with Medicaid (14%) or private insurance (13%). One study found that only 3% of those who were uninsured or underinsured enrolled in clinical trials. It is possible that adolescents and their guardians may also have misperceptions of the cost of clinical trials and confusion over what is covered by Medicare, private insurance, or funding allocated by state programs.

Although there are financial barriers that can potentially affect clinical trial enrollment, facilitators to enrollment may also be present. Participants in clinical trials and other research studies are often provided with monetary compensation for their time spent as part of the trial and may also benefit from receiving free treatment. Although compensation varies, it is possible that adolescents and their families may perceive these forms of compensation as compelling incentives that warrant clinical trial participation. Research is needed to examine if these factors and others promote clinical trial enrollment.

Other sociodemographic characteristics such as employment or student status, available time to participate in the clinical trial, and travel time and expenses can serve as barriers and/or facilitators to adolescent enrollment. One study examining adolescent cancer survivor enrollment in randomized controlled trials reported that a lack of time and proximity to the treatment site were primary reasons for refusal of participation.

Issues Concerning Clinical Trial Consenting Process

The informed consent process is a required component of clinical trial enrollment. Perceptions of and emotional response to the consenting process by parents, providers, and adolescent patients with cancer can have a profound impact on the ultimate decision made concerning clinical trial enrollment. Although studies have reported that adolescents and their parents agreed on research participation decisions 74% of the time, the ability to come to a unified decision to enroll can be greatly influenced by several barriers inherent to the consenting process. Poor readability, understandability, and clarity of the consent forms used in recruitment of children and adolescents to cancer research and clinical trials have been noted as barriers. Specifically, verbal and written consent information presented with excessive technical jargon and at a level that is not cognitively appropriate for adolescents may deter participation in clinical trials. This finding may be especially true for adolescents and their guardians with low health literacy. Language barriers, including recruitment information and consent forms not available in the native language of the adolescent, are also problematic and serve as barriers to effective communication during the consenting process.

Other factors that can affect an adolescent’s ability or desire to provide valid informed consent for participation in clinical trials are the physical setting in which consenting is conducted and the adolescent’s perception of authority given to others during the consenting process. Effective communication between health care providers, parents, and adolescents during the consenting process may serve an important role in facilitating accrual. Involving adolescents in the consenting process through active engagement in asking questions and making decisions has been shown to increase an adolescent’s sense of control, autonomy, and overall ability to practice making informed medical decisions. Unfortunately, the role of communication with adolescent cancer survivors concerning the decision to enroll in a clinical trial has only been examined in a few studies.

Published research has shown that children and adolescents prefer that providers and parents explain the purpose of the clinical trial before requesting enrollment. The importance of speaking directly to the child or adolescent, instead of solely to the parent, was also reported. Children and adolescents aged 7 to 18 years in the same study also reported that speaking to other children and adolescents who are already enrolled in clinical trials would be helpful during the decision-making and consenting process. These aspects could be better implemented into the consenting process.

Relationships With Providers, Peers, and Family

Relationships between adolescent cancer survivors and their parents can negatively or positively influence their decision to enroll in clinical trials. Adolescents have been shown to value the opinions of their parents and are often influenced by their parents regarding the desire to participate in research. Broome and Richards found that children and adolescents aged 8 to 22 years reported that their parents had a strong influence over their enrollment decisions because they believed that their parents would “protect them, gather enough information to help them make the right decision, and involve them in the ultimate decision about research participation.”

Although adolescent and provider communication and its impact on clinical trial accrual have been explored in select studies, there have been no studies examining the adolescent’s perceived relationship with their provider and how this association affects enrollment. However, research has delineated that adolescents who report a strong patient–provider relationship perceive their provider as someone who is nonjudgmental, honest, expresses concern and empathy, and respects the adolescent and members of his or her family.
Peer influence has also been a strong predictor of adolescent decision-making and behavior, independent of illness. For adolescent cancer survivors, engaging in social relationships with other adolescents with cancer has been shown to provide several important benefits, including: improved coping skills, increased knowledge acquisition, independence, self-confidence, self-efficacy, and increased emotional support. Although the impact of peer relationships and their influence on clinical trial enrollment has not been examined among adolescent cancer survivors, it is possible that peers can influence medical decision-making and provide helpful information about cancer clinical trials in ways that are unthreatening and well understood by other adolescents.

**PSYCHOSOCIAL BARRIERS AND FACILITATORS AFFECTING ADHERENCE TO CLINICAL TRIALS**

Although adherence to clinical trials is reportedly lower for adolescents diagnosed with cancer than for children and older adults, true estimates are unclear due to a scarcity in research on large-scale, population-specific incidence and prevalence rates and related adherence levels. Cohort studies beginning in the 1970s, which only include AYA patients as part of their sample, have reported adherence rates from 27% to 60% for clinical trials and other therapeutic treatments for several chronic disease types.

Barriers and facilitators to treatment adherence have been examined for adolescents with diabetes, cystic fibrosis, HIV, and asthma. However, there is a dearth of research exploring factors affecting clinical trial adherence among adolescents diagnosed with cancer. A few research studies have examined “compliance” and/or “adherence” to cancer treatment in this population. However, it is unclear if these treatments were part of a clinical trial or a personalized treatment regimen prescribed by a physician. Within these studies, psychosocial factors affecting adolescent adherence have been minimally reported.

Tamaroff et al surveyed 34 adolescent cancer survivors participating in oral treatment regimens to assess psychological variables associated with treatment adherence. Poor adherence was significantly associated with less developed concepts of the illness related to causality and diagnosis, perception of reduced vulnerability, disease-related denial, and poor future orientation. No demographic factors were found to be correlated with adherence. Tebbi et al also surveyed 46 children and adolescents aged <23 years regarding their compliance with prescribed treatment of cancer. Poor compliance, in this study, was associated with having a higher number of siblings in the home, forgetting to take prescribed medication, and having a busy schedule. Increased compliance was associated with understanding and feeling satisfied with illness information provided by physicians, but it was not significantly associated with seeking out information about illness or treatment-related information from their physician or other sources. Other factors explored that were not significantly associated with compliance were: belief in the effectiveness of the treatment, feeling in control over one’s health, and demographic factors, including gender of the survivor, family income, and parent marital status.

This limited body of available literature contains small sample sizes, is not specific to clinical trials, examines both children and adolescents, and was conducted >20 years ago. For these and other methodologic reasons, it is important to consider the possibility that there may be several unexplored psychosocial factors affecting adherence among adolescents. Adolescent cancer survivors are at risk for experiencing cognitive late effects, high-risk health behaviors, and increased rates of family stress, anxiety, and posttraumatic stress disorder compared with children and older adults. It is possible that these cognitive, emotional, behavioral, and family dynamic concerns may be associated with adherence. The influence of peer relationships on adherence, compared with those with parents and providers, should also be further examined for adolescents diagnosed with cancer. Adolescents may be positively or negatively motivated to engage in certain behaviors based on the need for acceptance by their peer groups. Children with diabetes have been less adherent to treatment when they report not wanting to be different than their healthy peers and subsequently hide their illness. Poor adherence to treatment may also provide unintended benefits to adolescents diagnosed with chronic illness. For example, adolescents may perceive that they are more accepted by their peers by not adhering to treatments, which can cause adverse effects (eg, cognitive or physical) and might also restrict their desire or physical ability to engage with their peers. Lastly, several psychosocial factors playing a role in clinical trial enrollment may also increase or decrease adherence to clinical trials among adolescents. Some of the factors may include: (1) openness and frequency of communication between the adolescent, parents, and providers; (2) the adolescent’s role in making decisions at different aspects of treatment; (3) the adolescent’s knowledge of treatment and treatment-related adverse effects; and (4) adolescents’ perceptions about their provider’s level of expertise and knowledge.

**FUTURE DIRECTIONS AND CONCLUSIONS**

Research and interventions to increase cancer clinical trial enrollment and
adherence are still lacking, despite the agreement that clinical cancer trials can be a life-saving option for adolescents who have not experienced the same survival gains as children and older adults. To date, there have been no published longitudinal or large population studies examining the association between psychosocial factors of adolescents and their enrollment and adherence to clinical trials. The AYA HOPE (Adolescent and Young Adult Health Outcomes and Patient Experience) Study, conducted by the NCI, is the first longitudinal study to look at these concerns among AYA patients aged 15 to 39 years.64

In addition to future research needs, there are several practice-based and applied considerations that can be implemented to improve enrollment and adherence among adolescents. Recognizing and respecting the need for autonomy versus dependency in adolescent medical decision-making is important for both parents and providers. Moving from making medical decisions for adolescents to including them in the decision-making process is an important transition. It is crucial for parents, providers, and adolescents to discuss these transitions and monitor the cognitive, emotional, and behavioral capacity of each adolescent when beginning to assume more responsibility in making clinical trial enrollment decisions. Clinicians may also benefit from receiving training on having developmentally relevant discussions with adolescent patients about pertinent issues (including clinical trials) related to their care (eg, identifying appropriate trials and recommending them to patients). Clinicians should also discuss informed consent, as well as parental consent versus adolescent assent; clearly define differences between clinical trials and nonclinical trials; and provide details concerning the treatment protocol by using age-appropriate and cognitively appropriate language.

Establishing dedicated AYA programs within cancer centers or other treatment settings in institutions that directly serve hard-to-reach populations can also be critical to improving upon accrual rates for adolescents that may not typically enroll in a clinical trial due to transportation, distance, or other financial barriers. The accrual process may also be improved by requiring the use of multidisciplinary teams of clinicians to work with adolescent cancer patients, including mental health professionals (eg, psychologists, psychiatrists, social workers) and qualified lay health workers and patient navigators. Although differences in clinical trial enrollment and adherence for adolescents based on race/ethnicity, gender, and other sociodemographic factors are unclear, multidisciplinary teams engaged in clinical trial enrollment that are racially, ethnically, and linguistically diverse and inclusive of both men and women may be an important best practice to incorporate. Research suggests that patients are more medically adherent, report increased satisfaction when communicating with their providers, and improvements in the quality of their medical care when they have a provider(s) who shares their same gender, race/ethnicity, perceived age, and are able to speak their primary language.65 In addition, studies conducted in adult populations have shown that patients are more likely to seek care from physicians who share their own race or ethnic group. This finding is particularly salient, as adult parents are often the initial points of contact for their adolescent’s medical care.

More effective monitoring of the psychosocial needs of adolescents and their families at the point of enrollment and throughout treatment is needed. Integration of psychosocial aims into the treatment protocols of clinical trials relevant to adolescent patients can potentially build a scientific knowledge base of how participation of adolescents in clinical trials affects the psychosocial outcomes of participants compared with nonparticipants. More specialized supportive services are also needed, which can assist in acute situations or address common issues such as school, job, and school integration, social and communication skills, and coping with psychological or physical impairments due to late effects.15 Routine incorporation of specialized supportive services could be especially instrumental in clinical trial adherence.

Additional efforts could also be made to provide educational information and support to adolescents making clinical trial enrollment decisions by leveraging peer support networks. Research conducted by Zebrack66 found that 40% of AYA patients with cancer reported unmet needs for peer support programs. Existing adolescent cancer peer groups or newly formed peer network groups at designated cancer centers can be used to offer psychosocial support to adolescent patients with cancer considering enrollment or needing support for adherence to clinical trials. Involving adolescents and families who have undergone enrollment and participated in clinical trials in the outreach and education process for new patients may also be beneficial. AYA organizations may also consider developing training materials for peer support specific to adolescents that can be disseminated to cancer peer support groups. In addition to offering peer support, AYA groups and organizations can work with cancer organizations to identify and engage public figures or persons of influence (eg, athletes, actors, popular media figures) who were diagnosed with cancer during adolescence to share their cancer experience with adolescent cancer patients.

Lastly, modern technological communication strategies such as social media, other Internet-based resources, and social gaming can also be leveraged to
engage adolescents and improve dialogue concerning clinical trials. Zebrack\cite{zebrack2006} found that 30% of AYA subjects report unmet needs for age-appropriate Internet sites with information about cancer and related topics. These findings suggest an opportunity for NCI-designated cancer centers, other health care settings that treat AYA patients, AYA cancer organizations, and community providers to work with adolescents to develop a centralized, age-appropriate Internet site that presents quality and accurate information about cancer and cancer clinical trials. Social media outlets (eg, Facebook, Twitter, YouTube), which are frequently used by adolescents, may also be another source for providing information about clinical trials. Social media outlets can be used to disseminate educational videos about the pros and cons of clinical research, brief and targeted messages, and the sharing of information between those actively considering clinical trial participation, those who are unaware of clinical research, and providers of treatment and supportive care, as well as stakeholders and advocates who are tasked with improving access to and knowledge about clinical trials. Although there are several barriers that may affect decision-making for adolescent cancer survivors and their families, future research as well as programmatic and community-based strategies can be leveraged to improve adolescent clinical trial accrual rates. Ultimately, the combined efforts of medical providers, patients, families, and other community stakeholders are needed to realize increased clinical trial accrual and related improvements in survival and quality of life.

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