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Ages and Stages Questionnaires-3 Developmental Screening of Infants and Young Children With Cancer

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Abstract

The Ages and Stages Questionnaires–3® (ASQ-3) for developmental screening in our young oncology patients was pilot tested in children 4 to 48 months of age with newly diagnosed cancer. Subjects were screened within 28 days of diagnosis (baseline), at 6 and 12 months. Twenty-six of 30 enrolled parents (87%) completed all 3 screens. Screens were completed by parents within 15 minutes. ASQ-3 screening identified unsuspected developmental delays as follows: 7 at baseline, 4 at 6 months, and 3 at 12 months. ASQ-3 developmental screening is feasible, identifies early developmental delays in young children with cancer, and helps initiate appropriate referrals.

Keywords

developmental screening; developmental delay; neurocognitive delay; Ages and Stages Questionnaires-3® (ASQ-3)

Introduction

The prevalence of developmental or behavioral disorders in “healthy” American children is estimated to be 12% to 16%. These data have led the American Academy of Pediatrics (AAP) to recommend consistent screening of infants and young children up to 5 years of age (AAP Committee on Children With Disabilities, 2001; Council on Children With Disabilities, Section on Developmental Behavioral Pediatrics, Bright Futures Steering Committee, Medical Home Initiatives for Children With Special Needs Project Advisory Committee, 2006). The neurodevelopmental effects of chemotherapy agents can cause subtle delays in the course of overall development that otherwise may be amendable to supportive developmental therapies, which can maximize the quality of life for children affected by pediatric cancer (Bornstein et al., 2012; Reddy & Witek, 2003). The Children’s Oncology Group (COG) reports that 80% of children diagnosed with cancer survive at least

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Declaration of Conflicting Interests

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5 years, and two thirds of survivors experience at least one neurocognitive effect of therapy (Nathan et al., 2007).

Neurodevelopmental morbidity observed in cancer survivors is often reported without baseline knowledge of developmental status prior to oncology diagnosis (Bhatia & Constine, 2009). To improve our understanding of the developmental consequences of childhood cancer therapy, prospective surveillance is needed throughout the course of cancer treatment. Significant deficits remain in understanding the physical, cognitive, social, and psychological impacts of childhood cancer therapy (Miles, 2003; Miles & Holditch-Davis, 2003). While deficits remain in our understanding of developmental consequences of childhood cancer therapy, the best methods to comprehensively monitor patients over the course of treatment remain unknown (Miles, 2003; Miles & Holditch-Davis, 2003).

Childhood cancer survivor data demonstrate that being younger than 3 years is an independent risk factor for neurodevelopmental morbidity, and that these children often have worse neurocognitive functioning as a result of cancer therapy (Nathan et al., 2007). Survivors who receive cranial irradiation are also more likely to have a 15- to 25-point lower intelligence quotient score compared with age-related peers who did not receive cranial radiation. Overall, studies have shown that 40% to 50% of acute lymphoblastic leukemia survivors, and 70% to 80% of brain tumor survivors require special education services (Nathan et al., 2007). Recently, young patients (<42 months old) with noncentral nervous system tumors were shown to have more deficits in motor, mental, and language development compared with controls while undergoing cancer therapy (Bornstein et al., 2012). Additionally, fatigue may affect the performance status, quality of life, and developmental evaluation of children undergoing cancer therapy (Hooke, Garwick, & Gross, 2011). These data necessitate the need to identify developmental delays promptly at diagnosis and throughout treatment in order to begin interventions that may improve long-term outcomes and quality of life.

Given the lack of consistent and convenient neurodevelopmental screening, it is likely that pediatric oncology providers are missing subtle developmental delays that may already exist at the time of cancer diagnosis. Krull et al. (2008) described a brief neurocognitive screen to be used in survivor follow-up, but no standards for screening at baseline exist. In order to improve quality of care for young oncology patients, we designed a prospective pilot study to assess the feasibility of performing developmental screening at Riley Children's Cancer Center. We wanted to understand whether implementation of a protocol for developmental screening could identify early effects of chemotherapy on development. We hypothesized that systematic screening would be feasible and allow for initiation of appropriate supportive care services among young cancer patients.

Materials and Methods

Patients and Eligibility Criteria

To test the feasibility of a developmental screening protocol at Riley Children's Cancer Center, we targeted enrollment of 30 consecutively enrolled patients with a new oncology diagnosis. Given that this was a pilot design to test feasibility, we estimated that evaluating

30 patients would provide sufficient data to plan future studies with larger sample sizes. The protocol was approved by the Scientific Review Committee of the Indiana University Simon Cancer Center and the Indiana University Health Institutional Review Board. The protocol ran from June 2009 until November 2010. Patients between 4 and 48 months old with a new oncology diagnosis were eligible. Exclusion criteria were having a benign hematology diagnosis or being in a non-English-speaking family. Consent was obtained and baseline evaluation was completed within 28 days of diagnosis by protocol design.

Developmental Screening Tool

The Ages and Stages Questionnaires, 3rd edition (ASQ-3®) is a broadband developmental screening tool that assesses a child's development from 2 to 60 months of age (Squires, Bricker, & Twombly, 2009). The ASQ-3 has been validated in the medical literature and has a sensitivity of 72% and a specificity of 86% (Squires, Bricker, & Potter, 1997). In our study, we used the ASQ-3 as a tool to identify potential neurocognitive impairments resulting from the initiation of chemotherapy and to make appropriate referrals for developmental services. Our study protocol adapts the clinical care guidelines for formal developmental screening of all children at 9, 18, and 30 months of age by general pediatric providers (Council on Children With Disabilities, Section on Developmental Behavioral Pediatrics, Bright Futures Steering Committee, Medical Home Initiatives for Children With Special Needs Project Advisory Committee, 2006). However, since newly diagnosed oncology patients may only see their oncology providers during the acute phase of cancer treatment, we sought to extend developmental screening of young pediatric patients and shared management between general pediatric and oncology providers.

The ASQ-3 evaluates 5 domains of development: communication, gross motor, fine motor, problem solving, and personal-social. Each domain has a set of 6 items and parents rate the most appropriate answer for the presence of each skill: "Yes," "Sometimes," "Not Yet," with point values of 10, 5, or 0, respectively. Each domain question set is totaled independently. Prespecified clinical cut-points for each subscale are provided to indicate whether the score falls within a normal developmental range based on chronological age, or if it represents "at risk" or delayed development.

Screening Protocol

Following enrollment, caregivers completed the baseline ASQ-3 within 28 days of the new oncology diagnosis. The age-appropriate ASQ-3 was administered at three intervals: baseline (within 28 days of diagnosis), 6 months, and 12 months after the baseline ASQ-3. If the ASQ-3 scores fell either into the "at-risk" or "delay present" range, then a referral was initiated on the same day as screening. Information about the results of developmental screening was communicated back to the referring provider by letter; however, a direct phone call was made to the referring primary care provider when delays were found and prompted referral on to developmental services.

Given the nature of this feasibility pilot investigation, descriptive statistics were used for data analysis. Results were calculated using means, standard deviations, counts, and percentages using Microsoft Excel, Version 2010.

Results

The first 30 patients consecutively identified who met eligibility criteria were enrolled in the study. No parents declined participation. Baseline demographics and characteristics of the sample are summarized in Table 1. The mean age of new oncology diagnosis was 26.9 ± 12.7 months. Acute lymphoblastic leukemia was the most frequent diagnosis (36.7%). Four of 30 patients (13.3%) had a prior diagnosis of developmental delay. Of note, 2 patients enrolled had a history of trisomy 21 and were diagnosed with acute myeloid leukemia. We did not exclude these patients because of their known history of trisomy 21 as the intent was to evaluate the process of implementing ASQ-3 screening into our practice.

A research assistant or study clinician gave the screens to families and most families required 10 to 15 minutes to complete the ASQ-3. Baseline ASQ-3s were completed within 12.8 ± 9.7 days of diagnosis. Six-month ASQ-3s were performed within 6.8 ± 1.0 months of diagnosis. Twelve-month ASQ-3s were completed within 13.9 ± 1.2 months of diagnosis.

Twenty-six of 30 patients completed all three ASQ-3 screens per protocol. One patient was lost to follow-up prior to 6-month screen whereas a second patient was lost to follow-up prior to 12-month screen. Both these patients were followed by pediatric oncology practices outside Riley Children's Cancer Center. One patient died prior to 6-month screen and another patient died prior to 12-month screen. Therefore, a total of 4 patients did not complete all data collection. Screening and referrals are summarized in Figure 1. We identified 7 new delays after baseline screening. Four new delays were identified after 6-month ASQ-3 screens and 6 new delays following 12-month ASQ-3 screens. Therefore, 36.7% (11/30), 32.1% (9/28), and 30.8% (8/26) of patients warranted use of developmental resources following baseline, 6-month, and 12-month ASQ-3 screens, respectively. Only 1 patient referred for services was unable to attend his or her appointment and therefore did not receive those services. The distribution of patients with abnormal ("referral") or borderline ("at risk") ASQ-3 scores and corresponding developmental domains are summarized in Figure 2A–C. Some patients had more than one abnormal or borderline domain score at a given screening time point (Table 2). As disease-specific chemotherapy is usually initiated promptly with a new diagnosis, all patients had begun their cancer treatment at the time of baseline ASQ-3 administration. Twenty-six of 28 patients continued on therapy at the time of 6-month ASQ-3 screening. Fourteen of 26 patients remained on therapy at the time of 12-month ASQ-3.

Discussion

ASQ-3 developmental surveillance and screening is convenient and feasible in young oncology patients. At each time point, periodic developmental screening was associated with identification of new developmental delays and referral for therapy by community providers. The ASQ-3 provides an efficient instrument, which can help the pediatric oncology provider identify emerging developmental delays, leading to supportive care referrals.

Despite extensive childhood cancer survivor literature that reports neurocognitive effects of cancer therapy, very little knowledge of baseline neurodevelopmental status at the time of

initial oncology diagnosis exists (Janzen & Spiegler, 2008; Leung et al., 2000). Recently, Pejnovic et al. (2012) reported the first feasibility study of neurobehavioral screening at diagnosis of pediatric cancer. In their study, 59 newly diagnosed patients were assessed using the Trackwell targeted screening assessment for patients >3 years old, whereas parents of children <3 years at diagnosis completed a parent-response Vineland Adaptive Behavior Scale (Pejnovic et al., 2012). We now extend this literature and report the study results of implementation of a broadband developmental screening tool in young oncology patients. In comparison with the Pejnovic (2012) study where the mean time from diagnosis to assessment was 5.17 weeks, our mean time to initial screen was shorter at 12.8 days. Although we did not specifically measure length of time to complete the ASQ-3, most parents reported taking 10 to 15 minutes to complete which is consistent with previous ASQ data (Squires et al., 1997; Squires et al., 2009). Brevity was more accurately assessed by Pejnovic et al. (2012), but likely to be significantly longer using their assessment tool at 49.4 minutes to completion.

Another approach to prospective neurocognitive assessment, COG study ALTE07C1, also recently reported the findings of a novel consolidated pediatric neurocognitive battery (Embry et al., 2012). Although ALTE07C1 could be effectively administered with data collection in multiple COG sites, the consolidated screening battery required 1 hour of administration time and a licensed psychologist (Embry et al., 2012). Despite improved brevity compared with traditional neurocognitive battery, requirement of an administering psychologist and length of each screening would likely limit its translation into all pediatric oncology practices.

A major strength to our study design and choice of using the ASQ-3 for screening is that no dedicated neuropsychologist is necessary for brief, effective developmental screening. Very few pediatric oncology centers are able to employ dedicated neuropsychologists, given limited resources and third-party reimbursement, for an extensive neurodevelopmental test battery. More formal neuropsychological battery is also time consuming, and even abbreviated screening tools recently published may be too long (Embry et al., 2012; Pejnovic et al., 2012). Moreover, use of the ASQ-3 is similar to what is being done within general pediatric practice. Therefore, some families may already be familiar with these types of screening tools and have little objection to completing the tool itself. If a family does in fact stop seeing their primary care provider for the duration of cancer treatment, our study shows it is feasible for the oncology provider to continue the periodic developmental surveillance and screening the primary care providers would have otherwise done.

Recently, a prospective case-control study reported on 61 children (42 months) with nonbrain cancers using neuropsychological test battery (Bornstein et al., 2012). Compared with healthy controls, young children with cancer had more motor, mental, and language deficits (Bornstein et al., 2012). Although limited by a lack of age-matched controls, we report a similar spectrum of deficits in our cohort (Figure 2). It appears that our ASQ-3 cohort was comparable in maintenance of cognitive abilities and emotional relationships on therapy similar to the report from Bornstein et al. (2012), which used dedicated neuropsychologists for assessments. Outside an externally funded clinical research investigation, prospective developmental surveillance using dedicated neuropsychologists is

unlikely to be feasible. Therefore, the use of the ASQ-3 screening instrument represents a more translatable tool for any pediatric oncology practice.

With the growing success of childhood cancer therapy, late effects will likely pose a significant burden on health care systems and primary care providers (Lancashire et al., 2010). Multidisciplinary models of survivor care are essential to address quality of life of childhood cancer survivors (Friedman, Freyer, & Levitt, 2006). Prospective developmental surveillance in young oncology patients can improve quality of care through appropriate use of supportive care resources to maximize the child's developmental and academic potential. In addition, use of age-appropriate developmental screening will help pediatric oncology providers better understand the earlier effects of chemo-radiotherapy on neurodevelopmental outcomes. ASQ-3 screening is convenient, efficient, and allows for continued shared management between general pediatricians and oncologists, while providing a means to identify developmental delays that may be associated with chemotherapy.

Some limitations of our research need to be considered when interpreting the results. Our pilot study had a small sample size, and thus the prevalence of developmental delays we report may not be generalizable to other pediatric oncology populations. However, to our knowledge, routine developmental assessment at the time of diagnosis and throughout the course of cancer treatment is not routinely done, and thus these data might not otherwise exist. In addition, 13.3% of children at the start of the study had a history of developmental delays, which is comparable to the national prevalence of developmental delays in the general population (Rosenberg, Zhang, & Robinson, 2008). For the remaining 26 children in the study, we did not verify with the child's pediatrician if the child had previously completed an ASQ-3 during routine well-child visits to the general pediatrician, or if the child had a known history of developmental delay and relied solely on parent report.

Eliciting parental concern has been shown to approach standards for screening tests and can be used to make reasonably accurate referral to services (Glascoe, 1997). Moreover, all parents in our sample completed the study protocol without distress, discomfort, or surprise at being asked to complete the ASQ-3 within a pediatric cancer clinic. However, it is unclear whether these delays would have been identified in the absence of our study protocol since we did not collect specific data from the families on whether they had continued seeing their primary pediatric providers in the interim, or if they had recently completed the ASQ-3 or similar developmental screening tool.

Lastly, it is important to consider feasibility of ASQ-3 screening in pediatric oncology practice if no research assistants were available to screen patients. Given the ease of administration, many primary care pediatric practices implement strategies that allow consistent and convenient completion of ASQ-3 screens. For example, practices often have age-appropriate ASQ-3s given to caregivers at the time of outpatient registration for clinic appointments. This allows parents to complete the ASQ-3 while waiting to be seen by the clinician. Another strategy would be to send the ASQ-3 screen home with a family to complete and return with their next scheduled appointment. The latter strategy may be associated with higher rates of incomplete data collection as families may forget to return with the completed questionnaire. Since the ASQ-3 is completed within 10 to 15 minutes,

we recommend implementation of a clinic-based protocol to have families complete the ASQ-3 while waiting for their appointment. The ASQ-3s can then be retrieved by providers and scored within seconds of collection. This would allow for efficient administration of ASQ-3s with minimal time demanded of providers.

Our study warrants careful consideration of the use of a broadband developmental screening tool at the time of new cancer diagnosis and throughout the course of cancer treatment in the pediatric population in alignment with published COG long-term follow-up guidelines (AAP Section on Hematology/Oncology COG, 2009). The incorporation of periodic developmental screening will likely aid in our understanding of the early effects of chemotherapy on pediatric development, facilitate timely developmental intervention, and may improve quality of life and daily functioning of the child with cancer. With increased utilization of developmental screening tools in pediatric primary care, developmental data prior to the diagnosis may be more readily available and can help improve ongoing care coordination as families transition between pediatric primary and oncology care. It is not clear whether sharing results of failed developmental screening tests may add additional stress for families already dealing with the stress of having a child with cancer (Lopez, Clifford, Minnes, & Ouellette-Kuntz, 2008; Rodriguez et al., 2012). However, it is possible that some parents may feel empowerment related to their role in obtaining developmental services for their child. Future studies examining whether families who successfully initiate developmental therapies at the earliest stages of cancer treatment have improved neurocognitive outcomes or enhanced quality of life would be beneficial to fully understand the impact of incorporating development screening in the pediatric oncology setting on pediatric cancer survivors.

ASQ-3 developmental screening is feasible, identifies early developmental delays in young children with cancer, and helps initiate appropriate referrals. This efficient screening tool facilitates continuity of care between primary care and oncology providers, an important consideration for children completing cancer therapy and transitioning back to primary care providers. Future prospective developmental surveillance of young oncology patients using ASQ-3 screening may help to differentiate neurodevelopmental sequelae of cancer therapy.

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Figure 1.
Study overview.

Figure 2. Distribution of baseline (A), 6-month (B), and 12-month (C) ASQ-3 (Ages and Stages Questionnaires-3) scores by domain. Numbers of patients at risk for delay (monitor only) and those warranting referrals are shown.

Table 1

Sample Demographics and Characteristics (n = 30).

Age at diagnosis (mean $\pm$ SD)	26.9 $\pm$ 12.7 months
Gender, n (%)	
Female	13 (43.3)
Male	17 (56.7)
Diagnosis, n (%)	
ALL	11 (36.7)
AML ^a	4 (13.3)
Wilms's tumor	4 (13.3)
CNS ATRT	1 (3.3)
Hepatoblastoma	1 (3.3)
JMML	1 (3.3)
Lymphoma	1 (3.3)
Medulloblastoma	1 (3.3)
Neuroblastoma	1 (3.3)
PNET	1 (3.3)
PPB	1 (3.3)
Rhabdoid tumor of the kidney	1 (3.3)
Rhabdomyosarcoma	1 (3.3)
Previous diagnosis of developmental delay, n (%)	4 (13.3) ^b

Abbreviations: SD, standard deviation; ALL, acute lymphoblastic leukemia; AML, acute myelogenous leukemia; CNS ATRT, central nervous system atypical teratoid rhabdoid tumor; JMML, juvenile myelomonocytic leukemia; PNET, peripheral neuroectodermal tumor; PPB, pleuropulmonary blastoma.

^aTwo patients with trisomy 21 and AML (Down syndrome–AML).

^bTwo patients diagnosed with trisomy 21.

Table 2

Patients With >1 Concomitant Delay by Ages and Stages Questionnaires-3 Screen.

Number of Delays ^a	Baseline (N = 30); n (%)	6 Months (N = 28); n (%)	12 Months (N = 26); n (%)
2	1 (3.3)	3 (10.7)	1 (3.8)
3	0	0	0
4	1 (3.3)	0	1 (3.8)
5	4 (13.3)	4 (14.3)	2 (7.7)

^aDenotes patients with actual delays and referrals for developmental services. Number of patients “at risk” with borderline scores in >1 domain at baseline, 6 months, and 12-months were 4, 2, and 1, respectively.