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The Children's Oncology Group: Organizational Structure, Membership, and Institutional Characteristics

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Abstract

Background: The Children's Oncology Group (COG) is the only organization within the National Cancer Institute's National Clinical Trials Network dedicated exclusively to pediatric cancer research. The purpose of this article is to provide an overview of COG's organizational structure, to characterize its institutional and individual membership, and to summarize enrollments onto COG clinical trials. Method: Data from 2013 to 2015 were compiled from sources internal (Network Operations, Statistics and Data Center, Chair's Office) and external (American Hospital Association, American Nurses Credentialing Center) to COG, to present a comprehensive overview of COG's structure, individual and institutional membership, and group operations. Results: In 2016, COG comprised 8,785 individuals from 223 member institutions, across seven countries. An average of 9,661 new patients were registered with COG per year over the most recent (2013-2015) 3-year period. Over the same 3-year time frame, there were an average of 16,836 enrollments onto therapeutic (i.e., treatment) and nontherapeutic (e.g., epidemiology, survivorship, biology) trials per year. Conclusions: COG institutions have diverse characteristics related to size, geographical location, and infrastructure. Individual membership also reflects diversity with representation from over 28 disciplines and groups. The diversity of COG institutions and individual members allows for unique perspectives and contributions to science unified under a common goal to enroll children/adolescents onto clinical trials. COG's collaborative, multidisciplinary approach to science functions to support the development of research that seeks to continually improve outcomes for children and adolescents with cancer.

Keywords

clinical trials, pediatric oncology, cooperative group, research

Introduction

The foundation for oncology clinical trials groups in the United States began in 1955, when funding was appropriated by Congress to the National Cancer Institute (NCI) in order to establish the Cancer Chemotherapy National Service Center (Mauer, Rich, & Schilsky, 2007). This set in motion collaborations between institutions to evaluate potential anticancer agents. First among these collaborations was Leukemia Group A-the vanguard of the legacy pediatric oncology clinical trials groups. Over the ensuing five decades, additional clinical trials groups were established with the overarching purpose of conducting multi-institutional trials to improve cancer outcomes, and a Cooperative Group Program to fund and support the infrastructure for oncology clinical trials was firmly established by the NCI. Four of the legacy groups founded during this era (the Children's Cancer Group, the Intergroup Rhabdomyosarcoma Study Group, the National Wilms Tumor Study Group, and the Pediatric Oncology Group) maintained a pediatric oncology focus, and voluntarily merged in the year 2000 to form the Children's Oncology Group (COG; O'Leary, Krailo, Anderson, & Reaman, 2008). The COG thus became the

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sole pediatric-focused clinical trials program among the 10-member NCI Cooperative Group Program.

Subsequent recommendations from the Institute of Medicine (Nass, Moses, & Mendelsohn, 2010) regarding the need for a more efficient, responsive, and collaborative clinical trials system led the NCI to restructure and transform the Cooperative Group system into the National Clinical Trials Network (NCTN), which was launched in March 2014. This change reduced the number of groups that receive NCI clinical trial funding support from 10 to 5, with four U.S.-based groups designated for adultfocused trials: (1) Alliance (Alliance for Clinical Trials in Oncology, formed by the merger of the American College of Surgeons Oncology Group, Cancer and Leukemia Group B, and North Central Cancer Treatment Group), (2) ECOG-ACRIN Cancer Research Group (Eastern Cooperative Oncology Group and the American College of Radiology Imaging Network), (3) NRG Oncology (formed through the merger of the National Surgical Adjuvant Breast and Bowel Project, the Radiation Therapy Oncology Group, and the Gynecologic Oncology Group), and (4) SWOG (formerly known as the Southwest Oncology Group)-and one group for pediatric-focused clinical trials: COG (U.S. Department of Health and Human Services, 2015). This massive change in infrastructure was implemented to reduce duplication of effort across groups and to position the funded groups to work together in order to maximize the potential for scientific progress in the era of precision medicine (U.S. Department of Health and Human Services, 2015).

Today, COG is the world's largest research organization dedicated exclusively to children and adolescents with cancer. In the United States, an estimated 10,270 children ages 0 to 14 years will be diagnosed with cancer in 2017 (Siegel, Miller, & Jemal, 2017), and over 90% of these children will be treated at COG member institutions (O'Leary et al., 2008). An additional 5,000 adolescents annually (ages 15-19 years) will be diagnosed with cancer in the United States (American Cancer Society, 2017).

Since its formation, COG has operated with the mission to cure and prevent childhood and adolescent cancer through scientific discovery and compassionate care (COG, 2000). As COG has matured, its structure and membership have evolved. The purpose of this article is to provide an overview of COG's current organizational structure and to characterize its membership, institutions and clinical trial enrollments.

Method

Data related to COG member institutions (i.e., geographic location, dates of membership, number of individual members, consortium participation), and aggregate individual membership data by discipline, were obtained from the Network Operations Center. Patient registration and clinical trial enrollment data (i.e., annual COG registrations and enrollments per institution, and therapeutic and nontherapeutic trial enrollments by disease type) were obtained from the Statistics and Data Center (SDC). Registrations were reported as the average number of unique patients registered with COG per institution per year over a 3-year rolling average (2013, 2014, 2015), while enrollments were reported as the average number of patients enrolled on therapeutic and nontherapeutic trials (excluding studies solely funded by industry) per institution per year over the same 3-year time period; all data were frozen as of December 12, 2015. Data related to COG's organizational structure, membership criteria, and leadership were obtained from the Group Chair's Office. Detailed institutional characteristics of member institutions (i.e., number of inpatient beds, teaching hospital status, hospital type, and funding struc-

ture) were abstracted from the American Hospital Association Guide (American Hospital Association, 2015) for institutions within the United States, and from publically available websites, when available, for institutions outside the United States. Institutions were categorized as teaching hospitals if they met one of the following criteria reported by the American Hospital Association Guide (American Hospital Association, 2015): approval through the Accreditation Council for Graduate Medical Education to participate in residency training; Medical School Affiliation, reported to the American Medical Association, or a Member of the Council of Teaching Hospitals of the Association of American Medical Colleges. Data regarding institutional characteristics were internally verified with COG members who were knowledgeable regarding member site affiliations and characteristics. The American Nurses Credentialing Center (ANCC) website was used to determine which COG institutions hold ANCC Magnet designation, a widely recognized indicator of quality nursing care (Morgan, Lahman, & Hagstrom, 2006). Additional institutional data (e.g., type of unit where pediatric oncology patients are treated, and proportion of non-Englishspeaking families) were collected as part of a comprehensive survey of COG member institutions conducted in 2014-2015 (response rate >90%), the methodology of which has been previously published (Withycombe et al., 2016).

Results

Organizational Structure

COG comprises multiple individuals and committees that provide leadership and function collectively to operationalize the mission of the organization (Figure 1). Five guiding principles form the foundation for the work of the organization: (1) integrating the best *science* (2) assuring the highest *ethical* standards for research conduct; (3) transforming

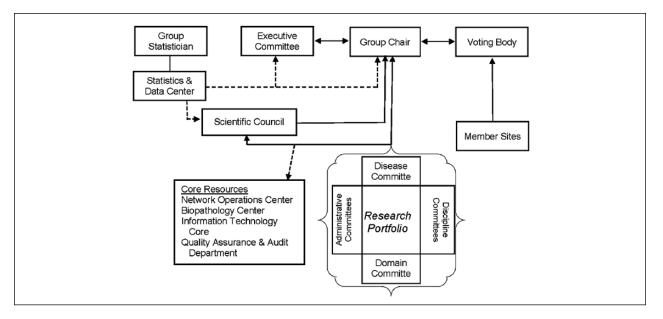


Figure I. Children's Oncology Group organizational structure.

outcomes through expert, multidisciplinary *collaboration*; (4) engaging the entire research community (children, families, patient advocates, frontline investigators, NCI, and industry partners) in *participating* in the development and conduct of research; and (5) recognizing *responsibility* to patients, families, science, and funding organizations.

Funding

As the sole pediatric clinical trials group operating within the NCTN, COG is primarily supported through NCI funding that includes primary grants for the Network Operations Center, the SDC, and the Biopathology Center. Additional network grants support the Phase 1/ Pilot Consortium as well as the NCI Community Oncology Research Program.

Leadership

COG's leadership structure encompasses three branches, which include the Group Chair, the Executive Committee, and the Voting Body. The Constitution and Bylaws, which guide the governance of the organization, were enacted in 2000 and are reassessed at least every 5 years. The Group Chair is an elected individual who serves as the organization's chief executive officer for a term of 5 years, renewable once. The Group Chair has responsibility for the overall administrative, fiscal, and scientific leadership of COG. This includes serving as principal investigator (PI) of the NCTN Group Operations Grant and other appropriate grants, leading the Executive Committee, appointing individuals to scientific leadership positions, overseeing

the Network Operations Center, and representing COG at the NCI. The Group Statistician is appointed by the Group Chair (with approval of the Executive Committee) to oversee the SDC, to serve as PI for the SDC grant, and to provide statistical direction to the Scientific Council. The Executive Committee is composed of the Group Chair and 18 additional voting members, including the vice chair, the Group Statistician, and representatives of the member institutions and the scientific and administrative committees. The Executive Committee is responsible for strategic planning of the organization and oversees fiscal, administrative, and legal issues. The Voting Body comprises PIs from each member institution and cofunctions with the Group Chair and the Executive Committee to provide guidance for ensuring execution of COG's mission. The Voting Body is also responsible for electing the Group Chair, approving new member institutions, and ratifying amendments to the organizational constitution. The Scientific Council, whose members are appointed by the Group Chair, provides guidance regarding the scientific direction of COG research, reviews scientific concepts, prioritizes research efforts, and assures conduct of research to the highest scientific standards.

Committees

Research proposals that support the overall COG mission arise from Disease, Discipline, and Domain Committees. These Committees serve to develop and vet research concepts and priorities, which are then submitted to the Scientific Council for consideration of further development. Table 1 details the array of the COG committees.

Table I. COG Com	mittees
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A	Iministrative Committees	Discipline Committees	Disease Committees	Domain Committees
•	Bioethics	Adolescent-Young Adult	Acute Lymphoblastic Leukemia	Cancer Control/ Supportive Care
•	Data and Safety Monitoring	Behavioral Science	 Acute Myeloid Leukemia 	Cellular Therapy
•	Diversity and Health Disparities	Clinical Research Associates	Bone Tumors	 Developmental Therapeutics
•	Executive	Cytogenetics	 Central Nervous System Tumors 	Epidemiology
•	Industry Relations Advisory	 Diagnostic Imaging 	Hodgkin Disease	Outcomes-Survivorship
•	Institutional Performance Monitoring	Hematology/Oncology	Neuroblastoma	
•	International Affairs	 Integrated Translational Science (Hematologic Malignancies) 	 Non-Hodgkin Lymphoma 	
•	Membership	 Integrated Translational Science (Solid Tumors) 	Rare Tumors	
•	NCORP	Laboratory Science	Renal Tumors	
•	Nominating	Neuroscience	• Soft Tissue Sarcomas	
•	Patient Advocacy	Nursing		
•	Return of Results	Pathology		
•	Scientific Chairs	Pharmacy		
•	Scientific Council	Radiation Oncology		
•	Voting Body	Statistics		
•	Young Investigators	Surgery		

Note. COG = Children's Oncology Group; NCORP = National Cancer Institute Community Oncology Research Program.

The Disease Committees are multidisciplinary teams that develop and implement top research priorities for their specific disease areas by designing clinical trials. Discipline Committees include members of a single discipline (e.g., Hematology/Oncology, Nursing, and Pharmacy) or members that share a particular area of expertise (e.g., Adolescent-Young Adult Oncology). Domain Committees (e.g., Outcomes-Survivorship) develop research concepts that bridge important topics across disease groups and/or disciplines. Some Discipline and Domain Committees have secured external funding to facilitate conduct of their studies within COG. Administrative Committees (e.g., Membership, Data, and Safety Monitoring) serve to ensure compliance with safety, membership, and regulatory requirements. The Patient Advocacy Committee is another Administrative Committee, which serves to provide the patient/family perspective on research-related processes as well as feedback regarding the development of educational materials. Finally, specialty consortia are groups of institutions that work with COG to carry out research pertaining to a specific focus area. For example, the Phase 1/ Pilot Consortium is aligned with the COG Developmental Therapeutics Domain Committee in order to identify and develop new agents for use in pediatric oncology.

Core Resources

Core Resources within the COG include (1) the Network Operations Center and Group Chair's Office, (2) the SDC, (3) the Biopathology Center, (4) the Information Technology Core, and (5) the Quality Assurance and Audit Department. The Network Operations Center and the Chair's Office are governed by the Group Chair and are responsible for endeavors such as protocol development, processing membership applications, preparation and management of grants, development and maintenance of policies and procedures, meeting planning, and managing collaborations with industry and other research sponsors. The SDC serves to provide statistical support related to protocol development, data analysis, and collaboration for abstract and manuscript development. The SDC is also responsible for overseeing patient registration, enrollment, and data collection as well as generating reports related to study progress, patient safety, and interim outcome analyses. The Biopathology Center is directly responsible for managing pathological and biological specimens that support COG research. This includes the provision of a central repository for pathologic materials (procurement, banking, and distribution), a uniform approach to the diagnosis of pediatric tumors, and confirmation of diagnosis for select protocols. The

Information Technology Core ensures maintenance of a secure, regulatory-compliant informatics environment, including a member website, application development, and integrations with NCI systems, to facilitate the work of COG. The Quality Assurance and Audit Department is responsible for assuring adherence with all regulatory requirements related to the protection of human subjects, and assurance of protocol compliance. This department conducts on-site audits for all member institutions in full accordance with regulatory entities (including but not limited to the NCI, the Clinical Trials Monitoring Branch, and the Food and Drug Administration). The Quality Assurance and Audit Department also works with the Institutional Performance Monitoring Committee to identify and resolve issues related to the conduct of COG trials. Although external to COG, the Pediatric Central Institutional Review Board (IRB; NCI, n.d.) was established in 2004 through the NCI to provide core regulatory support by partnering with local institutions to conduct IRB reviews of selected NCI-sponsored pediatric trials. This initiative was implemented to help reduce the administrative burden on local IRBs in relationship to opening multiple COG trials.

Membership Characteristics

Children's Oncology Group membership occurs on two levels: individual and institutional.

Individual Membership. Individuals may submit an application for membership if they are affiliated with a COG institution or support unit (e.g., the Operations Center), are activity engaged in the care of children with cancer or assist with other support activities, and meet the membership criteria for a specific discipline. Individual applications must receive approval from the Membership Committee and the Group Chair. In 2016, there were 8,785 individual COG members. Individual membership is multidisciplinary (Figure 2) consisting of pediatric oncologists (21%), pediatric oncology nurses (27%), clinical research associates (12%), pharmacists (11%), surgeons (5%), fellows/other guest members (5%), pathologists (4%), radiation oncologists (4%), behavioral scientists (2%), and other professionals (9%) including representatives from cytogenetics, neuroscience, statistics, administration, bioethics, cardiology, endocrinology, information technology, consultants, other medical practitioners, nutrition, patient advocacy, laboratory science, and epidemiology.

Nursing represents one of the largest disciplines within COG and is actively engaged in many aspects of clinical trial development and implementation. Nursing activities include *clinical trial involvement* (e.g., serving as nursing representatives on Clinical Trials or Disease Committees), *nursing research* (e.g., developing and

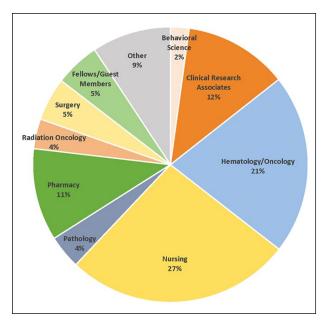


Figure 2. Individual Children's Oncology Group membership by discipline (as of December 31, 2015; N = 8,785).

implementing nurse-led research studies), *evidence-based practice* projects (e.g., conducting systematic reviews and developing evidence-based summaries to guide clinical trials-related pediatric oncology nursing practice), and *education* (e.g., development of the COG *Family Handbook* and creation and presentation of clinical trial-related educational programs for nurses).

Institutional Membership. Institutional membership requires submission of an application from a medical center, independent hospital, or research institute that meets the requirements for pediatric cancer centers as established by COG. Each member institution must have a pediatric oncologist committed to serving as PI for COG studies and other related activities, as well as multidisciplinary members who meet discipline-specific membership requirements. All member institutions must be committed to enrolling patients on COG clinical trials and must continue to meet membership criteria pertaining to competence, required enrollment numbers, performance, and compliance on an ongoing basis, as outlined in COG's constitution and bylaws.

As of 2016, COG institutional membership (Table 2) includes 223 institutions located in 7 countries. While 87% of institutions are located within the United States, additional member sites are located in Canada, Australia, Ireland, New Zealand, Saudi Arabia, and Switzerland. Within the United States, the state of California has the largest number of COG member institutions (n = 19), while all other U.S. states are represented by at least one member institution, with the exception of Kansas, Montana, and Wyoming. Overall, 21 institutions participate in the COG Phase 1

(N = 223).			
Characteristic	N	%	
Geographic location			
United States	194	87.0	
Canada	15	6.7	
Australia	8	3.6	
Other	6	2.7	
COG annual registrations per institution (3 average) ^a	G annual registrations per institution (3-year rolling rage) ^a		
<20	62	27.8	
20-50	102	45.7	
>50	59	26.5	
M (SD)	43.3	40. I	
Mdn (range)	31	3-339	
COG annual enrollments per institution (3- average) ^a	tution (3-year rolling		
<20	20	9.0	
20-50	83	37.2	
>50	120	53.8	
M (SD)	75.5	65.6	
Mdn (range)	56	I-364	
Length of COG institutional membership, y >15 (prior to pediatric cooperative	vears 187	83.8	
group merger)			
6-15	18	8. I	
1-5	18	8. I	
Average no. of individual COG members p		tion	
M (SD)	39.8	33.8	
Mdn (range)	30	9-193	
COG consortium participation			
COG Phase I consortium site	21	9.4	
NCORP site	38	17.0	
COG Stem Cell Transplant Center Hospital structure $(n = 218)^{b}$	88	39.5	
Freestanding children's hospital	63	28.9	
Children's hospital within adult medical center	114	52.3	
Other (e.g., community hospital) No. of inpatient beds $(n = 206)^{b}$	41	18.8	
<100	5	2.4	
100-400	76	36.9	
401-700	75	36.4	
>700	50	24.3	
Hospital unit type (caring for newly diagnost patients; $n = 201$) ^b	sed oncol	ogy	
General pediatric	88	43.8	
Specialized pediatric oncology Educational affiliation $(n = 194)^{b}$	113	56.2	
Teaching hospital	185	95.4	
Nonteaching hospital	9	4.6	
ANCC magnet accreditation $(n = 218)^{b}$	•		
Yes	76	34.9	
No	142	65.I	

Table 2. Characteristics of COG Member Institutions (N = 223).

(continued)

Table 2. (continued)

Characteristic	N	%
Institutional financial structure $(n = 2 4)^{b}$		
Nonprofit	145	67.8
Government-owned	59	27.5
For-profit	10	4.7
Proportion of non- or limited-English-speak institution $(n = 194)^{b}$	ing families	at
≥25%	66	34.0
<25%	128	66.0

Note. COG = Children's Oncology Group; NCI = National Cancer Institute; NCORP = National Cancer Institute Community Oncology Research Program; ANCC = American Nurses Credentialing Center. Table partially adapted and updated from Withycombe et al. (2016). ^aYears 2013-2015. ^bData available only for the number of institutions indicated.

Consortium, while 88 institutions are designated as stem cell transplant centers. Within the United States, 38 sites are NCI Community Oncology Research Program participants, with 14 of these categorized as serving underserved/minority populations. The average $(M \pm SD)$ number of individual members per institution is 39.8 ± 33.8 ; (Mdn = 30; range = 9-193). The large majority of institutions (84%) were members of the NCI's Cooperative Group Program prior to the merger of the four pediatric legacy groups that formed COG over 16 years ago; 36 additional institutions secured membership following the merger.

Twenty-nine percent of COG institutions are freestanding children's hospitals, while 52% are organizationally aligned with adult hospitals (i.e., children's hospitals within larger adult medical centers), and the remaining 19% of sites comprise other hospital types (e.g., community hospitals, freestanding cancer centers). Newly diagnosed pediatric oncology patients are cared for on specialized pediatric oncology units at 56% of member institutions, and on general pediatric wards at the remaining 44% of sites. Thirty-four percent of institutions reported that at least 25% of families at their sites were limited- or non-English-speaking. The majority (68%) of institutions reported a not-for-profit funding structure, and 95% (of U.S. institutions) function as teaching hospitals. In addition, 36% of U.S. institutions have 100 to 400 inpatient beds, 36% have 401 to 700 and 25% have \geq 701 beds. Thirty-five percent of COG sites have achieved ANCC Magnet® accreditation.

Research Portfolio Characteristics

The key to achieving COG's mission hinges on the ability to consistently develop and open effective research studies and to successfully meet accrual goals for these studies in a timely manner. COG maintains a diverse research portfolio that includes therapeutic trials spanning the spectrum of

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Phase	2013	2014	2015
Phase 2	14	12	14
Phase 3	21	20	17

 Table 3. Open Therapeutic Trials by Year.

Note. Number of trials with active enrollment/year.

pediatric cancer diagnoses, including acute lymphoblastic leukemia (Hunger et al., 2013), acute myeloid leukemia (Gamis et al., 2013), Hodgkin (Kelly et al., 2013) and non-Hodgkin lymphoma (Bollard, Lim, Gross, & COG Non-Hodgkin Lymphoma Committee, 2013), central nervous system tumors (Gajjar et al., 2013), bone tumors (Gorlick et al., 2013), soft tissue sarcomas (Hawkins Spunt, Skapek, & COG Soft Tissue Sarcomas Committee, 2013), renal tumors (Dome et al., 2013), neuroblastoma (Park et al., 2013), and rare tumors (Rodriguez-Galindo et al., 2013). These studies are designed to address important gaps in scientific knowledge and advance the field of pediatric oncology (Adamson, 2013).

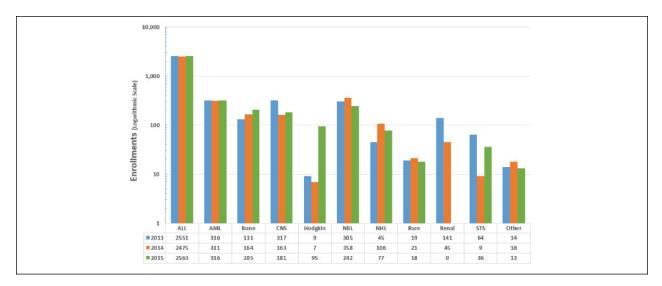
During 2013 to 2015, there were 40 Phase 2 and 58 Phase 3 trials open with active patient enrollment (Table 3). COG maintains a strong developmental therapeutics program that includes a Phase 1 consortium and industry collaborations. A variety of nontherapeutic studies are also ongoing, including correlative/biology (Adamson, 2013), cancer control (Sung et al., 2013), epidemiology (Spector, Ross, Olshan, & COG Epidemiology Committee, 2013), and survivorship/long-term follow-up (Armenian et al., 2013) studies. The diverse portfolio of research often provides opportunities for patients to participate in more than one study during the course of treatment and follow-up.

Across COG, an average of 9,661 new patients were registered per year over the most recent (2013-2015) 3-year period ($M \pm SD$ registrations per institution = 43.3 \pm 40.1; *Mdn* = 31; range = 3-339]). Over the same 3-year timeframe, there were an average of 16,836 enrollments onto therapeutic (i.e., treatment) and nontherapeutic (e.g., epidemiology, survivorship, biology) trials per year ($M \pm$ SD enrollments per institution = 75.5 ± 65.6 ; Mdn = 56; range = 1-364). Annual enrollments averaged <20patients at 9% of sites; 20 to 50 patients at 37% of sites; and >50 patients at 54% of sites. During 2013 to 2015, there were a total of 11,335 enrollments onto therapeutic clinical trials (across all disease types; Figure 3), including 8,532 enrollments onto leukemia trials, 905 enrollments onto neuroblastoma trials, 661 enrollments onto trials for central nervous system tumors, 609 enrollments onto bone and soft tissue sarcoma trials, 339 enrollments onto lymphoma trials, 186 enrollments onto trials for renal tumors, and 58 enrollments onto trials for rare tumors. During 2013 to 2015, there were also 38,350 enrollments onto nontherapeutic trials (Figure 4), including 14,248 enrollments onto biology trials (Figure 5). Importantly, all institutions made substantial contributions to study enrollments, regardless of size; with almost half (47.2%) of study enrollments contributed by institutions enrolling 100 or fewer patients per year (Figure 6). Enrollments from smaller and midsized institutions often represent diverse and underserved populations, such as Native Americans and those from rural areas.

Discussion

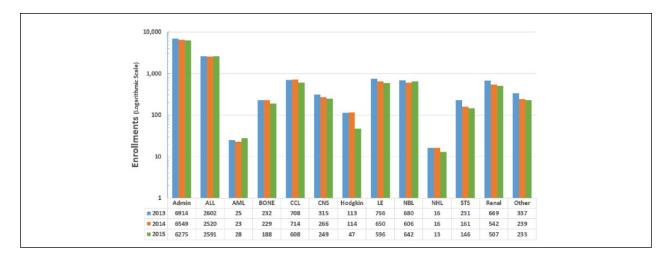
To our knowledge, this article is the first to provide an overview of COG's organizational structure and to describe the characteristics of its individual and institutional membership. While we found wide variability in institutional characteristics across COG, this was not unexpected; in fact, this variability may be viewed as an organizational strength. The diverse geographic locations of the member institutions ensure that participation in contemporary COG clinical trials is an option for almost all children diagnosed with cancer within the United States. This aligns with NCTN's goal to increase accessibility of clinical trials for potential participants (U.S. Department of Health and Human Services, 2015) and enhances the probability that a large proportion of eligible children will be enrolled onto COG clinical trials. Despite the variability in institutional characteristics, such as size, hospital type, and geographic location, COG institutional membership facilitates the standardization of treatment for pediatric cancers by enrollment of children onto treatment protocols across settings. This strengthens COG's ability to rapidly address important questions and improve outcomes for children with cancer. Additionally, because of the wide range of institutions participating in COG, children representative of the broader characteristics of the population can be adequately recruited for study enrollment, enhancing generalizability of study findings. Over one third of COG institutions reported that at least 25% of families at their sites were limited- or non-English-speaking. This speaks to the diversity of COG's patient population. COG has committed efforts toward providing supportive literature for patients and families in multiple languages, which serves as an example of the efforts required to ensure that vulnerable subgroups of patients are not marginalized. For example, the COG Family Handbook (Murphy, 2011) is available in English, Spanish, and French. Continued awareness and attention to the needs of non-English-speaking patients and their families are warranted.

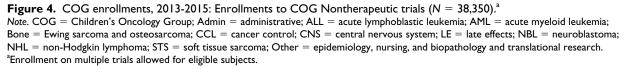
With regard to COG's individual membership (Figure 2), variability also exists related to the multidisciplinary nature of the organization and representation from diverse groups (e.g., hematologists/oncologists, nurses, pharmacists, laboratory scientists, and others such as patient advocates). This





Note. COG = Children's Oncology Group; ALL = acute lymphoblastic leukemia; AML = acute myeloid leukemia; Bone = Ewing sarcoma and osteosarcoma; <math>CNS = central nervous system; NBL = neuroblastoma; NHL = non-Hodgkin lymphoma; Rare = germ cell tumors, liver tumors, and retinoblastoma; STS = soft tissue sarcoma; Other = stem cell transplant and developmental therapeutics. ^aEnrollment on multiple trials allowed for eligible subjects.





provides an environment rich for networking and sharing expertise across disciplines. Multidisciplinary involvement of the membership through appointments to Disease and Domain Committees helps ensure thoughtful attention to all aspects of planned studies.

The primary limitation of this article is that the institutional data obtained from the American Hospital Association (2015) Guide is reported at an aggregate level. Therefore, certain data (e.g., number of beds) may have been reported for the entire organization and may not be a true representation of the characteristics of pediatric facilities that are located within larger medical centers. To more accurately reflect the size and volume of the pediatric oncology programs at each member institution, we reported COG enrollment and registration data. Additionally, the institutional survey data were reported by a single individual at each COG site, and it is possible that this information could be biased or inaccurate; however, this possibility was controlled for by using a stringent recruitment method that required experienced and

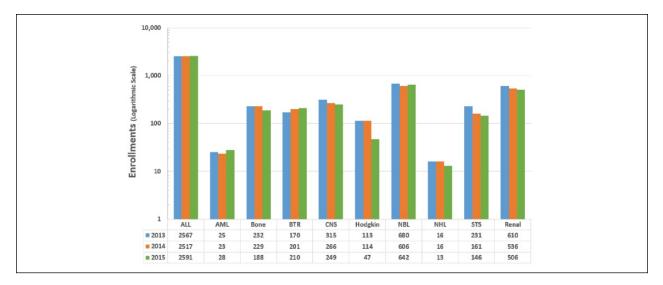


Figure 5. COG enrollments, 2013-2015: Enrollments to COG biology trials (N = 14,248).^a

Note. COG = Children's Oncology Group; ALL = acute lymphoblastic leukemia; AML = acute myeloid leukemia; Bone = Ewing sarcoma and osteosarcoma; BTR = biopathology and translational research; CNS = central nervous system; NBL = neuroblastoma; NHL = non-Hodgkin lymphoma; STS = soft tissue sarcoma.

^aEnrollment on multiple trials allowed for eligible subjects.

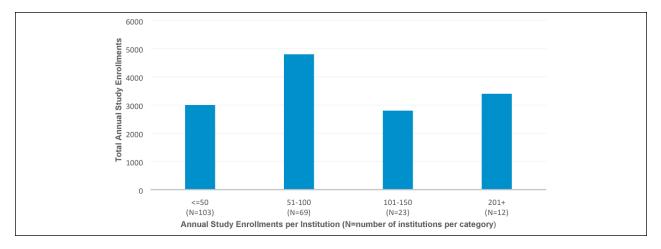


Figure 6. COG enrollments, 2013-2015: Annual COG study enrollments categorized by average enrollments per institution. *Note.* COG = Children's Oncology Group. The average number of annual enrollments per institution are shown on the *x*-axis and the total annual enrollments contributed by sites are shown on the *y*-axis.

knowledgeable individuals to represent each institution. Despite these limitations, this study has numerous strengths, including the use of data from multiple sources, as well as data provided directly from the COG Network Operations Center and SDC.

Our findings suggest that there is variability in the characteristics of COG institutions, with regard to infrastructure (e.g., hospital type), size (number of inpatient beds, annual COG registrations and enrollments), and other characteristics (e.g., number of individual members, Phase 1 or Stem Cell Transplant sites, proportion of non– or limited–English-speaking families). Characteristics of the 8,785 individual members of COG are also diverse, with representation from over 28 unique disciplines and/ or groups. This extensive diversity within COG represents a significant strength, as it brings substantial expertise and unique perspectives to the development and conduct of clinical trials aimed at improving outcomes in children and adolescents with cancer.

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