

# ASH Highlights and Commentary: Additional Topics of Interest

## Abstract 884

### Outcomes and Treatment Patterns in Patients With Aggressive B-Cell Lymphoma After Failure of Anti-CD19 CAR T-Cell Therapy

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Visit <https://doi.org/10.1182/blood-2021-147433> for a complete list of contributor affiliations and full graphics.

**Background:** Anti-CD19 chimeric antigen receptor T-cell therapy (CAR T) is a highly active therapy for relapsed/refractory (R/R) aggressive B-cell lymphoma. Nonetheless, most patients (pts) ultimately develop progressive disease (PD). There is little guidance on the optimal treatment approach(es) for these pts. We performed a multicenter retrospective analysis with a primary objective to assess treatment patterns and outcomes in pts with R/R aggressive B-cell lymphoma who develop PD after anti-CD19 CARTs.

**Methods:** Pts with aggressive B-cell lymphoma treated with anti-CD19 CART between 2015 and 2020 across 12 US academic medical centers were included. Demographic and clinical characteristics were collected along with CART toxicities and response. Regimens administered as salvage post CART were assessed. Univariate

analyses (UVA) were performed to determine impact of demographic and clinical variables on survival outcomes. All *p*-values were two-tailed. Survival curves were calculated using the Kaplan-Meier method.

**Results:** A total of 400 pts received anti-CD19 CARTs and were included for analysis. For the entire cohort: median PFS and OS from time of CART infusion were 11 months [mo] and 27 mo respectively. On log-rank testing, pts who received  $\geq 3$  lines of pre-CART therapy and those with refractory disease pre-CART had significantly worse PFS ( $p=0.004$  &  $0.001$ ) and OS (both  $p<0.001$ ).

With median follow-up 22.4 mo, 190 pts (48%) had PD after CART; demographic and clinical variables of pts with and without PD are detailed in Table 1. Biopsy to confirm PD and assess CD19 status was done in 69 pts (36%) with CD19 negative relapse seen in 11 (16%). Of pts with PD, median PFS and OS from time of PD was 83 days (in pts who received salvage) and 174 days (for all PD pts) respectively. Pts with PD were more likely to have elevated LDH ( $p=0.001$ ) and extranodal disease ( $p=0.003$ ) at apheresis.

For pts with PD after CART: 125 (65.5%) received further therapies. Pts were more likely to receive salvage therapies if their best response to CART was CR ( $p=0.026$ ) or PR ( $p=0.015$ ). Response rates of select first- and second-line therapies and PFS of first line therapies received after CART failure are detailed in figure 1. ORR and CRs were highest for polatuzumab, bendamustine, & rituximab (pola-BR; 73% & 40%), followed by BTK inhibitors (BTKi; 50% & 38%), and bispecific antibodies (bsAb) (50% & 25%). Five of 7 pts who received a BTKi had non-germinal center (GC) cell of origin (COO; 1 unknown COO).

On log-rank testing, pts with elevated LDH ( $p=0.003$ ) at time of apheresis and those with intermediate/high IPI ( $p=0.013$ ) had inferior PFS

Table 1: Clinical characteristics of patients with and without progression after CAR-T therapy

Characteristic	No progression, N = 207 <sup>1</sup>	Progression, N = 190 <sup>1</sup>	p-value <sup>2</sup>	Characteristic	No progression, N = 207 <sup>1</sup>	Progression, N = 190 <sup>1</sup>	p-value <sup>2</sup>
<b>Age (at CAR-T)</b>	63 (22-85)	62 (19-84)	0.3	<b>Extranodal disease<sup>3</sup></b>			0.003
<b>Sex</b>			0.4	No	78 (38%)	46 (24%)	
Female	86 (42%)	71 (37%)		Yes	126 (62%)	143 (76%)	
Male	121 (58%)	119 (63%)		Missing	3	1	
<b>Histologic subtype</b>			0.005	<b>CNS disease<sup>4</sup></b>			0.14
de novo DLBCL	128 (62%)	141 (74%)		No	196 (96%)	174 (92%)	
tFL	56 (27%)	25 (13%)		Yes	9 (4.4%)	15 (7.9%)	
PMBCL	4 (1.9%)	4 (2.1%)		Missing	2	1	
Richter's	8 (3.9%)	4 (2.1%)		<b>Prior allogeneic HCT</b>			>0.9
Other	11 (5.3%)	16 (8.4%)		Yes	2 (1.0%)	2 (1.1%)	
<b>Subtype</b>			0.8	No	205 (99%)	188 (99%)	
Non-GCB	64 (42%)	67 (43%)		<b>Prior autologous HCT</b>			0.8
GCB	90 (58%)	88 (57%)		Yes	58 (28%)	55 (29%)	
Missing	53	35		No	149 (72%)	135 (71%)	
<b>Lines of therapy<sup>5</sup></b>	2 (1-6)	3 (1-6)	0.018	<b>Double/Triple Hit</b>			0.051
<b>LDH elevation<sup>4</sup></b>			0.001	Yes	41 (41%)	21 (27%)	
No	99 (55%)	61 (37%)		No	58 (59%)	56 (73%)	
Yes	82 (45%)	102 (63%)		Missing	108	113	
Missing	26	27		<b>CAR-T product</b>			0.1
<b>IPI<sup>6</sup></b>			0.3	Liso-cel	21 (10%)	20 (11%)	
0	9 (5.4%)	4 (2.4%)		Tisa-cel	53 (26%)	67 (36%)	
1	34 (20%)	28 (17%)		Axi-cel	127 (63%)	99 (53%)	
2	51 (30%)	44 (27%)		Missing	6	4	
3	48 (29%)	51 (31%)					
4	22 (13%)	35 (21%)					
5	4 (2.4%)	3 (1.8%)					
Missing	39	25					

Abbreviations: axi-cel: axicabtagene ciloleucel; DLBCL: diffuse large B-cell lymphoma; GCB: germinal center B-cell; LDH: lactate dehydrogenase; PMBCL: primary mediastinal B-cell lymphoma; tisa-cel: tisagenlecleucel; tFL: transformed follicular lymphoma  
<sup>1</sup>Median (Minimum-Maximum); n (%); <sup>2</sup>Wilcoxon rank sum test; Pearson's Chi-squared test; Fisher's exact test; <sup>3</sup>Prior to CAR-T; <sup>4</sup>At apheresis

Figure 1: First- and second-line therapies with agents of interest post-CAR-T progression

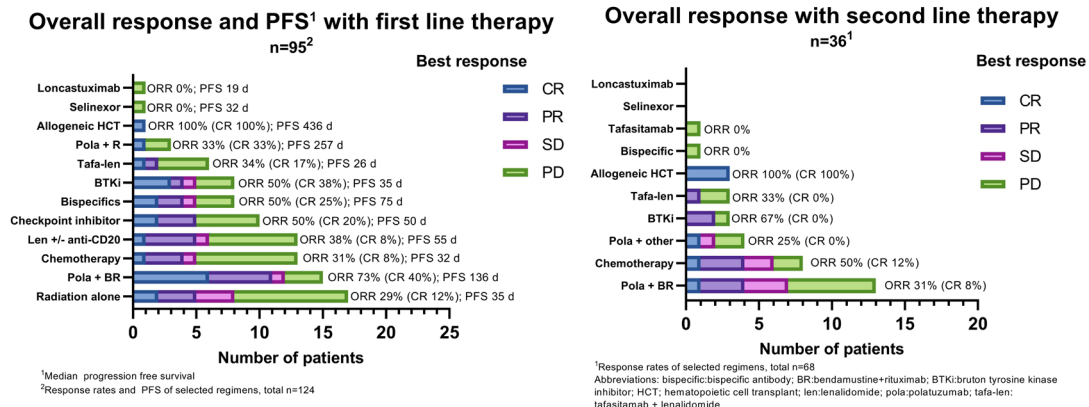


Table 2: Clinical characteristics of patients who received allogeneic HCT after failure of CAR-T

Characteristic	N = 12	Characteristic	N = 12
<b>Age (at CAR-T)</b>	59 (41-68)	<b>Prior allogeneic HCT</b>	
<b>Sex</b>		Yes	1 (8.3%)
Female	3 (25%)	No	11 (92%)
Male	9 (75%)	<b>Prior autologous HCT</b>	
<b>Histologic subtype</b>		Yes	6 (50%)
de novo DLBCL	9 (75%)	No	6 (50%)
tFL	1 (8.3%)	<b>Double/Triple Hit</b>	
PMBCL	1 (8.3%)	Yes	1 (25%)
Transformed MZL	1 (8.3%)	No	3 (75%)
<b>Subtype</b>		Missing	8
Non-GCB	3 (30%)	<b>CAR-T product</b>	
GCB	7 (70%)	Liso-cel	1 (8.3%)
Missing	2	Tisa-cel	3 (25%)
<b>LDH elevation<sup>2</sup></b>		Axi-cel	8 (67%)
No	4 (40%)	<b>Best response to CAR-T</b>	
Yes	6 (60%)	CR	6 (50%)
Missing	2	PR	3 (25%)
<b>Extranodal disease<sup>3</sup></b>		SD	2 (17%)
No	3 (25%)	PD	1 (8.3%)
Yes	9 (75%)	<b>CD19 status at relapse</b>	
<b>Lines of therapy<sup>3</sup></b>	2 (1-4)	Negative	2 (29%)
<b>IPI<sup>2</sup></b>		Positive	5 (71%)
1	3 (27%)	Missing	5
2	3 (27%)		
3	4 (36%)		
4	1 (9.1%)		
(Missing)	1		

Abbreviations: axi-cel: axicabtagene ciloleucel; DLBCL: diffuse large B-cell lymphoma; GCB: germinal center B-cell; LDH: lactate dehydrogenase; liso-cel: isocabtagene maraleucel; PMBCL: primary mediastinal B-cell lymphoma; tisa-cel: tisagenlecleucel; tFL: transformed follicular lymphoma  
<sup>1</sup>Median (Minimum-Maximum); n (%); <sup>2</sup>At apheresis; <sup>3</sup>Prior to CAR-T

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with first salvage regimens. Median PFS was highest for pola-BR (4.5 mo, n=14), followed by bsAb (2.5 mo, n=8), lenalidomide +/- anti-CD20 antibody (1.8 mo, n=13), checkpoint inhibitors (CPI; 1.6 mo, n=10), BTKi (1.2 mo, n=8), radiation alone (1.2 mo; n=17), chemotherapy (1.1 mo, n=12), and tafasitamab + lenalidomide (0.9 mo, n=5). Median PFS for all treated pts was 1.8 mo. OS from start of first salvage regimen was highest for CPI (OS 12.4 mo, n=10), followed by pola-BR (8.9 mo, n=14), BTKi (8.8 mo, n=8), lenalidomide +/- anti-CD20 (8.7 mo, n=13), radiation alone (7.1 mo, n=17), bsAb (5.9 mo, n=8), chemotherapy (5.4 mo, n=12), and tafasitamab + lenalidomide (1.2 mo, n=5). 12 pts (6.3%) later received an allogeneic hematopoietic cell transplant (alloHCT). In alloHCT pts at last follow-up, 10 were evaluable for response: 7 had CR and 5 remain in CR. Clinical characteristics of pts who received alloHCT are detailed in table 2. Notably, median age

was 59 years (41-68), 1 (8.3%) had a prior alloHCT, and 6 (50%) had prior autologous HCT. The majority had CR or PR as best response to CART (CR n=6, 50%; PR n=3, 25%), and only 1 pt (8.3%) with PD as best response to CART was salvaged with alloHCT.

Conclusions: This is the largest reported analysis to date of pts with aggressive B-cell lymphoma who develop PD post-CART. The highest ORRs were with pola-BR, bsAb, and BTKi as first line of salvage. High response rates with BTKi may be attributed to non-GC COO in the majority of treated pts and perhaps a beneficial immunomodulatory effect on previously administered CARTs. AlloHCT remains a potential curative therapy for select pts with over half with durable remission; however, few ultimately received alloHCT. Despite increased use of novel therapies, survival in pts who progress after CART is still dismal warranting more effective therapies.

### **The Advanced Practitioner Perspective: Sandra Kurtin, PhD, ANP-C, AOCN**

The addition of anti-CD20 antibodies to the treatment paradigm for non-Hodgkin lymphomas in the 1980s changed the treatment landscape for these diseases. Unfortunately, many patients become refractory to these drugs. CD19 is expressed earlier and longer than CD20 in B lymphocytes and has become the focus of newer treatments for lymphomas, including anti-CD19 chimeric antigen receptor (CAR) T-cell therapy, approved for relapsed/refractory (R/R) aggressive B-cell lymphoma. Unfortunately, the durability of response to CAR T-cell therapy in these patients is limited, and most patients relapse. Therapies available in patients who progress following CAR T-cell therapy are limited, and guidelines have been uncertain.

12 different academic centers in the US were included in this retrospective analysis of 400 patients with R/R aggressive B-cell lymphoma treated with anti-CD19 CAR T-cell therapy between 2015 and 2020. The aim was to describe post-CAR T-cell therapy regimens, demographics, and outcomes in these patients. Among the 400 patients, median progression-free survival (PFS) was 11 months and overall survival (OS) was 27 months, emphasizing the inevitable relapse for most patients.

Patients who received  $\geq 3$  lines therapy prior to CAR T-cell therapy and those with refractory disease pre-CAR T-cell therapy had significantly worse PFS and OS after CAR T-cell therapy. At a median of 22.4 months, 48%, or 190 patients, had progressive disease. In these 190 patients, the median PFS was 83 days and OS was 174 days for those able to receive salvage therapy. An elevated lactate dehydrogenase and the presence of extranodal disease were associated with progressive disease. Patients who achieved a complete response (CR) or partial response (PR) were more likely to go on to post-CAR T-cell therapies. The most effective therapies in these patients included rituximab-bendamustine-polatuzumab with a median PFS (mPFS) of 136 days; bispecific antibodies with a mPFS of 75 days; rituximab and lenalidomide ( $R^2$ ) with a mPFS of 55 days; and Bruton tyrosine kinase inhibitors with a mPFS of 35 days.

12 patients (6.3%) of median age of 59 later received an allogeneic hematopoietic cell transplant, with 10 evaluable patients at last follow-up: 7 had CR and 5 remain in CR. Allogeneic hematopoietic cell transplant remains a potential curative therapy for select patients with over half with durable remission; however, few ultimately received allogeneic hematopoietic cell transplant, and all patients require therapies to bridge to transplant.

**Implications for the Advanced Practitioner**

Understanding the therapeutic targets in non-Hodgkin lymphoma, how these are exploited for therapeutic benefit, and which post-CAR T-cell therapies hold benefit as a bridge to allogeneic stem cell transplant for those eligible is critical for the advanced practitioner in oncology. Understanding the sequencing of therapies, particularly emerging therapies, and where these therapies fit best in the overall therapeutic landscape requires continued

investigation by all hematology/oncology health-care providers. The Advanced Practitioner Society of Hematology and Oncology (APSHO) is embarking on a project to better describe biomarker-driven therapies and produce resources for the advanced practitioner to help guide them in their practice.

**Disclosure:** Dr. Kurtin has served as a consultant for AbbVie, Amgen, Epizyme, Incyte, Jazz, and Takeda.

**Abstract 1897****Oncology Advanced Practice Providers Chemotherapeutic Prescribing Practices**

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**Background:** Physician Assistants (PA) and Nurse Practitioners (NP), referred to as Advanced Practice Providers (APPs), are an integral part of cancer care today in community oncology (ONC) and academic institutions across the country. It has been shown, a team approach using APPs can extend the ONC workforce (PMID: 25009939). The need for ONC services will increase with the rise in cancer incidence and prevalence. As the rise continues, studies have shown ONC services will dramatically increase due to the predicted shortages of oncologists. Increasing the use of APPs is a viable solution to this shortage (PMID: 21037868). PAs and NPs have validated their value by safely prescribing chemotherapy (CT) as they provide cancer care. This value has been key for both patient and physician colleagues. The Association of Physician Assistants in Oncology (APAO) pursued research to better understand CT prescribing practices of ONC PAs. The focus was on whether or not PAs were allowed to prescribe CT drugs in their day to day practice.

**Methods:** A survey was used to collect data. The survey focused on APPs scope of practice to

include prescribing CT independently (IND) or were there restrictions by the state or organizations they are employed by. For those allowed to prescribe CT, further questions regarding training programs and time periods to demonstrate competency were asked. The survey also viewed physician and employer attitudes towards APPs prescribing CT. The survey was sent in January 2021 to 1307 APAO members via email with a 30-day collection period. Eleven percent were returned (N=149).

**Results:** Respondents (R) were PAs, 95%, NPs, 3% and other 1%. The majority of R worked in Hematology/Medical ONC, 87%, with fewer in Surgical ONC 6%, Radiation ONC 1%, other 6%. R came from 34 states with the largest number representing Texas, 13%, New York 12%, Pennsylvania, 8%, North Carolina, 7%, Massachusetts 6% and Florida 5%. Most of the R had been in ONC for 1-8 years (y) (59%), followed by 9-16 y (21%), 17-24 y (16%), and 25+ y (3%). The survey was divided into two arms, those who could IND sign CT orders and those who could not IND sign CT orders. The survey demonstrated 44% of the R were able to IND sign CT orders and 56 % of the R could not. With regard to work setting, 60% of R in this arm worked in academic ONC centers and 35% worked in community ONC centers. Also in this arm, 23% were only allowed to sign existing CT plans that did not require modification and 77% were not. The majority of R could sign existing CT orders (89%) and fewer could initiate and sign new CT orders (35%). Most R were able to prescribe intravenous and oral medication (98%), while fewer could prescribe intrathecal (34%) and clinical trial medications (49%).

Of the R in the second arm, 74% worked at academic ONC centers and 19% worked at community ONC practices. When asked if their state medical board prohibited prescribing CT, the majority (77%) reported this was not the case, then if their institution/facilities prohibited prescribing CT, the majority (69%) reported this was true. To explore physician/employer attitudes, a question was posed to ask the APP if their physicians believe that limiting CT to physicians is a safety measure. Responses were mixed, 36% reporting this is true, 33% reporting this was false and 31% as unsure. Next, the APPs were asked if their physicians believed experienced APPs should be allowed to prescribe CT. Again, responses were mixed, 44% agreeing, while 11% disagreeing. Finally, 44% were unsure. When asked if their employer believed limiting CT to physicians is an important safety

measure, 47% of the R reported this is true, 19% R reported this is false and 34% were unsure. When asked if their employer believed experienced APPs should be allowed to prescribe CT, 30% of the R reported this is true, 20% R report this is false and 49% were unsure.

**Conclusion:** CT prescribing privileges, are not universal for APPs and the reason for inconsistencies in prescribing CT is not clear. This survey provided insight to the wide range of prescribing practices throughout the US based on ONC settings, geographic regions, and experience of the APP. As APPs are valued team members in extending the ONC workforce, and prescribing CT is a common practice in cancer care which APPs participate in. This would seem worthy of further research to understand the reasons why such discrepancies exist.

### **The Advanced Practitioner Perspective: Sandra Kurtin, PhD, ANP-C, AOCN**

Advanced practitioners (APs) in oncology are an integral part of cancer care across community and academic settings. The role of the AP is complex, with many direct and indirect patient care responsibilities. The shortage of oncology physicians and the continued growth of the cancer population, having been long anticipated, are now upon us. Having all members of the health-care team practicing at the top of their license is imperative to meet this challenge.

Advanced practitioner scope of practice varies by state, including the ability to prescribe antineoplastic therapies independently or at all. Organizations may also apply restrictions to AP scope of practice, regardless of state or national guidelines. Some of the institutional guidelines are influenced by perceptions among individuals in administrative, academic, or practice leadership positions. As we learned from the American Medical Association #StopScopeCreep campaign, barriers to APs practicing at the top of their license may come from unfounded claims and proprietary sources.

This survey aimed to describe physician and employer attitudes towards APs prescribing antineoplastic therapy among members of the Association of Physician Assistants in On-

cology (APAO). The survey was distributed to 1,307 APAO members in January 2021, with a 30-day turnaround. Eleven percent were returned (N = 149), representing 34 states. Ninety-five percent of participants were physician assistants working in hematology/oncology (87%) with 1 to 8 years of oncology experience (59%). Most participants worked in an academic setting (60%), with fewer in the community setting (35%). 44% of the APs in this study were able to independently sign chemotherapy orders including intravenous and oral medications; 56% could not. There were some restrictions for intrathecal medication and clinical trial medications, and 23% of those who could sign orders could not sign new orders or existing orders that required modification.

Most restrictions for prescribing were institutionally based as opposed to state based. When asked about physician attitudes toward safety of the AP prescribing chemotherapy, 36% reported that this was indeed a factor, 33% disagreed, and 31% were unsure. When asked if the physician believed that experienced APs should be able to prescribe chemotherapy, again, responses were mixed, with 44% agreeing, while 11% disagreeing. Similarly, when asked if the employer believed that limiting CT prescribing to physicians was a safety measure, 47% agreed, 19% disagreed, and 34% were unsure. When asked if the employer believed that experienced

APs should be able to prescribe CT, 30% agreed, 20% disagreed, and 49% were unsure.

#### Implications for the Advanced Practitioner

This survey emphasizes the ambiguity around AP prescriptive authority for antineoplastic therapies. The state-by-state legislation on AP prescriptive authority is continuously changing and expanding. Recognizing the growing demand for oncology providers and the expanding AP workforce, the National Cancer Institute issued a statement in September 2021 allowing APs registered in NCI's Registration and Credentialing Repository (RCR) to sign orders independently if in line with the institution's policy, local, state, and international laws, and regulations. Institutional policies

must include information about AP credentialing for writing study agent orders. Sites must also include in their institution policies how the Guidelines for Good Clinical Practice (GCP) requirements for APs are being met. This includes that a qualified physician investigator is responsible for all trial-related medical decisions, including providing oversight of APs in their capacity of ordering study agents. The Advanced Practitioner Society for Hematology and Oncology (APSHO) has embarked on an antineoplastic therapies prescribing course to meet this need.

**Disclosure:** Dr. Kurtin has served as a consultant for AbbVie, Amgen, Epizyme, Incyte, Jazz, and Takeda.

#### Abstract 3047

### A Comparative Analysis of Patient Experience and Patient-Doctor Communication in Patients With Lymphoma and CLL: Clinical Trials Versus Non-Clinical Trials

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**Introduction:** Clinical trials are essential in ensuring that new treatments are safe and effective and are also a way to improve standard of care. Patients enrolled in clinical trials receive optimal clinical care due to the close management included in trial design. Using the 2020 Lymphoma Coalition (LC) Global Patient Survey (GPS) on Lymphomas and CLL, this study aims to provide insight to the experience of patients with lymphoma and CLL who have participated in a clinical trial compared to those who have not. This study will focus on 1) their experience and disease management, 2) their involvement in healthcare decision-making, and 3) communication with their doctors.

**Methodology:** Globally, 11,878 respondents made up of 9,179 patients and 2,699 caregivers took part (90+ countries) in the LC 2020 GPS.

This analysis compared a subgroup of patients with lymphoma or CLL who had been in a clinical trial (n=939) ('CT patients') against a subgroup of patients who had never been in a clinical trial, but who received or were currently receiving any form of treatment for their lymphoma/CLL (n=5079) ('non-CT patients').

Demographics of both patient groups were examined, and questions relating to patients' disease management and experiences, decision-making, and patient-doctor communication were analysed. Univariate and bivariate analysis were completed as needed, and the statistical analyses were performed with IBM SPSS v27.

**Results:** CT patients were significantly different from non-CT patients in age-grouping, sex, and subtype distribution (Table 1). CT patients had a higher proportion of older respondents (60-69 and 70+ yrs combined) compared to non-CT patients (48% vs 40%, respectively), and over half of CT patients (51%) were males compared to the non-CT group (42%).

Patients were asked to indicate how much they agree or disagree with statements relating to their experience and disease management. CT patients were 54% more likely to agree than disagree that they know what their prescribed medicines do, compared to non-CT patients [OR=1.54 (1.1-2.0); p=0.002] (Table 2). They were also 47% more likely than non-CT patients to agree than disagree

Table 1. Demographic and lymphoma subtype distribution of patients with lymphoma (CT vs non-CT patients)

	CT n (%)	Non-CT n (%)	Chi square (p value)
<b>Age (yrs)</b>			
18-29	64 (7)	406 (8)	28.7 (p<0.001)
30-39	101 (11)	756 (15)	
40-59	321 (34)	1897 (37)	
60-69	256 (27)	1118 (22)	
70+	196 (21)	901 (18)	
<b>Sex</b>			
Male	476 (51)	2119 (42)	26 (p<0.001)
Female	462 (49)	2954(58)	
<b>Subtype</b>			169 (p<0.001)
CLL	228 (24%)	537 (11)	
Burkitt's	6 (1)	61 (1)	
DLBCL (subtype unknown)	99 (11)	633 (13)	
DLBCL (GCB)	14 (2)	131 (3)	
DLBCL (ABC)	26 (3)	199 (4)	
Follicular	125 (13)	915 (18)	
Hodgkin	151 (16)	821 (16)	
MALT/Marginal zone	7 (1)	124 (2)	
Mantle Cell	34 (4)	127 (3)	
Peripheral T-cell	13 (1)	79 (2)	
Anaplastic Large cell	10 (1)	3 (1)	
Extranodal Killer T-cell	19 (2)	86 (2)	
Transformed	19 (2)	89 (2)	
Waldenstrom macroglobulinaemia	80 (9)	512 (10)	
Other indolent	24 (3)	158 (3)	
Other aggressive lymphomas	27 (3)	157(3)	
Cutaneous	3 (0)	49 (1)	
Mycosis Fungoides	31 (3)	261 (5)	
Sezary syndrome	8 (1)	24 (1)	

Table 2. Experiences, disease management, healthcare decision-making, and patient-doctor communication of patients with lymphoma (CT vs non-CT patients)

	CT n(valid%)	Non-CT n(valid%)	OR (p-value)
<b>Patients' disease management and experience</b>			
I know what each of my prescribed medicines do			
Strongly agree/ agree	613 (75)	3122 (72)	1.54(1.2-2.0)
Strongly disagree/disagree	65 (8)	513 (12)	P=0.002
I am confident in my ability to get information I need from my doctor			
Strongly agree/ agree	789 (84)	3982 (79)	1.47(1.1-2.0)
Strongly disagree/disagree	50 (6)	372 (7)	P=0.01
I always understand my doctor's advice and treatment plans			
Strongly agree/ agree	795 (86)	4109 (82)	1.24(0.4-3.9)
Strongly disagree/disagree	36 (4)	254 (5)	P=0.71
I am confident in finding reliable info about my lymphoma/CLL			
Strongly agree/ agree	666 (73)	3567 (71)	1.36 (0.95-1.9)
Strongly disagree/disagree	83 (9)	405 (8)	P=0.09
<b>Healthcare decision making</b>			
Are you as involved as much as you want to be, in decisions about your care and treatment?			
Yes, definitely	547 (58)	2568 (51)	P<0.001
Yes, to some extent	304 (32)	1899 (37)	
No, I would like to be more involved	78 (8)	502 (10)	
-No, but I do not want to be involved	10 (1)	110 (2)	
**Have you talked to your doctor about wanting to change your treatment to better meet your needs, within the last 2 years?			
Yes, I have, and I chose the treatment recommended by my doctor	302 (34)	1214 (24)	P<0.001
Yes, I have, and I chose the treatment NOT recommended by my doctor	38 (4)	163 (3)	
No, but I would have liked to	33 (4)	352 (7)	
No, and I did not want to	130 (15)	794 (16)	
<b>Patient-doctor communication</b>			
I have good conversations with my doctor about my care and treatment plans			
Strongly agree/ agree	771 (83)	3879 (78)	1.40(1.03-1.9)
Strongly disagree/disagree	54 (6)	377 (8)	P=0.03
I am confident to tell doctor my concerns even when they do not ask			
Strongly agree/ agree	824 (88)	4140 (82)	1.70(1.2-2.4)
Strongly disagree/disagree	41 (4)	352 (7)	P=0.002
Did you discuss the treatment side effects you experienced with your doctor?			
Yes, definitely/ Yes, to some extent	810 (97)	4393 (93)	2.20 (1.4-3.6)
No	20 (2)	245 (5)	P<0.001

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that they were confident in their ability to get information from doctor [OR=1.47(1.1-2.0); p=0.01] (Table 2). Although not statistically significant, CT patients were also more prevalent in reporting that they understood their doctor's advice and treatment plans, and that they are confident in finding reliable information about their lymphoma/CLL, compared to non-CT patients (Table 2).

Patients were asked if they are involved as much as they want to be in decisions about their care and treatment (Table 2). More patients in the CT group (58%) were sure that they were as involved in decisions about their care and treatment, as much as they wanted to be, compared to non-CT patients (51%) (p<0.001). CT patients were also more prevalent (34%) in reporting that they have talked to their doctors about wanting to change their treatment to better meet their needs within the last 2 years compared to non-CT patients (24%) (p<0.001). These differences are statistically significant (Table 2).

When asked about patient-doctor communication, CT patients were 40% more likely to report having good conversations with their doctor about their care and treatment plans [OR=1.40 (1.03-1.9);

p=0.03], 70% more likely to be confident in communicating their concerns to the doctor [OR=1.70 (1.2-2.4); p=0.002], and twice as likely to discuss their treatment side effects with their doctors compared to non-CT patients [OR=2.20(1.4-3.6); p<0.001] (Table 2).

**Conclusion:** The results show that patients with lymphoma or CLL who have been in a clinical trial generally reported being more involved in their healthcare decision-making and being more confident and having better conversations in their interaction with their doctors, compared to those patients who have never been in a clinical trial. These differences may be because patients in clinical trials have an increased accessibility to their health teams, which encourages more patient/doctor communication.

LC advocates for all patients to be informed of clinical trials they may qualify for and encourages the same level of communication between patients and doctors that occurs in a clinical trial in all patient-doctor interactions. In the future, LC would also like to explore how demographic differences may have confounded results.

**The Advanced Practitioner Perspective:  
Sandra Kurtin, PhD, ANP-C, AOCN**

Clinical trials are essential to ensuring that new treatments are safe and effective and improve the standard of care. Patients enrolled in clinical trials receive optimal clinical care due to the close management included in the trial design. Advanced practitioners (APs) in oncology play an integral role in the conduct of clinical trials.

The 2020 Lymphoma Coalition (LC) Global Patient Survey (GPS) on lymphomas and CLL evaluated the experience of 9,179 patients and 2,699 caregivers across more than 90 countries. The study compared 939 patients with lymphoma and CLL who had participated in a clinical trial compared with 5,079 patients receiving treatment but not participating in a clinical trial. The survey aimed to describe (1) the patient experience in disease management, (2) patients' involvement in health-care decision-making, and (3) communication with their doctors.

Clinical trial participants were generally over the age of 60 (48%) and male (51%). Other attributes with statistically significant association with CT participation included: (1) Knowledge about medications ( $p = .002$ ), (2) confidence in the ability to get information ( $p = .01$ ), (3) involvement in decision-making ( $p < .001$ ), (4) self-advocacy for treatments that meet their needs ( $p < .001$ ), (5) good patient-provider communication ( $p = .03$ ), (6) confident in communicating their concerns ( $p = .002$ ), and (7) twice as likely to discuss their treatment side effects ( $p < .001$ ).

**Implications for the Advanced Practitioner**

Effective patient-centered communication is inherent to clinical trial participation, starting with informed consent, adverse event tracking and monitoring, and accessibility to the clinical trial team. In addition to offering patients treatment options that they may not otherwise have access to, clinical trial participation may improve patients' outcomes through enhanced patient-provider communication and increased patient engagement in self-management. It is critical for APs in oncology to familiarize themselves with the design and conduct of clinical trials and how to discuss clinical trial participation with patients. In addition, implementing elements of the clinical trial process in patients receiving standard-of-care therapies may improve the overall patient experience.

The 2020 JADPRO Article of the Year, "Clinical Trial Design and Drug Approval in Oncology: A Primer for the Advanced Practitioner in Oncology" (Kurtin & Taher, 2020) provides a comprehensive overview of the clinical trials process and strategies for APs to incorporate these principles into practice. The Advanced Practitioner Society for Hematology and Oncology (APSHO) has incorporated AP research and quality improvement into its strategic plan and as such has launched the Research and Quality Improvement Committee.

**Disclosure:** Dr. Kurtin has served as a consultant for AbbVie, Amgen, Epizyme, Incyte, Jazz, and Takeda.