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Clinical and sociodemographic predictors of intensive care unit admission following chemotherapy in acute myeloid leukemia

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Running Title: Clinical and sociodemographic predictors of critical illness in AML

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Treatment-related mortality remains a major driver of early death in Acute Myeloid Leukemia (AML). Advances in supportive care have reduced early mortality but fail to benefit patients equitably[1-3]. Our previous work confirmed Black-White survival disparities in newly diagnosed AML and indicated that Intensive care Unit (ICU) admission during induction chemotherapy was a significant mediator of these disparities[4]. Current prediction tools to identify the risk of Treatment Related Mortality (TRM) in AML rely on clinicopathologic variables such as marrow reserve, age, performance status, and organ function, but fail to consider the social determinants of health (SDOH) that are increasingly recognized to impact the success of AML therapy[5]. This represents the first study to integrate sociodemographic with clinicopathologic characteristics as predictors of ICU admission during induction chemotherapy.

The Chicago AML registry provides a unique resource for performing a detailed analysis of the early treatment course in a contemporary, diverse population. Data was collected in Research Electronic Data Capture (REDCap) hosted at the University of Illinois Chicago using an Institutional Review Board-approved protocol and data use agreement at each institution. We examined 950 adult patients consecutively diagnosed with non-promyelocytic AML between January 2012 and 2022 who received intensive induction chemotherapy at one of 6 academic institutions and excluded 32 patients missing data on ICU admission. The objective was to identify predictors of critical illness in the early period following chemotherapy incorporating self-reported race and census tract measures. To account for missing data, multiple imputation was conducted and the multiply imputed datasets analyzed. Using the method of chained equations, we multiply imputed missing values for each of the patient and clinical risk factors in Table 1. Binary variables were modeled in logistic regression, whereas multinomial logistic regression was used for variables with multiple categories. Allogeneic stem cell transplantation rates and survival were evaluated to determine the long-term clinical impact of critical illness during initial therapy.

A total of 918 newly diagnosed AML patients were included in this analysis **(Supplementary Table S1)**. The population comprised 65% Non-Hispanic White (NHW), 12% Non-Hispanic Black (NHB),13% Hispanic and 10% Other patients. The median age was 57 years (interquartile range 47, 65). NHB and Hispanic patients were significantly younger than NHW patients (19% NHB vs 26% Hispanic vs 13% NHW were under 40 years). Two thirds of NHW patients were married compared to 38% of NHB and 57% of Hispanic patients. The NHB and Hispanic patients were overrepresented in moderate and high disadvantage tracts and underrepresented in high affluence tracts. Compared to NHW patients, NHB patients were more likely to have public insurance (65% vs 44%) and Hispanic patients were likeliest to be uninsured (20% vs 2% in NHW and 3% NHB).

Comorbidities were highest in the NHB patients; 39% NHB vs 25% NHW vs 24% Hispanic patients had a Charlson Comorbidity Index $\geq$ 3. ELN 2017 classification differed significantly based on race/ethnicity. Hispanic patients were most likely to

have a favorable ELN 2017 risk group (24% vs. 18% NHB and 21% NHW patients). Hyperleukocytosis was seen in 17% of patients, and 7% presented with extramedullary disease involvement. The majority of patients had fibrinogen level derangement; 25% had low fibrinogen (<100 mg/dl) while 38% had elevated fibrinogen (>380 mg/dl).
Hispanic patients were most likely to have elevated fibrinogen (46% vs 34% NHW and 44% NHB). Hypoalbuminemia, a known predictor of adverse AML outcomes[6], was more prevalent in NHB patients (24% vs 15% NHW and 12% Hispanic patients). Rates of primary treatment failure were similar between groups (12-18%) although numerically lowest in Hispanic patients.

A total of 161 patients representing 17.5% of the study population required ICU admission following chemotherapy. Treatment details were available for 143 patients; the majority (n=105) received standard 7+3 based regimens while 37 patients received high-dose Cytarabine containing regimens (e.g. FLAG, Cytarabine-Mitoxantrone).
Twenty percent of ICU patients (n= 29) received novel therapies (CPX-351, midostaurin, and investigational agents). For 89 patients with available data on indication for ICU admission, 30 (34%) had infectious complications, 25 (28%) respiratory failure, 16
(18%) cardiovascular complications, 13 (15%) patients bleeding and 5 patients altered mental status. In the 72 patients with available data, the median number of days between start of induction and ICU admission was 22 (IQR:10-57).

Patient characteristics associated with ICU admission following chemotherapy were examined. In univariate analysis **(Table 1)**, race/ethnicity was a baseline predictor of ICU admission, with the highest rates of ICU admission in Hispanic patients at 27% compared to 19% of NHB and 14% of NHW patients (p = 0.004). Charlson Comorbidity Index (CCI) was also associated with ICU admission; a CCI score of 0-1 was associated with an ICU admission rate of 14-16% compared to 20-21% for CCI of 2 or higher (p = 0.03). Patients with high census tract disadvantage were likeliest to be admitted to the ICU compared to those from intermediate or low disadvantage tracts (61% vs 41% and 48% respectively; p=0.09). Disease-specific characteristics also predicted ICU admission. Patients with a high ELN 2017 genomic risk score were more likely to be admitted to the ICU compared to those with a moderate or low ELN score (21% compared to 16% and 13% respectively, p = 0.01). Patients with high disease burden as measured by significant white blood cell count elevation (WBC > 50K) were more likely to be admitted to the ICU. Additionally, low albumin (< 3 g/dL) and elevated fibrinogen level (> 380 mg/dl) at diagnosis were also associated with ICU admission.

Interestingly, established factors for mortality in AML including older age, ECOG performance status and elevated creatinine (>1 g/dl) did not predict ICU admission.

As previously published[7], elevated BMI was not predictive of adverse chemotherapy outcomes in AML. Marital status and insurance type were not associated with ICU admission.

Separate multivariable models **(Table 2)** were constructed for each risk factor, controlling for potential confounding variables. We did not control for variables potentially in the causal pathway from the risk factor of interest to ICU admission as conceptualized in **Supplementary Figure S1**. Compared to NHW patients, Hispanic ethnicity (RR =1.87, 95% CI 1.31, 2.67; p = 0.001) and Other race (RR=1.70, 95% CI 1.10, 2.62; p = 0.02) were predictors of ICU admission after adjusting for age and gender. Patients with adverse molecular/cytogenetic characteristics defined by ELN 2017 score were more likely to require intensive care (RR 1.85, 95% CI 1.16, 2.96; p = 0.01) adjusting for race, age, gender, insurance and social determinants. Examining lab measures at diagnosis, WBC count, serum albumin and fibrinogen were independent predictors of ICU admission adjusting for race/ethnicity, age, gender, social determinants, insurance, comorbidities and ELN risk score.

Critical illness during intensive chemotherapy negatively impacted the ability to receive further therapies and served as a surrogate for inferior survival (HR for OS=1.88, 95% CI: 1.44, 2.44; p<0.0001). Patients admitted to the ICU during induction therapy were less likely to undergo curative therapy with allogeneic stem cell transplant (60% vs. 40.5%, RR=0.67, 95% CI: 0.55, 0.82). ICU admission during induction therapy was also associated with a 3.9-fold greater risk of death at 90 days, RR = 3.95 (95% CI:2.39, 6.52) and a 54% greater risk of death at 1 year (RR = 1.54, 95% CI: 1.25, 1.90) **(Figure 1).**

In this well-annotated contemporary cohort of AML patients treated with intensive chemotherapy, 15% of patients developed critical complications requiring admission to the ICU, similar to previous studies reporting rates of 15-28%[8,9]. In addition to short-term morbidity and 90-day mortality, these ICU patients demonstrated compromised long-term outcomes.

We integrate validated clinical and molecular predictors of outcome in newly diagnosed AML[10] with SDOH and showed for the first time that self-reported race/ethnicity and neighborhood disadvantage are associated with increased incidence of critical illness following intensive chemotherapy. ECOG performance status was not a signifcant predictor although this variable was limited by significant (>25%) missing data which may have underestimated its influence. In multivariable analysis, adjusting for age and gender, Hispanic ethnicity was independently predictive of ICU admission despite younger patient age and more favorable-risk disease. Previous studies have reported inferior AML survival in Hispanic patients[11] and our results suggest this may be linked to differences in treatment tolerability.

Differences in cumulative frontline organ toxicity may lead to differential treatment at

relapse and drive subsequent survival racial disparities in AML.[12] Our data in adult AML confirm that ICU admission has downstream consequences including lower likelihood of curative allogeneic stem cell transplant and decreased 90 day and 2-year survival.

Targeted low intensity therapies in AML provide highly effective alternatives to intensive chemotherapy but the latter remains the preferred curative approach for patients under 60 years of age. Recent data demonstrate that within favorable molecular subsets of AML, the survival benefit of chemotherapy is modulated by race[13]. The current findings suggest the integration of race/ethnicity and allostatic load measures [14] including albumin and fibrinogen as prognostic biomarkers into current AML treatment mortality calculators merits further study. Improved selection criteria for intensive therapy incorporating measures and biomarkers of SDOH may reduce early treatment complications and mitigate survival disparities in AML.

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Table 1. Sociodemographic and clinicopathologic factors associated with intensive care unit admission following high-intensity induction therapy for acute myeloid leukemia					
	N	ICU	%	Missing	p-Value
Race/Ethnicity					0.004
NHW	597	86	14		
NHB	117	22	19		
Hispanic	123	33	27		
Other	81	20	25		
Age at Diagnosis					
18-39	151	27	18		
40-59	367	61	17		
60-74	376	68	18		
75+	24	5	21		
Gender					
Male	429	79	18		
Female	489	82	17		
Married				6	
Yes	576	95	16		
No	336	65	19		
Tract disadvantage				51	0.09
Low	288	48	17		
Moderate	288	41	14		
High	291	64	22		
Tract Affluence				51	
Low	294	55	19		
Moderate	288	53	18		
High	285	45	16		
Health Insurance					
Uninsured	46	10	22		
Public	426	75	18		
Private/commercial	446	76	17		
Body Mass Index				9	0.10
Underweight	39	2	5		
Normal weight	239	42	18		
Overweight	297	54	18		
Obese I	193	32	17		
Obese II	141	29	21		
Charlson Comorbidity Index				87	0.03
0	325	47	14		
1	154	25	16		
2	130	26	20		
3+	222	47	21		

ELN 2017 Classification				17	0.01
Favorable	165	21	13		
Intermediate	402	66	16		
Adverse	334	71	21		
White blood cell count (thous/μl)				41	0.05
< 50	727	119	16		
≥ 50	150	35	23		
Hemoglobin (g/dL)				47	
Normal (≥10)	221	35	16		
Low (0 - 10)	650	119	18		
Platelets (thous/μL)				45	
Very Low (0 -19)	110	19	17		
Creatinine (mg/dL)				81	
Normal (<1)	582	94	16		
High (≥ 1)	255	51	20		
Bilirubin (mg/dL)				80	
Normal (0 - 1.4)	795	137	17		
High (≥1.5)	43	7	16		
Albumin (g/dL)				84	0.03
Low (0 - 2.99)	131	31	24		
Normal (≥ 3)	703	110	16		
Lactate dehydrogenase (U/L)				110	
Normal (0 - 199)	152	24	16		
High (≥ 200 - 1000)	574	95	17		
Very High (≥ 1000)	82	20	24		
Fibrinogen (g/dL)				247	0.0001
Low (< 100)	168	14	8		
Normal (≥ 100-380)	248	44	18		
High (> 380)	255	58	23		
Bone marrow blasts (%)				44	
Lower (0- 20)	68	15	22		
Middle (≥ 20 - 50)	324	54	17		
Higher (≥ 50 - 100)	482	82	17		
ECOG performance status				533	0.1
0	155	12	8		
1	197	25	13		
2+	33	5	15		
Extramedullary Disease				22	
Yes	67	13	19		
No	829	144	17		

NHW: Non-Hispanic White, NHB: Non-Hispanic Black, ELN: European Leukemia Net,ECOG: Eastern Cooperative Oncology Group.
p-values > 0.10 are suppressed

Table 2. Multivariable adjusted predictors of Intensive Care Unit admission following high-intensity induction therapy			
	RR	95% CI	p
Race/Ethnicity[1]			
NHW	Ref.		
NHB	1.29	(0.84, 1.98)	
Hispanic	1.87	(1.31, 2.67)	0.001
Other	1.70	(1.10, 2.62)	0.02
Age at Diagnosis[1]			
18-39	Ref.		
40-59	1.01	(0.67, 1.52)	
60-74	1.15	(0.77, 1.74)	
75+	1.33	(0.55, 3.22)	
Gender (male vs. female)[1]	0.89	(0.67, 1.18)	
Married (Yes vs. No)[2]	0.88	(0.64, 1.20)	
Tract disadvantage[2]			
Low	Ref.		
Moderate	0.82	(0.55, 1.23)	
High	1.15	(0.71, 1.86)	
Tract Affluence[2]			
Low	Ref.		
Moderate	1.14	(0.78, 1.65)	
High	1.04	(0.66, 1.65)	
Health Insurance[3]			
Uninsured	Ref.		
Public	1.01	(0.54, 1.87)	
Private/commercial	1.14	(0.63, 2.09)	
ELN 2017 Classification[4]			
Favorable	Ref.		
Intermediate	1.44	(0.90, 2.30)	0.13
Adverse	1.85	(1.16, 2.96)	0.01
Body Mass Index[5]			
Underweight	0.30	(0.08, 1.18)	0.09
Normal weight	Ref.		
Overweight	1.12	(0.78, 1.61)	
Obese I	0.95	(0.63, 1.45)	
Obese II	1.15	(0.75, 1.76)	
Charlson Comorbidity Index[5]			
0	Ref.		

1	1.17	(0.74, 1.86)	
2	1.39	(0.89, 2.17)	0.15
3+	1.47	(1.00, 2.16)	0.05
ECOG Performance Status[5]			
0	Ref.		
1	1.30	(0.66, 2.55)	
2+	1.53	(0.61, 3.83)	
White blood cell count (thous/µl) ≥ 50[6]	1.65	(1.06, 2.58)	0.03
Hemoglobin[6] (g/dL) < 10	0.96	(0.65, 1.43)	
Platelets[6] (thous/µl) < 20	0.99	(0.62, 1.56)	
Creatinine[6] (mg/dL) > 1	1.13	(0.78, 1.62)	
Bilirubin[6] (mg/dL) > 1.5	0.79	(0.39, 1.61)	
Albumin[6] (g/dL) < 3	1.50	(1.00, 2.25)	0.05
Lactate dehydrogenase[6] (U/L)			
< 200	Ref.		
200-1000	1.01	(0.64, 1.60)	
≥ 1000	1.29	(0.72, 2.32)	
Fibrinogen[6] (g/dL)			
< 100	0.50	(0.28, 0.90)	0.021
100-380	Ref.		
≥ 380	2.45	(0.83, 1.84)	0.292
D-Dimer[6] (g/dL) > 0.5	1.00	(0.49, 2.03)	
Bone marrow blasts[6] (%)			
0-20	Ref.		
> 20 to 50	0.74	(0.42, 1.31)	
≥ 50	0.69	(0.37, 1.30)	
Peripheral blasts[6] (%)			
0-5	Ref.		
≥ 5 to 25	1.04	(0.49, 2.21)	
≥ 25	0.73	(0.31, 1.74)	
Extramedullary disease[6]	0.93	(0.53, 1.66)	

[1] Adjusting for race/ethnicity, age and gender. [2] Adjusted for variables from (1) plus tract disadvantage, tract affluence and marital status. [3] Adjusted for variables from (1,2) plus health insurance. [4]Adjusted for variables from (1,2,3) plus ELN 2017. [5] Adjusted for variables from (1,2,3,4) plus Body Mass Index, ECOG performance status and Charlson Comorbidity Index. [6] Adjusted for all variables shown in the table.

NHW: Non-Hispanic White
NHB: Non-Hispanic Black
ELN: European Leukemia Net
ECOG: Eastern Cooperative Oncology Group

Figure Legend

Figure 1. Kaplan-Meier estimates of survival in non-intensive care unit patients and intensive care unit patients with Acute Myeloid Leukemia. HR 1.88 (95% CI 1.44-2.44, $p<0.0001$)

Figure 1

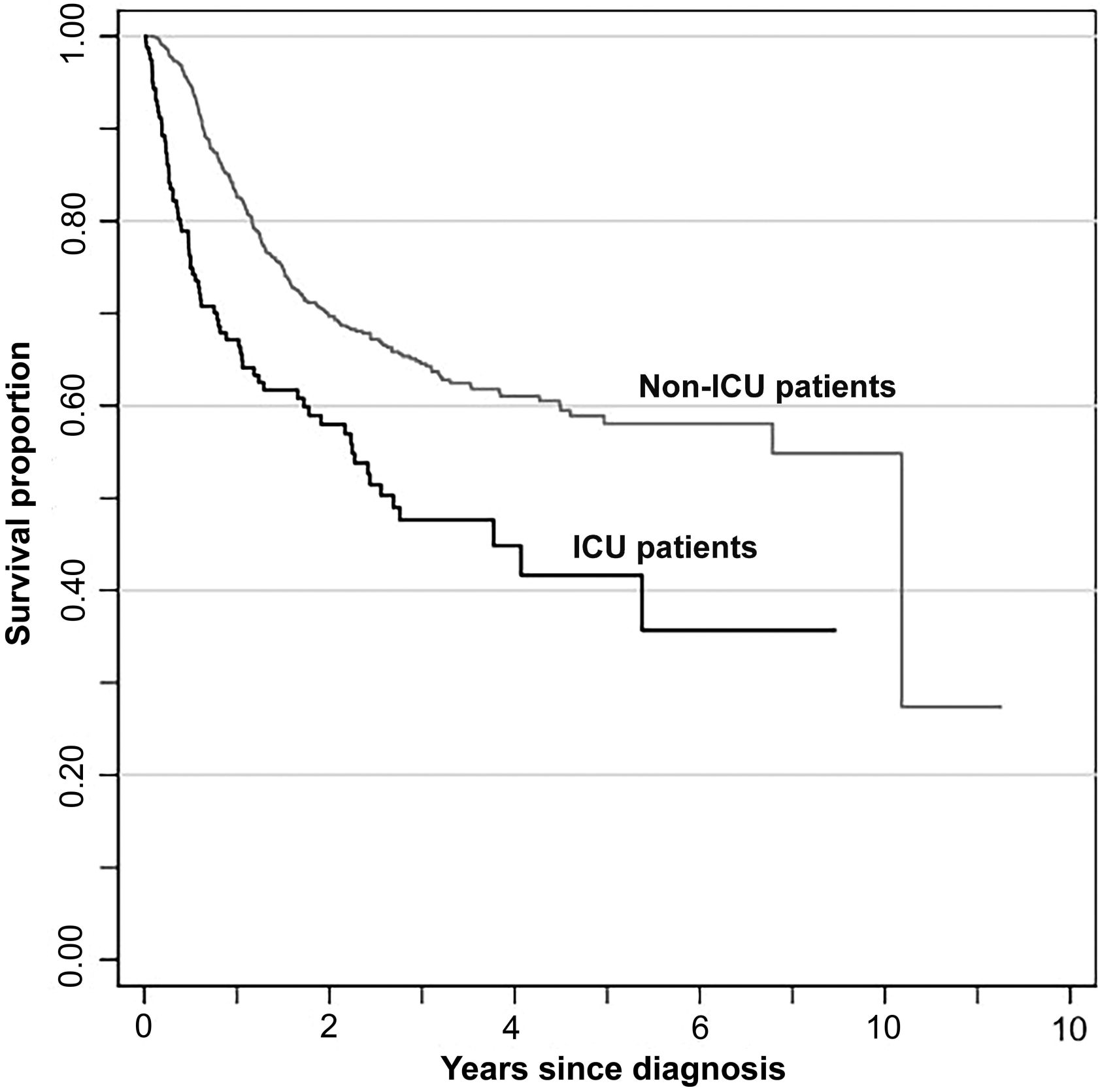
Survival proportion
1.00
0.80
0.60
0.40
0.20
0.00
Non-ICU patients
ICU patients
0
2
4
6
10
10
Years since diagnosis

Figure S1.

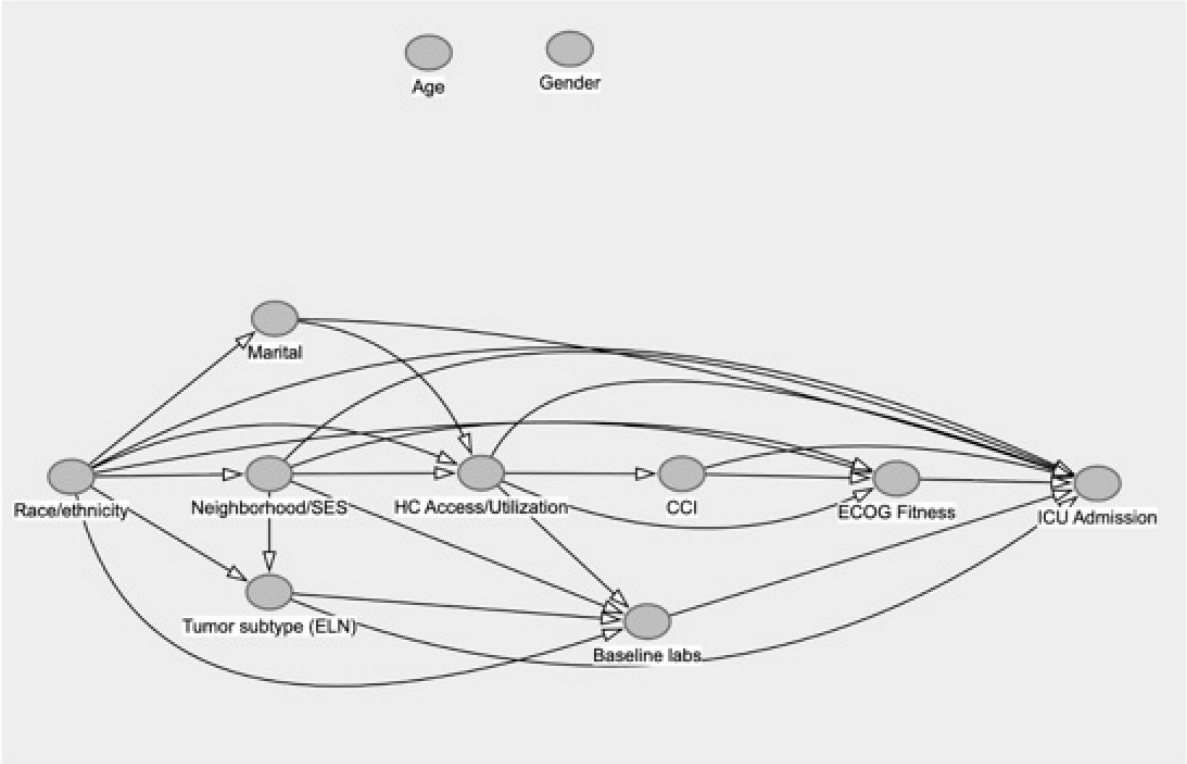

Figure S1. Causal diagram of variables that can influence intensive care unit admission following intensive chemotherapy in acute myeloid leukemia.

SES: Socioeconomic Status
HC: Healthcare
CCI: Charlson Comorbidity Index
ELN: European Leukemia Net
ECOG: European Cooperative Oncology Group
ICU: Intensive Care Unit

Table S1. Baseline sociodemographic characteristics by race/ethnicity for patients receiving intensive induction therapy												
	NHW			NHB			Hispanic			Other		
	No.	%	p	No.	%	p	No.	%	p	No.	%	p
ICU Admission			Ref.						0.001			0.02
No	511	86		95	81		90	73		61	75	
Yes	86	14		22	19		33	27		20	25	
Age at Diagnosis			Ref.			0.03			<0.0001			
18-39	83	13		23	19		34	26		14	17	
40-59	244	39		50	42		59	46		31	37	
60-74	274	44		45	38		33	26		36	43	
75+	18	3		1	1		3	2		2	2	
Gender			Ref.			0.09						0.008
Male	290	47		66	55		62	48		26	31	
Female	329	53		53	45		67	52		57	69	
Married			Ref.			<0.0001			0.04			0.04
No	205	33		73	62		54	43		18	22	
Yes	411	67		45	38		72	57		65	78	
Tract disadvantage			Ref.			<0.0001			<0.0001			
Low	250	43		10	9		11	9		28	37	
Moderate	227	39		13	12		31	24		28	37	
High	104	18		89	79		85	67		20	26	
Tract Affluence			Ref.			<0.0001			<0.0001			
Low	150	26		55	49		79	62		15	20	
Moderate	199	34		37	33		35	28		28	37	
High	232	40		20	18		13	10		33	43	
Health Insurance			Ref.			<0.0001			<0.0001			
Uninsured	14	2		3	3		25	20		9	11	
Public	272	44		77	65		54	42		31	37	
Private/commercial	333	54		39	33		49	38		43	52	
Body Mass Index			Ref.									
Underweight	28	5		7	6		0	0		6	8	
Normal weight	162	26		28	24		42	33		22	28	

Overweight	204	33		38	32		30	23		29	36	
Obese I	137	22		15	13		32	25		13	16	
Obese II	81	13		31	26		25	19		10	12	
Charlson Comorbidity Index			Ref.			0.001						
0	235	41		27	25		46	43		28	41	
1	108	19		23	21		18	17		10	14	
2	89	16		16	15		17	16		13	19	
3+	142	25		42	39		26	24		18	26	
ELN 2017 Classification			Ref.						0.003			
Favorable	104	17		25	21		30	24		11	13	
Intermediate	279	46		43	37		69	54		37	45	
Adverse	222	37		49	42		28	22		35	42	
White blood cell count (thous/µl)			Ref.									
< 50	489	82		100	88		100	83		60	78	
≥ 50	105	18		13	12		21	17		17	22	
Hemoglobin (g/dL)			Ref.			0.03						
Normal (≥10)	161	27		20	18		29	24		19	25	
Low (0-10)	427	73		94	82		91	76		58	75	
Platelets (thous/µL)			Ref.									
Normal-Low (≥ 20)	516	88		101	89		101	83		69	90	
Very Low (0 -19)	73	12		13	11		20	17		8	10	
Baseline creatinine (mg/dL)			Ref.						0.07			
Normal (0 - 1)	384	68		75	68		90	77		50	68	
High (≥ 1)	178	32		36	32		27	23		23	32	
Bilirubin (mg/dL)			Ref.									
Normal (0 - 1.5)	537	95		106	95		113	96		65	92	
High (≥1.5)	28	5		5	5		5	4		6	8	
Albumin (g/dL)			Ref.			0.02						
Normal (≥ 3)	481	85		84	76		103	88		61	86	
Low (0 - 2.99)	82	15		26	24		14	12		10	14	
Lactate dehydrogenase (U/L)			Ref.									
Normal (0 - 199)	103	19		21	20		18	16		11	16	

High (≥ 200 - 1000)	391	72		74	70		85	75		48	71	
Very High (≥ 1000)	52	10		11	10		11	10		9	13	
Fibrinogen (g/dL)			Ref.						0.006			
Low (< 100)	114	25		26	30		14	14		14	24	
Normal (≥ 100-380)	185	41		23	26		39	39		16	27	
High (> 380)	151	34		38	44		46	46		29	49	
D Dimer (g/dL)			Ref.									
Normal (0.1 - 0.5)	27	9		6	9		9	15		1	2	
High (≥ 0.5)	289	91		58	91		50	85		44	98	
Bone marrow blasts (%)			Ref.									
Lower (0 - 20)	48	8		9	8		10	8		4	5	
Middle (≥ 20 - 50)	219	37		37	33		48	40		29	37	
Higher (≥ 50 - 100)	328	55		65	59		61	51		45	58	
Peripheral blasts (thous/μL)			Ref.									
0 - 5	87	30		18	26		15	19		8	21	
≥ 5 - 25	71	25		21	31		28	35		9	23	
≥ 25	128	45		29	43		36	46		22	56	
ECOG Performance Status			Ref.									
0	113	41		11	30		18	49		13	36	
1	142	51		22	59		17	46		18	50	
2+	23	8		4	11		2	5		5	14	
Extramedullary Disease			Ref.									
No	566	94		106	90		114	91		71	90	
Yes	37	6		12	10		11	9		8	10	
Induction Treatment Failure	108	18		22	19		15	12		16	21	

Calculated p-values > 0.10 are suppressed. A multinomial logistic regression of nominal race/ethnicity against individual risk factors modeled as binary or ordinal were used to calculate p-values.

NHW: Non-Hispanic White
NHB: Non-Hispanic Black
ELN: European Leukemia Net
ECOG: Eastern Cooperative Oncology Group