

HEPATITIS B TREATMENT PATTERNS IN US CLINICAL CARE FOLLOWING TAF APPROVAL

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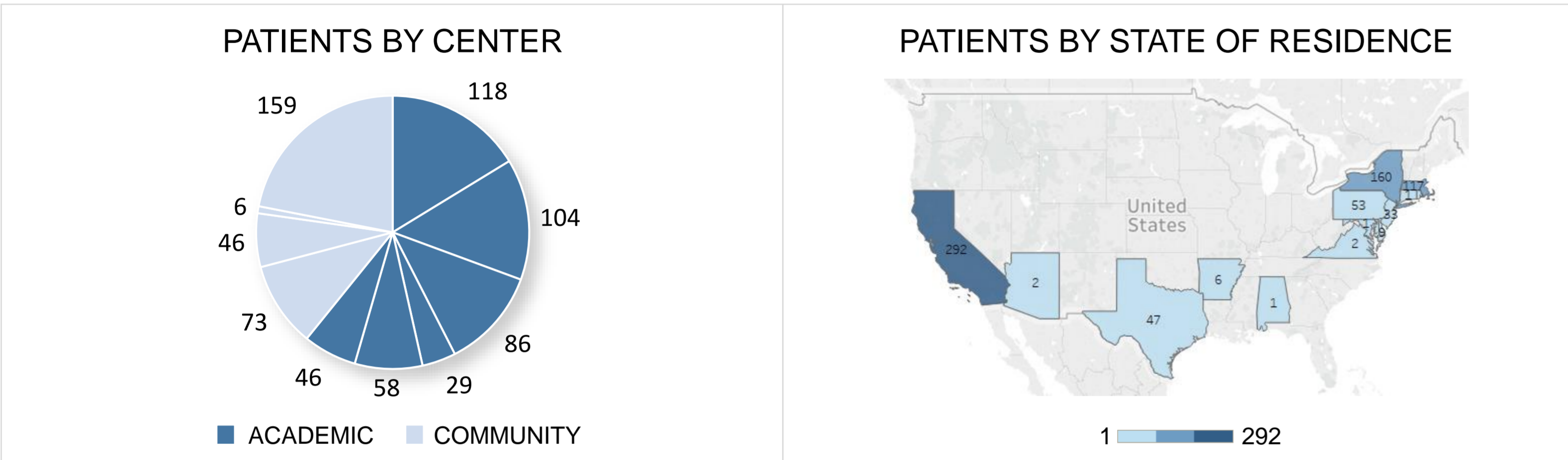


1.BACKGROUND AND AIM

Few studies have evaluated the treatment landscape of chronic HBV in the US, where estimates range from 850,000 to 2.2 million people living with HBV. TRIO analytics has developed a national HBV network of academic and community centers with the goal of understanding real-world HBV treatment in US clinical practice. We report here the demographic, clinical, and treatment characteristics of HBV patients during the first 24 months of data collection.

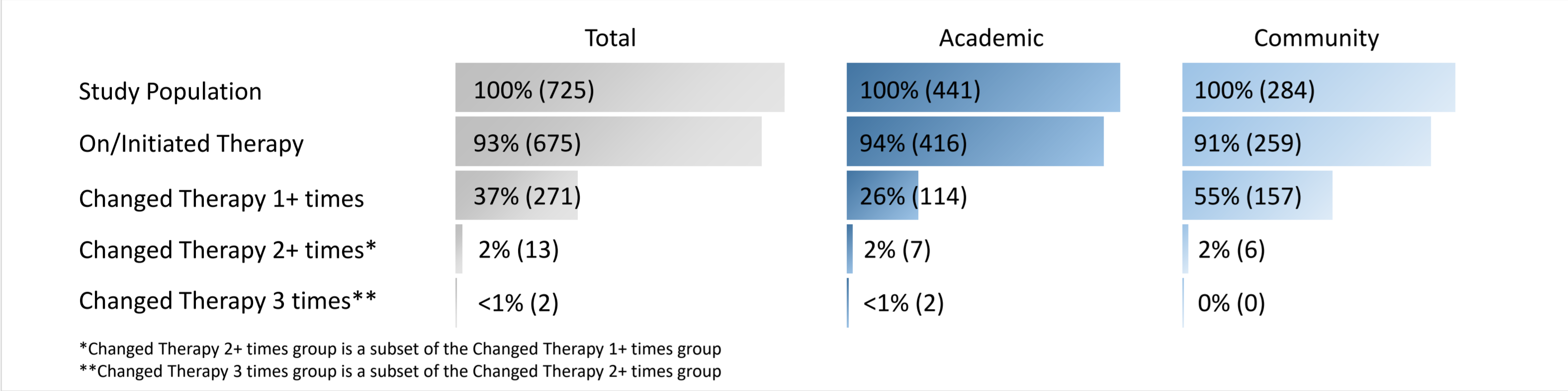
2.METHODS

This is a 3-year, observational, retrospective and prospective study of HBV patients enrolled Nov 2016 to Jan 2017. At enrollment, patient demographics, treatment experience, disease characteristics, comorbidities, and lab measures were retrospectively obtained from patient records through an electronic registry. For each subsequent visit, HBV data were collected with final data collection estimated in April 2020. Data presented here are limited to 24 months following enrollment (725 patients out of 1037). Comparisons between subgroups were made using chi-square or Fisher's Exact test (categorical variables) or Students T-test (continuous variables).



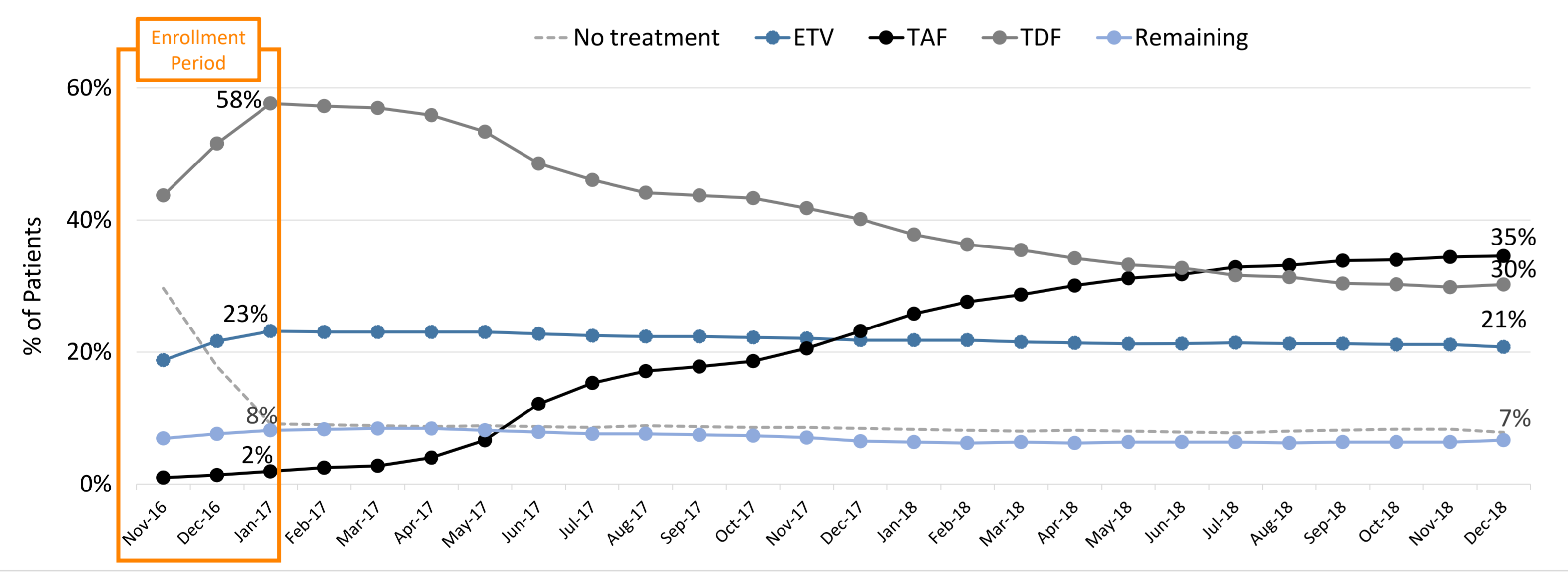
3.PATIENT DISPOSITION

For the total study population, 7% (50/725) patients were untreated while 37% (271/725) received >1 regimen during the observation window. Compared to Academic sites of care, Community sites had a higher rate of treatment switch (55% v 26%).



4.TREATMENT CHOICES DURING OBSERVATION WINDOW

Patient distribution (n=725) by month. At end of enrollment, TDF represented 58% of treatment but decreased to 30% by the end of the observation period. Conversely, TAF share increased from 2% to 35%. ETV use largely remained flat throughout the period.



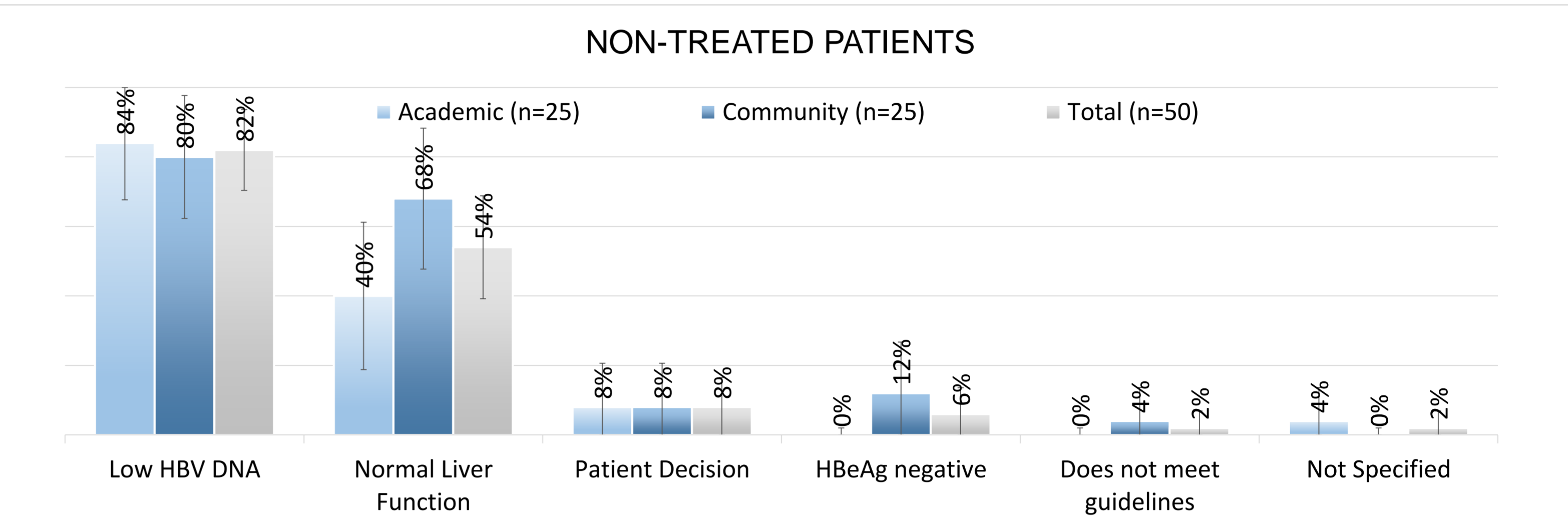
5.PATIENT CHARACTERISTICS AT ENROLLMENT

Community practices had a higher percentage of Asian patients and a lower percentage of black patients compared to Academic practices. The not treated group had a lower percentage of HBeAg positive and higher percentage of HBV DNA >2K IU/ml compared to the treated group. Treated patients who switched therapy had a higher percentage of Asian and lower percentage of black patients, hyperlipidemia, and HBV DNA >2K IU/ml.

No. (%) unless indicated	Academic (n=441)	Community (n=284)	p	Not Treated (n=50)	Treated (n=675)	p	Non-Switch (n=404)	Switched Therapy (n=271)	p	Total (n=725)
Age mean (SD)	51 (13)	53 (13)	0.044	51 (10)	52 (13)	0.595	52 (13)	52 (13)	1.000	52 (13)
BMI mean (SD)	24.9 (4.4)	24.4 (3.7)	0.113	25.0 (4.1)	24.7 (4.2)	0.626	24.8 (4.4)	24.6 (3.9)	0.545	24.7 (4.2)
Male	257 (58%)	156 (55%)	0.374	23 (46%)	390 (58%)	0.105	225 (56%)	165 (61%)	0.181	413 (57%)
Asian	356 (81%)	265 (93%)	<0.001	37 (74%)	584 (87%)	0.015	339 (84%)	245 (90%)	0.015	621 (86%)
Black	34 (8%)	10 (4%)	0.021	6 (12%)	38 (6%)	0.069	29 (7%)	9 (3%)	0.033	44 (6%)
Hyperlipidemia	55 (12%)	41 (14%)	0.446	7 (14%)	89 (13%)	0.870	67 (17%)	22 (8%)	0.001	96 (13%)
Hypertension	101 (23%)	77 (27%)	0.199	13 (26%)	165 (24%)	0.805	108 (27%)	57 (21%)	0.091	178 (25%)
Diabetes	41 (9%)	36 (13%)	0.149	3 (6%)	74 (11%)	0.347	45 (11%)	29 (11%)	0.858	77 (11%)
HBeAg positive	131 (30%)	68 (24%)	0.090	2 (4%)	197 (29%)	<0.001	119 (29%)	78 (29%)	0.850	199 (27%)
HBV DNA >2K IU/ml	28 (6%)	23 (8%)	0.369	14 (28%)	37 (5%)	<0.001	28 (7%)	9 (3%)	0.043	51 (7%)
FIB-4 >3.25	12 (3%)	17 (6%)	0.029	0 (0%)	29 (4%)	0.253	17 (4%)	12 (4%)	0.890	29 (4%)
eGFR <60 ml/min	33 (7%)	14 (5%)	0.173	1 (2%)	46 (7%)	0.243	26 (6%)	20 (7%)	0.633	47 (6%)
Reach-B mean (SD)	6.6 (2.6)	6.6 (2.4)	1.000	5.9 (2.7)	6.6 (2.5)	0.058	6.5 (2.5)	6.8 (2.5)	0.127	6.6 (2.5)

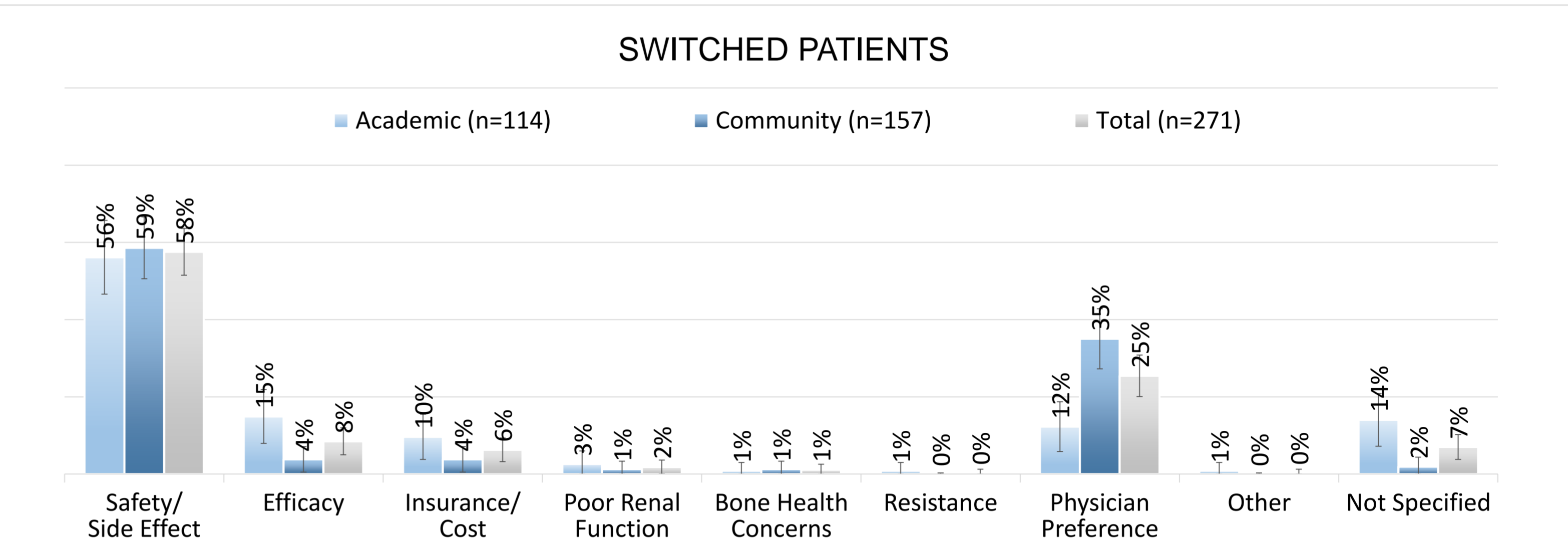
6.REASONS FOR NON-TREATMENT

Multiple reasons for non-treatment were provided for most patients. Low HBV DNA (82%, 41/50) and normal liver function (54%, 27/50) were most common.



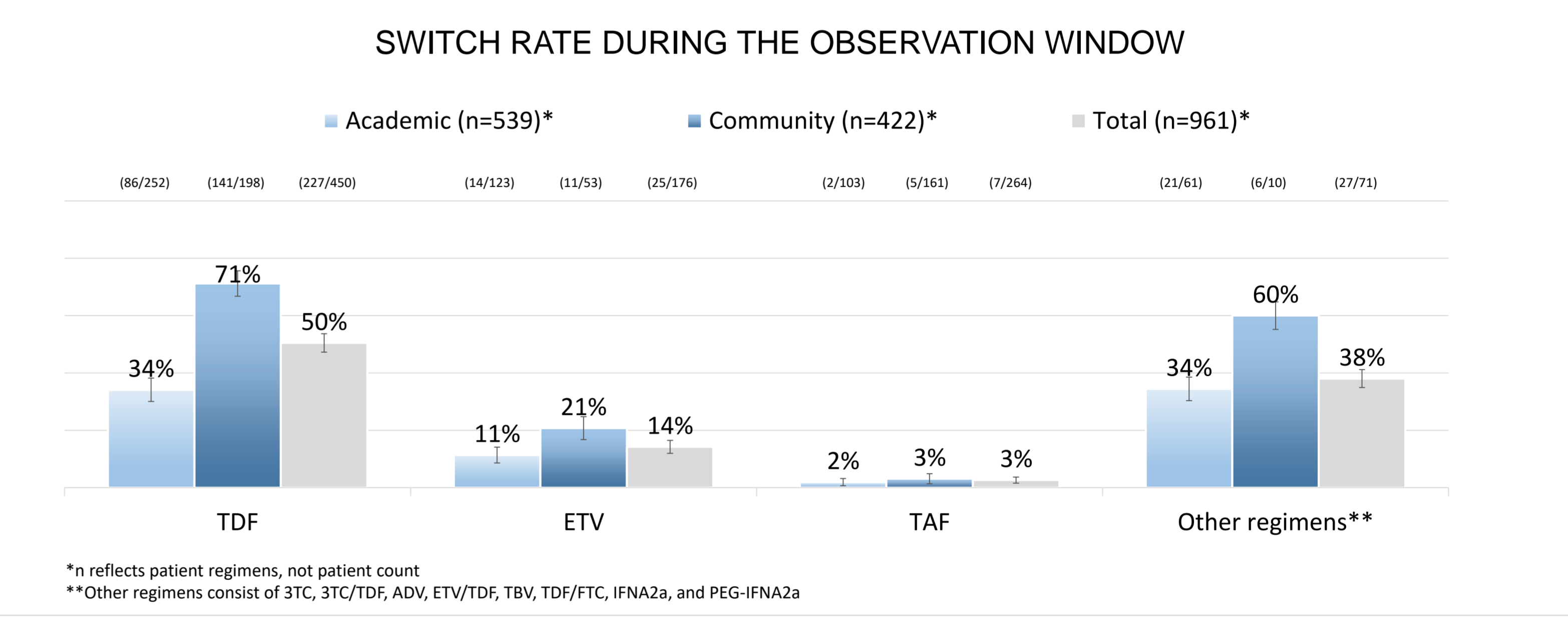
7.REASONS FOR SWITCHING

Multiple reasons for switching were provided by a few patients. Safety/Side Effect (58%, 156/271) and physician preference (25%, 69/271) were most common.

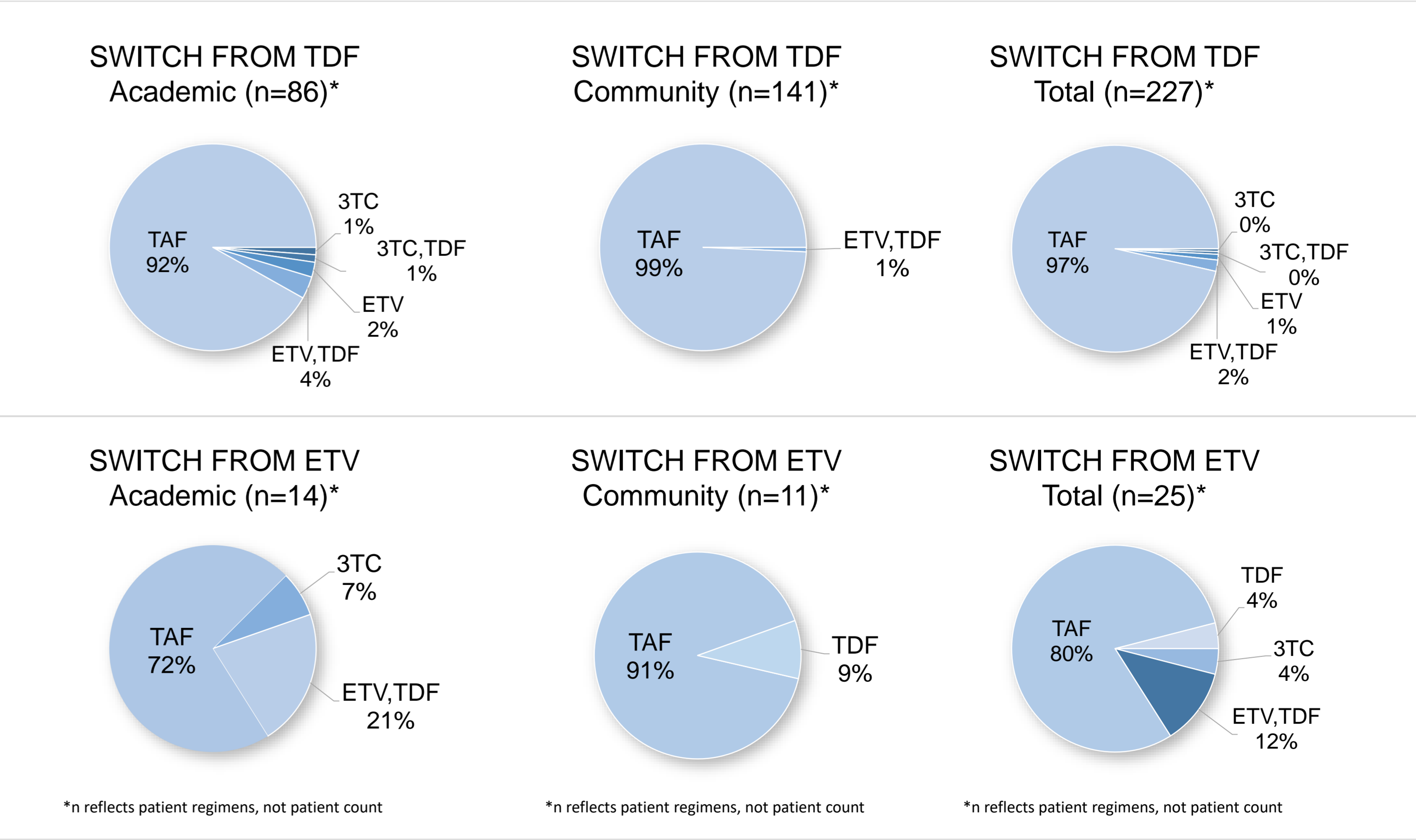


8.SWITCHING PATTERNS

Treatment Switch Rates were higher overall and by each regimen in Community practices compared to Academic.



97% of switches from TDF were to TAF. Switches away from ETV were to TAF for 80% of the population.



9.SUMMARY

This HBV population represents 725 patients residing in 14 US states and in care by 10 sites of care, 6 of which are Academic and 4 Community. In the two years of data collection, 7% (50/725) patients were untreated while 37% (271/725) received >1 regimen during the observation window. Reasons for non-treatment were varied though predominantly included low HBV DNA and normal liver function. For the population receiving treatment, initial or ongoing treatments were mostly TDF and ETV. During the observation window, switches away from the initial therapy were largely to TAF, which accounted for 35% of all treatments by the end of the observation window. Differences between Academic and Community sites included patient characteristics and the rate of switching from initial therapy, though care was largely similar between these different types of practices.