LDL-C Management Trends in US Individuals with ASCVD During 2021/2022

An analysis of the Family Heart Database™

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Study Design and Objectives

Aim: Characterize LDL-C management during 2021/2022

Design: Non-interventional, retrospective cohort study

Population: Individuals diagnosed with ASCVD

Data source: Family Heart Database 2012-2022

Study objectives are to characterize during 2021/2022:

- Type of LDL-C lowering drugs used: *specific drugs; mono, combo, no therapy*

- Duration of use of LDL-C lowering therapy (LLT): *21-24 mths; 13-20 mths; ≤12 mths; none*

- LDL-C goal attainment: *<70 mg/dl; <55 mg/dL*

- Disparities in LDL-C management: *age, sex, race/ethnicity, household income, education*

Family Heart Database – General Overview

Including ASCVD and nonASCVD Patients

- ❑ De-identified data
- ❑ Integrated
  - Medical claims
  - Lab data: primarily lipids
- ❑ Longitudinal
  - Most from 2012-2022
- ❑ Specialized analysis methods
  - ASCVD and associated conditions
  - ASCVD events
  - Lipid-lowering therapies

# Unique Individuals	2012 to 2022 in millions	2022 in million
Any Medical Claims Data	315 M	193 M
Diagnosis (DX)	*278 M*	*122 M*
Procedure (PX)	*278 M*	*122 M*
Medication (RX)	*278 M*	*167 M*
Surgical (SX)	*36 M*	*3.9 M*
Any Lab Data	132 M	26 M
Total Cholesterol	*104 M*	*25 M*
LDL-C	*51 M*	*25 M*
Lp(a)	*1.3 M*	*390,000*
Claims and Lab Data	107 M	21M
Any Data	340 M	197 M

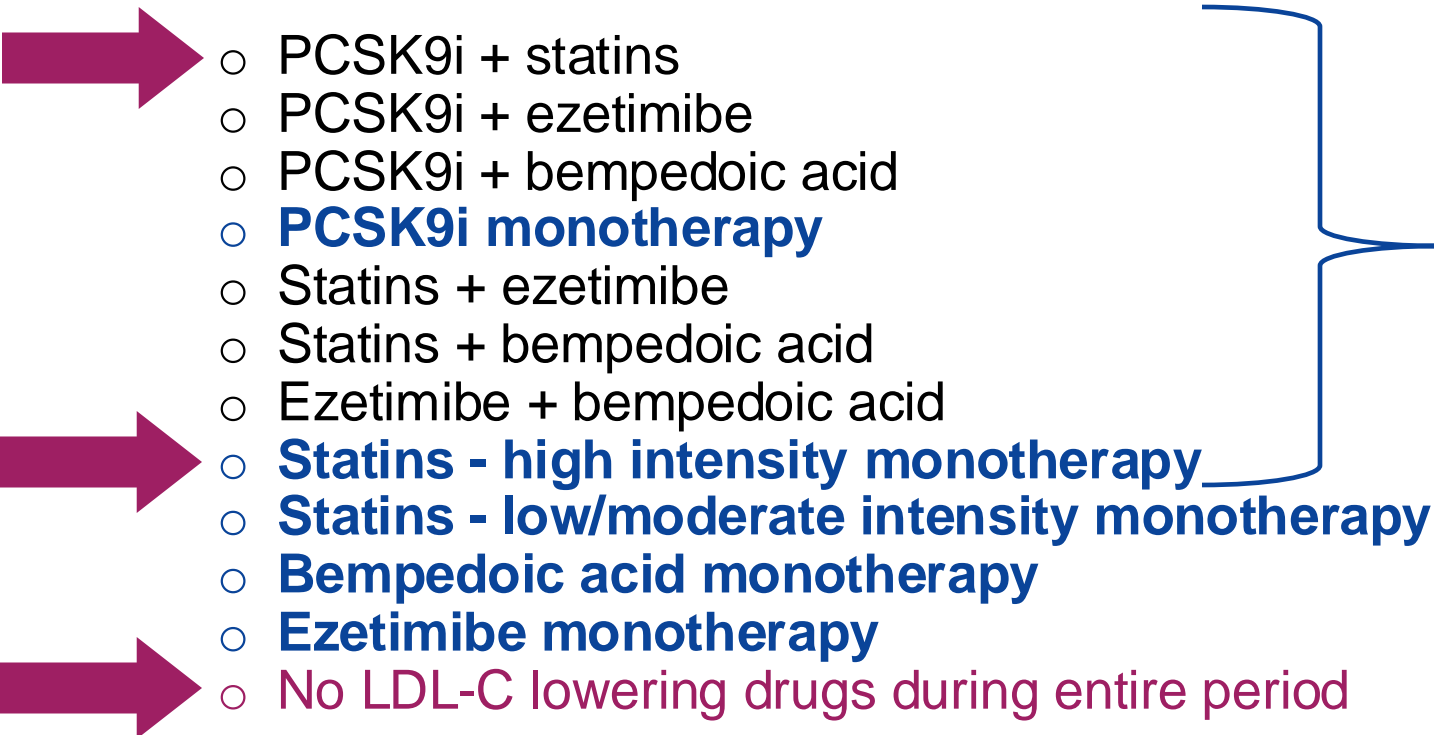# Study Entry Criteria and Other Details
n=3,440,885 Individuals with ASCVD during 2021/2022

- Entry Criteria:
  - Adults $\geq$ 18 years of age prior to 1 Jan 2021
  - Diagnosed with ASCVD prior to 1 Jan 2021
  - At least 1 prescription claim in EACH of year 2021 and 2022
  - At least 1 LDL-C measure at any time in 2021 or 2022

- ASCVD definition:
  Qualified medical claims corresponding with MI, acute ischemic heart disease, percutaneous coronary intervention [PCI], coronary artery bypass graft [CABG], unstable and stable angina; ischemic stroke/TIA and other cerebral vascular disease; peripheral vascular disease (PVD); and general ASCVD

- Duration of drug use = **estimated** based on prescription fill date and days of coverage

- Combination therapy = **estimated** based on **any** overlap in days of coverage of $\geq$2 combo-therapy drugs

Study Entry Criteria and Other Details

LDL-C lowering drugs = **filled prescriptions** of statins, PCSK9i, ezetimibe and/or bempedoic acid **by order of intensity**:

- PCSK9i + statins
- PCSK9i + ezetimibe
- PCSK9i + bempedoic acid
- **PCSK9i monotherapy**
- Statins + ezetimibe
- Statins + bempedoic acid
- Ezetimibe + bempedoic acid
- **Statins - high intensity monotherapy**
- **Statins - low/moderate intensity monotherapy**
- **Bempedoic acid monotherapy**
- **Ezetimibe monotherapy**
- No LDL-C lowering drugs during entire period

Consistent with guideline-recommended therapy

# Demographics and Medical Characteristics
n=3,440,885 Individuals *with ASCVD during 2021/2022*

		n=3,440,885
	Age, median (IQR)	69 (60-77) years
	Female	48%
Race/Ethnicity Reported in EHR	Black	11%
	White	55%
	Hispanic	11%
	Other	5%
	Unknown	20%
Comorbidities	Hypertension	87%
	Diabetes	44%
LDL-C	Mean (SD)	90 (34) mg/dL
	Median (IQR)	85 (66-110) mg/dL

IQR = Interquartile range, EHR = Electronic health records; SD = Standard deviation.

Other Characteristics
## n=3,440,885 *Individuals with ASCVD during 2021/2022*

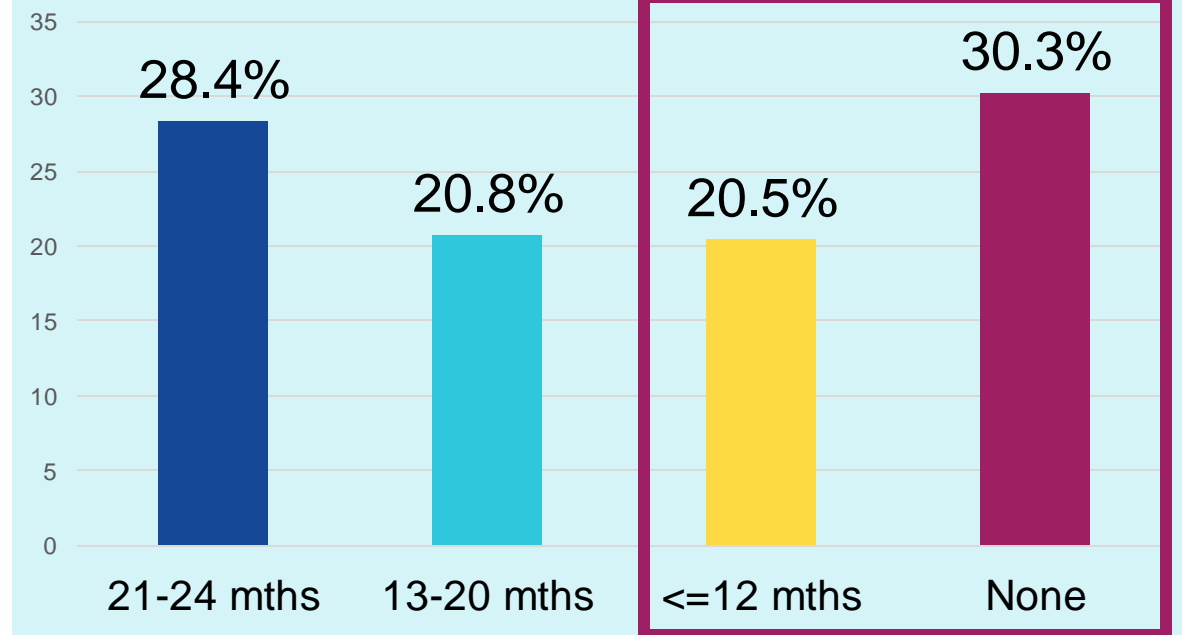|		n=3,440,885
Household Income	<$30K	17%
	$30-74K	29%
	$75-99K	13%
	>$100K	19%
	Unknown	22%
Education Level	High School or less	23%
	Some College	36%
	Assoc/Bachelor Degree +	21%
	Unknown	21%
Payer (>50% of prescriptions)	Medicare	53%
	Commercial Insurance	33%
	Medicaid	8%
	Assistance*	3%
	Combination	2.4%
	Cash	0.3%
	Unknown	0.1%

* Includes public and private programs intended to offsetting costs.

Use of LDL-C Lowering Drugs
Individuals with ASCVD During 2021/2022

Mono- and Combo- LLT Use at ANY Time During 2021/2022

- 30.3%
- 6.6%
- 63.1%

■ Monotherapy ■ Combotherapy ■ None
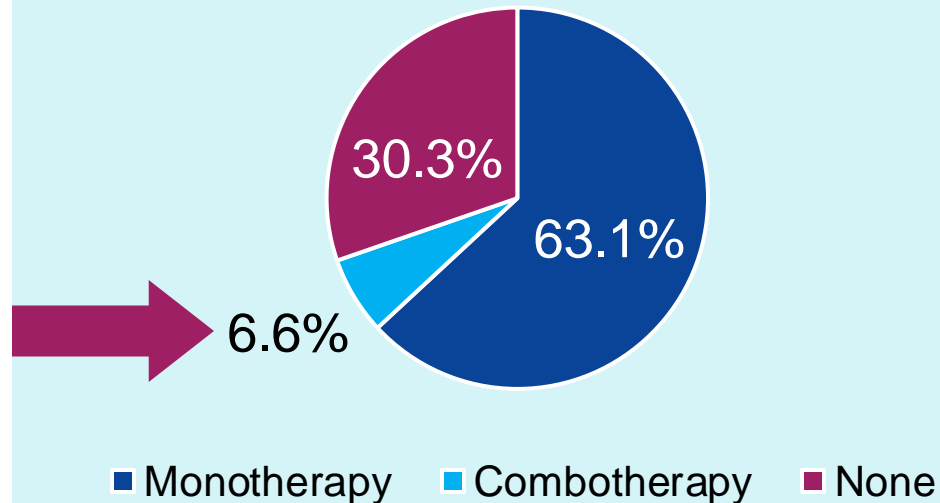
Duration of LLT Use Over 24 Months

- 21-24 mths: 28.4%
- 13-20 mths: 20.8%
- <=12 mths: 20.5%
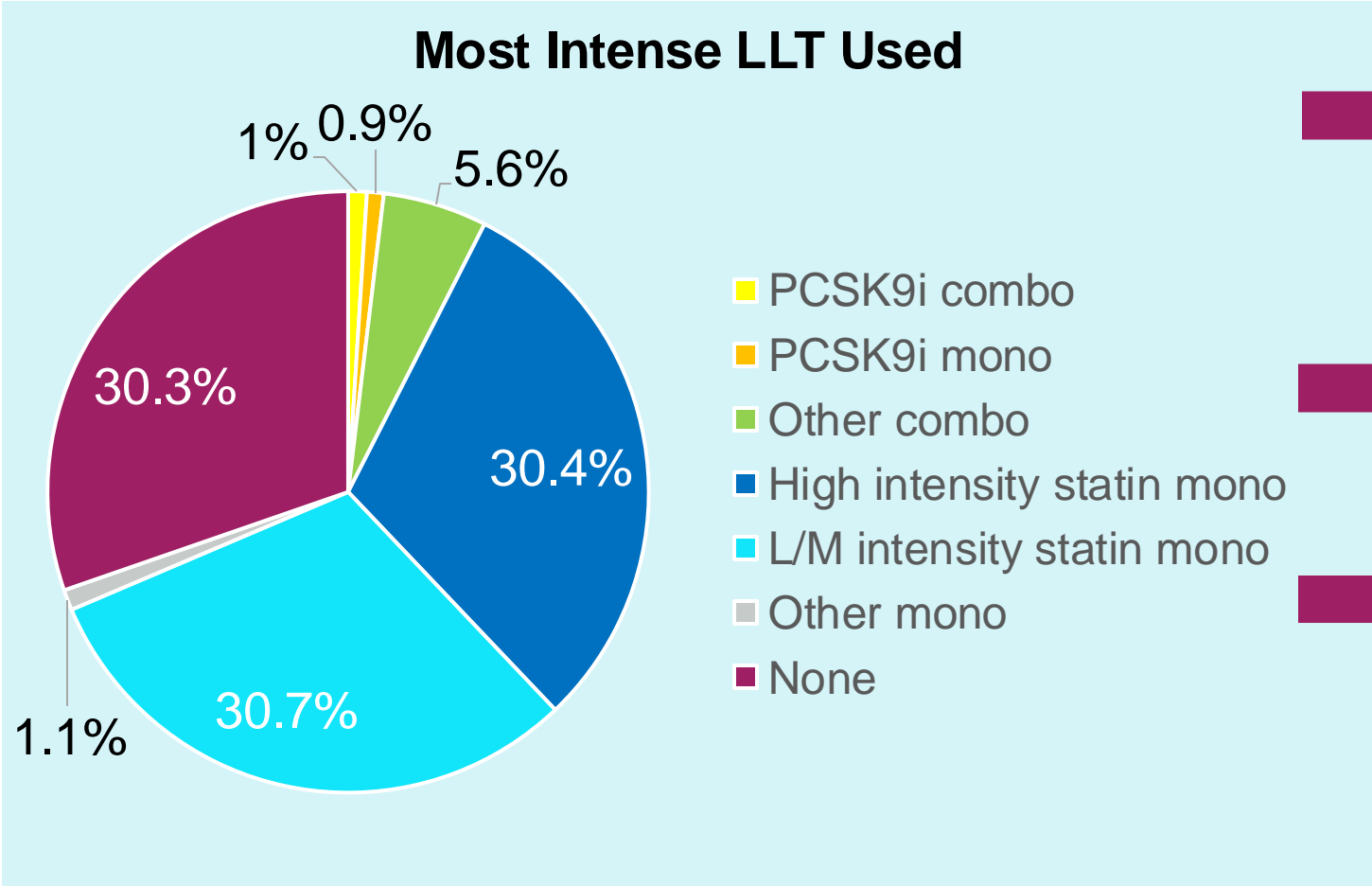- None: 30.3%

- Combination therapy was rarely used
- Most individuals used LLT infrequently (21%; ≤12 of 24 months) or not at all (30%)
- Smaller group (28%) consistently use LLT

Most Intense LDL-C Lowering Drug Used
Individuals with ASCVD During 2021/2022

Most Intense LLT Used

Legend:
- PCSK9i combo
- PCSK9i mono
- Other combo
- High intensity statin mono
- L/M intensity statin mono
- Other mono
- None

Pie chart values: 1%, 0.9%, 5.6%, 30.4%, 30.7%, 1.1%, 30.3%
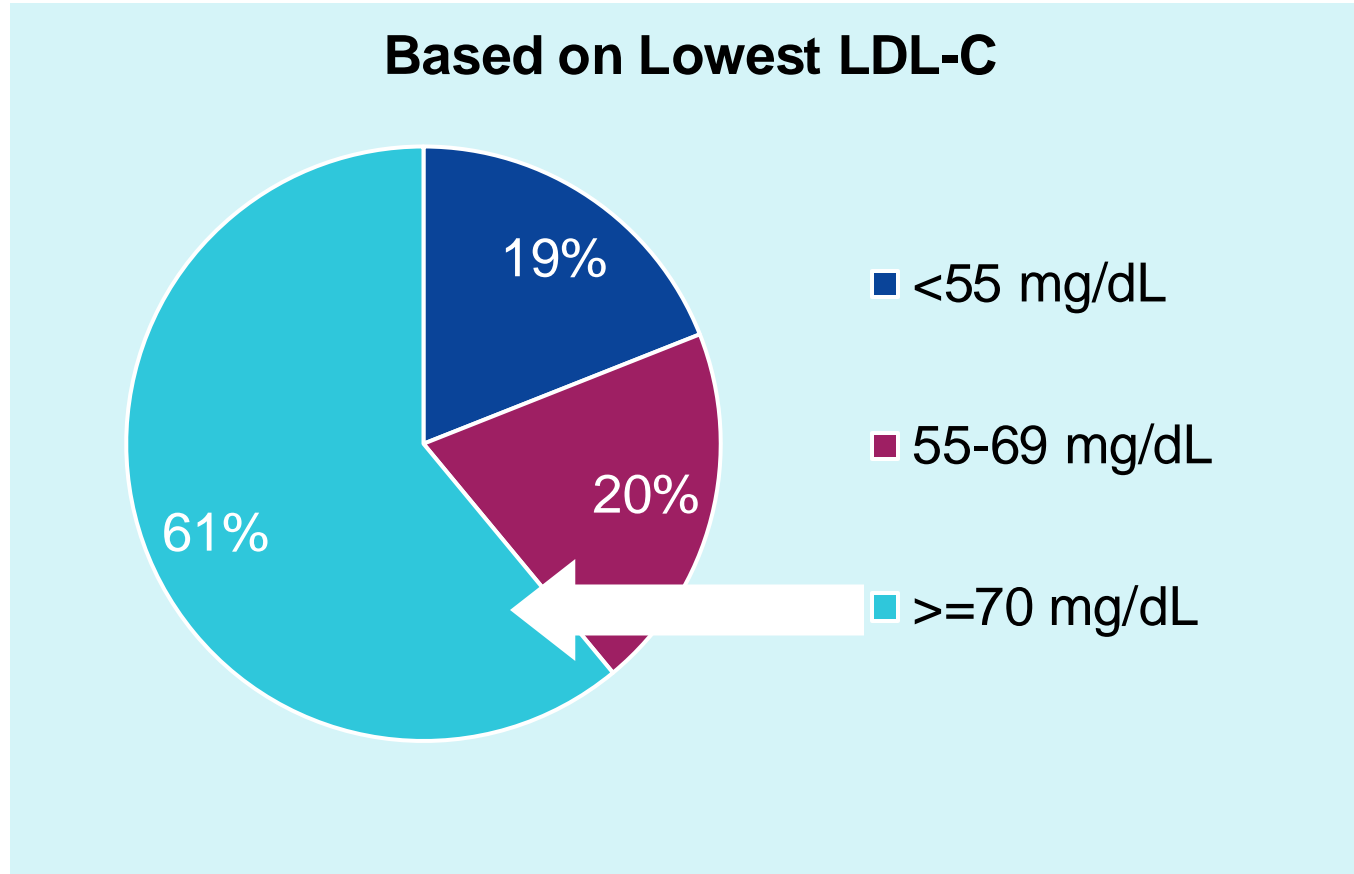
Few individuals received intensive LLT:

→ 30% received high intensity statin monotherapy

- 6% received "other" combo therapy, mostly ezetimibe + statin

→ 2% received PCSK9i (1% mono, 1% combo)

Most received:

→ Low/moderate intensity statin monotherapy: 31%

- Nothing: 30%

LDL-C Goal Attainment
Individuals with ASCVD During 2021/2022

Based on Lowest LDL-C

19% — <55 mg/dL

20% — 55-69 mg/dL

61% — >=70 mg/dL

Individuals who NEVER achieved an LDL-C <70 mg/dL = 61%

Persistent Use of Guideline-Recommended LLT
Individuals with ASCVD During 2021/2022
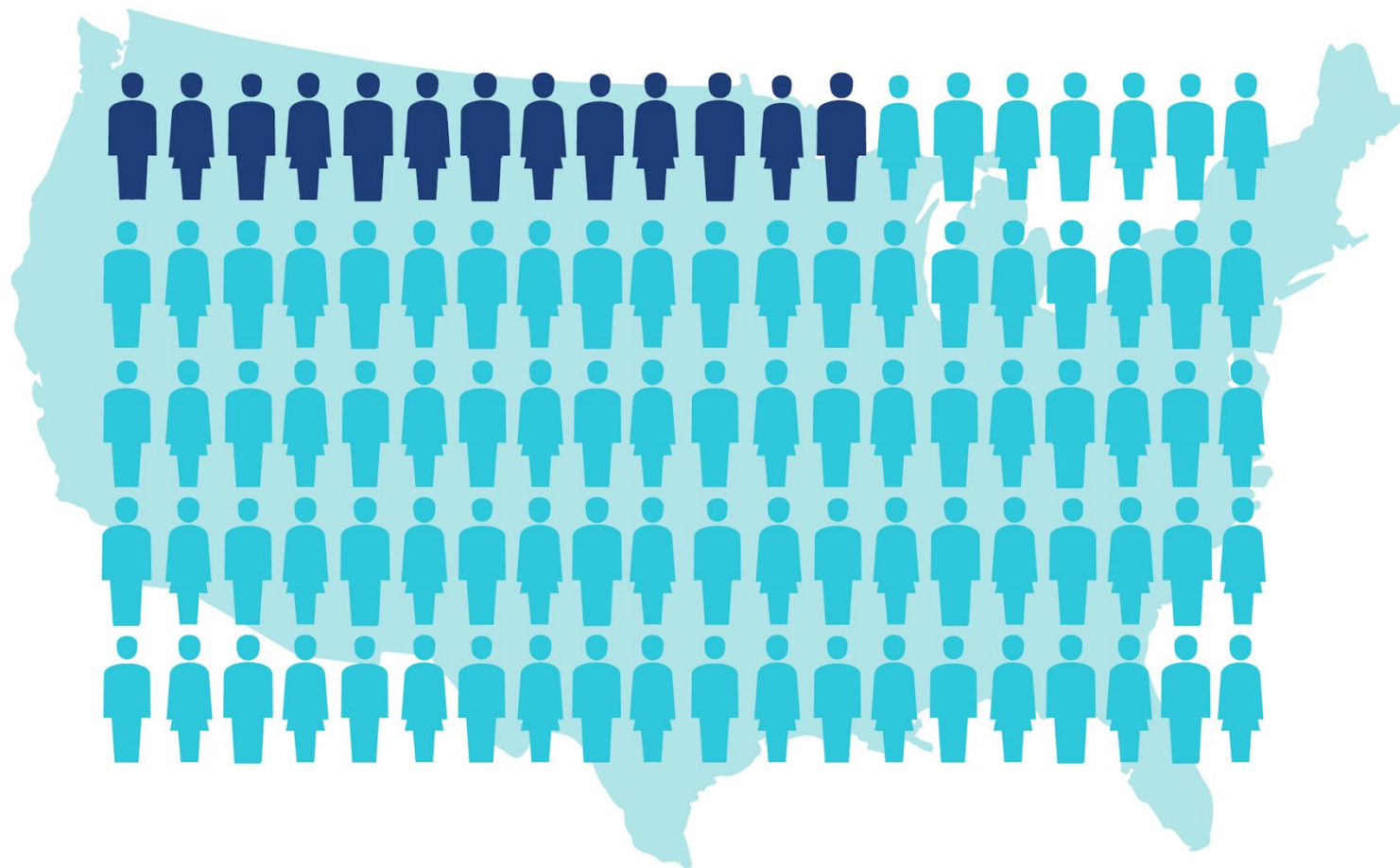
13/100 individuals used guideline recommended high intensity mono- or combo-therapy for 21-24 months

Disparities by LDL-C Goal Attainment
Individuals with ASCVD During 2021/2022

	Lowest LDL-C in 2021–2022			
	<55 mg/dL N=657,521 (19%)	55–69 mg/dL N=692,227 (20%)	≥70 mg/dL N=2,091,137 (61%)	Total N=3,440,885
Age (yrs), n (%)				
<50	23,770 (10)	29,075 (12)	185,355 (78)	238,200 (100)
50–59	79,225 (15)	86,737 (16)	376,138 (69)	542,100 (100)
60–69	194,516 (19)	203,958 (20)	623,196 (61)	1,021,670 (100)
≥70	360,010 (22)	372,457 (23)	906,448 (55)	1,638,915 (100)
Sex, n (%)				
Women	219,909 (13)	282,669 (17)	1,140,799 (69)	1,643,377 (100)
Men	437,612 (24)	409,558 (23)	950,338 (53)	1,797,508 (100)
Race/Ethnicity, n (%)				
Black	56,320 (16)	64,301 (18)	242,153 (67)	362,774 (100)
White	372,170 (20)	395,578 (21)	1,116,980 (59)	1,884,728 (100)
Hispanic	69,743 (19)	69,148 (19)	222,649 (62)	361,540 (100)
Other	33,998 (22)	33,153 (21)	87,631 (57)	154,782 (100)
Unknown	125,290 (19)	130,047 (19)	421,724 (62)	677,061 (100)

NEVER achieved an LDL-C <70 mg/dL

All Individuals: 61%

This was worse in:

- Individuals <50 yrs: 78%
- Individuals 50–59 yrs: 69%
- Women: 69%
- Black individuals: 67%

Disparities by LDL-C Goal Attainment
Individuals with ASCVD During 2021/2022

	Lowest LDL-C in 2021–2022			
	<55 mg/dL N=657,521 (19%)	55–69 mg/dL N=692,227 (20%)	≥70 mg/dL N=2,091,137 (61%)	Total N=3,440,885
Education level, n (%)				
High school grad or less	143,284 (18)	150,399 (19)	487,159 (62)	780,842 (100)
Some college	235,906 (19)	250,374 (20)	742,386 (60)	1,228,666 (100)
Assoc/Bachelor degree plus	147,098 (20)	155,292 (21)	421,758 (58)	724,148 (100)
Unknown	131,233 (19)	136,162 (19)	439,834 (62)	707,299 (100)
Household income, n (%)				
<$30K	100,918 (17)	110,020 (18)	386,711 (65)	597,649 (100)
$30–49K	81,531 (19)	85,533 (20)	267,208 (62)	434,272 (100)
$50–74K	110,170 (20)	115,338 (21)	328,738 (59)	554,246 (100)
$75–99K	90,137 (20)	94,908 (21)	260,335 (58)	445,380 (100)
$100K+	132,429 (20)	138,985 (21)	379,015 (58)	650,429 (100)
Unknown	142,336 (19)	147,443 (19)	469,130 (62)	758,909 (100)

Disparities by Adherence to LLT
Individuals with ASCVD During 2021/2022

Duration on lipid-lowering therapy in 2021–2022						
	No therapy N=1,042,519 (30%)	≤12 months N=704,426 (20%)	13–20 months N=715,509 (21%)	>20 months N=978,431 (28%)	Total N=3,440,885	
Age (yrs), n (%)						
<50	128,406 (54)	50,302 (21)	31,904 (13)	27,588 (12)	238,200 (100)	
50–59	172,439 (32)	131,841 (24)	113,550 (21)	124,270 (23)	542,100 (100)	
60–69	265,671 (26)	217,853 (21)	227,186 (22)	310,960 (30)	1,021,670 (100)	
≥70	476,003 (29)	304,430 (19)	342,869 (21)	515,613 (31)	1,638,915 (100)	
Sex, n (%)						
Women	563,273 (34)	346,351 (21)	327,613 (20)	406,140 (25)	1,643,377 (100)	
Men	479,246 (27)	358,075 (20)	387,896 (22)	572,291 (32)	1,797,508 (100)	
Race/Ethnicity, n (%)						
Black	110,364 (30)	88,574 (24)	80,260 (22)	83,576 (23)	362,774 (100)	
White	573,380 (30)	345,836 (18)	375,664 (20)	589,848 (31)	1,884,728 (100)	
Hispanic	106,072 (29)	83,214 (23)	81,466 (23)	90,788 (25)	361,540 (100)	
Other	43,980 (28)	30,068 (19)	33,608 (22)	47,126 (30)	154,782 (100)	
Unknown	208,723 (31)	156,734 (23)	144,511 (21)	167,093 (25)	677,061 (100)	

NO LLT most likely to be:
- <50 yrs
- Women

Least likely to adhere to LLT >20 months:
- <50 yrs
- 50–59 yrs
- Lesser extent, women and Black individuals

Disparities by Adherence to LLT
Individuals with ASCVD During 2021/2022

	Duration on lipid-lowering therapy in 2021–2022				
	No therapy N=1,042,519 (30%)	≤12 months N=704,426 (20%)	13–20 months N=715,509 (21%)	>20 months N=978,431 (28%)	Total N=3,440,885
Education level, n (%)					
High school grad or less	227,991 (29)	174,337 (22)	169,885 (22)	208,629 (27)	780,842 (100)
Some college	378,085 (31)	240,266(20)	250,246 (20)	360,069 (29)	1,228,666 (100)
Assoc/Bachelor degree plus	218,566 (30)	126,898 (18)	144,582 (20)	234,102 (32)	724,148 (100)
Unknown	217,877 (31)	162,925 (23)	150,796 (21)	175,631 (25)	707,229(100)
Household income, n (%)					
<$30K	181,775 (30)	139,182 (23)	129,439 (22)	147,253 (<25)	597,649 (100)
$30–49K	130,393 (30)	94,970 (22)	92,573 (21)	116,372 (27)	434,272 (100)
$50–74K	165,554 (30)	108,111 (20)	114,696 (21)	165,885 (30)	554,246 (100)
$75–99K	134,617 (30)	80,919 (18)	89,371 (20)	140,473 (32)	445,380 (100)
$100K+	196,654 (30)	111,495 (17)	129,061 (20)	213,219 (33)	650,429 (100)
Unknown	233,526 (31)	169,749 (22)	160,405 (21)	195,229 (26)	758,909 (100)

Conclusions

These data highlight a ***lack of urgency to manage LDL-C* and follow US guideline recommendations** in high-risk individuals:

- Most individuals (61%) with ASCVD are failing to attain an LDL-C goal <70 mg/dL.
- This is worse in those:
    - <50 years,
    - women, and
    - Black individuals
- Few individuals (13/100; 12.7%) used guideline directed medical therapy (GDMT) for 21-24 months

Conclusions

Available strategies to improve LDL-C management are not being implemented:

- o New, innovative and highly effective LDL-C lowering therapies like PCSK9i are rarely used (2% of individuals)
- o Combination therapy is rarely used (7% of individuals)
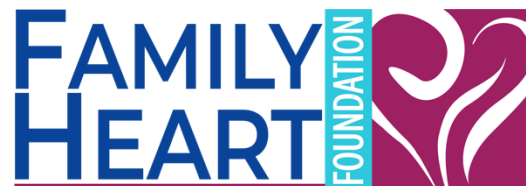- o High intensity statin monotherapy is used infrequently (30% of individuals)

Throughout 2021 and 2022, most individuals received:

- Low/moderate intensity statin monotherapy: 31%
- Nothing: 30%

Thank you

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