72% of High-Risk Hypercholesterolemia Patients Never Reach Below ACC/AHA Guideline LDL-C Thresholds

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BACKGROUND

Based on extensive clinical trial data, demonstrating lower LDL-C reduces heart attacks, strokes, and need for interventional surgery, the *2018 Multidisciplinary Guideline on the Management of Blood Cholesterol* calls for initiation and intensification of lipid-lowering therapies (LLT) if LDL-C exceeds defined thresholds in high-risk patients.

Achievement of LDL-C below thresholds in high-risk patients was assessed using real-world data from the Family Heart Database™.

METHODS

The Family Heart Database is comprised of diagnostic/procedural /prescription data from claims and/or laboratory data for >324 million individuals in the US from 2012 to 2021.

The dataset used in this analysis included high-risk patients with sufficient diagnostic, procedure, medication and lab data.

Patient Risk Category	Definition	LDL-C Threshold
High	Severe primary hypercholesterolemia (LDL-C ≥190 mg/dL)	≥100 mg/dL
High	ASCVD	≥70 mg/dL
Very High	Multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions	≥70 mg/dL

Patient histories were divided into contiguous ”episodes” characterized by the LLT use (including none), prescription filling, and LDL-C level (see Figure 1).

RESULTS

This analysis included 38,110,734 high-risk patients.

See center panel for key results.

Mean assessment period was 2565 days/patient. For those patients who did reach below LDL-C threshold, mean number of episodes below threshold was 2.3, and mean duration of episodes was 159 days.

Comparison of the proportion of high-risk patients with LDL-C below threshold before and after 2019 showed minimal difference (data will be added prior to submission)

Real-world data from the Family Heart Database shows that, despite effective and safe lipid-lowering therapies, most high-risk patients remain above guideline LDL-C thresholds or go below for only brief, insufficient durations.

- **Only 27.8% of all high-risk patients ever reached below guideline LDL-C thresholds.**
- **For those with episodes below LDL-C thresholds, mean duration of each episode was 159 days.**
- **80.5% of clinicians never prescribed combination LLT though the guideline provides direction and rationale for doing so.**
- **Only 2.2% of high-risk patients received combination LLT.**

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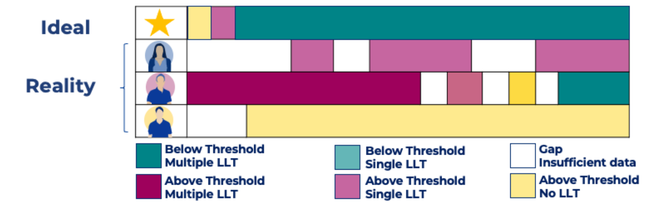
CONCLUSION and DISCUSSION

For the highest risk American patients, the 2018 AHA/ACC Guideline recommends high intensity statin followed by combination LLT to reach below LDL-C thresholds.

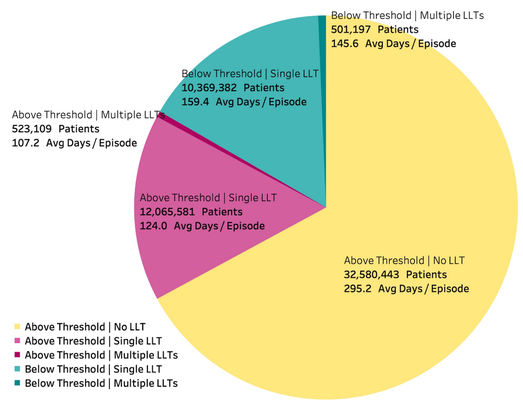
Unfortunately, real-world data show that most patients remain above LDL-C thresholds. Patients rarely use, and physicians rarely prescribe, LLTs as recommended, despite many effective and safe LLT options. This elevates further these patients’ risk for ASCVD events.

FIGURE 1



Representative patients with complex and variable lipid profiles over time, including *episodes* (represented by colored blocks) that are characterized by LDL-C level and LLT use. Periods of time with missing or insufficient data appear as white gaps and are not episodes.

FIGURE 2



Proportion of high-risk patients above and below LDL-C thresholds while taking combination, single, or no LLT. **Note: Some patients are counted in multiple categories.**

TABLE 1

Receiving/ Prescribing:	High-Risk Patients N (%)	Treating Clinician N (%)
Combination LLT	849,692 (2.23%)	162,596 (20.46%)
Single LLT, combination LLT and none	38,110,734 (100%)	794,710 (100%)

High-risk patients receiving and clinicians prescribing combination LLT.

DISCLOSURE INFORMATION

Author Disclosures: none

FAMILY HEART FOUNDATION
Lipoprotein(a) & Familial Hypercholesterolemia