

# Mevacor™ Daily 20 mg Tablets Rx-to-OTC Switch

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# Overview

- Important aspects of an actual use study
- Actual use issues to address for Mevacor OTC
- Actual Use Study # 084 (CUSTOM)
  - Results of consumer behavior
  - Differences in data analysis

# Important Aspects of an Actual Use Study

- Simulate OTC use
  - Recruitment through mass media
  - Site locations in pharmacies or grocery stores
- Have few exclusion criteria

# Important Aspects of an Actual Use Study

- Objectives depend on the specific product and concerns related to that product:
  - Self-diagnosis
  - Self-selection
  - De-selection
  - Compliance, dosing, duration of use
  - Off-label use
  - Safety and efficacy in OTC population

# Actual Use Issues to Address for Mevacor OTC

- Are consumers able to:
  - Self-diagnose hypercholesterolemia
    - Know their cholesterol values
    - Understand serum cholesterol values
  - Identify risk factors for CHD
  - Self-select based on the label eligibility criteria and the contraindications for use

# Actual Use Issues to Address for Mevacor OTC

- Are consumers able to self-treat:
  - Follow label directions
    - for dosing and duration of use
    - for follow-up cholesterol test
    - when to see a physician
  - Understand the treatment goal
  - De-selection
    - Identify risks during therapy with Mevacor



# Study #084

## Consumer Use Study of OTC MEVACOR™ (CUSTOM)

# Label Criteria

**Drug Facts**

Active ingredient (in each tablet)	Purpose
Lovastatin 20 mg	Cholesterol reducer

**Use** To help lower LDL "bad" cholesterol, which may prevent a first heart attack. This product is for people who meet the requirements in the sections below.

**Warnings**  
Do not use if

- Liver disease: Do NOT use if you have liver disease.
- Do NOT use if you have had any muscle pain, weakness or tenderness from taking a cholesterol-lowering medicine.
- Pregnant or breast-feeding: Do NOT use if you are pregnant or breast-feeding.
- Allergic to lovastatin: Do NOT use if you know you are allergic to lovastatin or the inactive ingredients in this medicine, as listed below.

Ask your doctor or pharmacist before use if you are taking

- Any prescription medicine: If you are taking any prescription medicine, ask your doctor or pharmacist before taking MEVACOR™ OTC. Certain drugs can interact with MEVACOR™ OTC and can increase the possibility of side effects.
- Other cholesterol-lowering medicine: Do NOT substitute MEVACOR™ OTC for your prescription or non-prescription cholesterol-lowering medicine without talking to your doctor.
- New prescriptions: Tell your doctor or pharmacist you are taking MEVACOR™ OTC before you begin taking any new prescription medicine.

Do NOT use unless directed by your doctor if you have

- very high LDL "bad" cholesterol 171-400 mg/dL
- high triglycerides 200-900 mg/dL
- healthy HDL "good" cholesterol 60-200 mg/dL
- had a stroke
- ever had heart disease (heart attack or angina)
- diabetes

Stop use and ask your doctor if you develop any unexplained muscle pain, weakness or tenderness. Stop use immediately. This can be a sign of a rare but serious side effect.

If you are diagnosed with a new medical condition, tell your doctor you are taking MEVACOR™ OTC.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

You must have YES (blue) answers to all 4 of the following.

<p><b>1</b> MEVACOR™ OTC is only for people 65 years of age or older.</p> <p><b>Yes, I am 65 years of age or older – continue</b></p>	<p><b>2</b> MEVACOR™ OTC is only for people whose total cholesterol is 130 mg/dL or higher.</p> <p><b>Yes, my total cholesterol is 130 mg/dL or higher – continue</b></p>	<p><b>3</b> MEVACOR™ OTC is only for people who are free of these conditions that increase their risk of heart disease (If yes to any, you may need to see your doctor):</p> <ul style="list-style-type: none"><li>▶ You are a smoker (may need to see your doctor)</li><li>▶ HDL "good" cholesterol 1-39 mg/dL</li><li>▶ Heart attack or angina in father or mother or sister before 65</li><li>▶ High blood pressure</li></ul> <p><b>Yes, I have one or more of the above – continue</b></p>	<p><b>4</b> MEVACOR™ OTC is only for people who are free of ALL conditions in the Warnings section above</p> <p><b>Yes, I am free of all Warnings above – continue</b></p>
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**Drug Facts (continued)**

**Inactive ingredients** Butylated hydroxytoluene, croscarmellose sodium, hydroxypropyl methylcellulose, hypromellose, polyethylene glycol, polyethylene glycol 400, polyethylene glycol 600, polyethylene glycol 800, polyethylene glycol 1000, polyethylene glycol 1500, polyethylene glycol 2000, polyethylene glycol 3000, polyethylene glycol 4000, polyethylene glycol 6000, polyethylene glycol 8000, polyethylene glycol 10000, polyethylene glycol 15000, polyethylene glycol 20000, polyethylene glycol 30000, polyethylene glycol 40000, polyethylene glycol 60000, polyethylene glycol 80000, polyethylene glycol 100000, polyethylene glycol 150000, polyethylene glycol 200000, polyethylene glycol 300000, polyethylene glycol 400000, polyethylene glycol 600000, polyethylene glycol 800000, polyethylene glycol 1000000

**Other information** See inside package for additional information or call toll free 1-800-XXX-XXXX or visit us on the web at www.xxxxxx.com



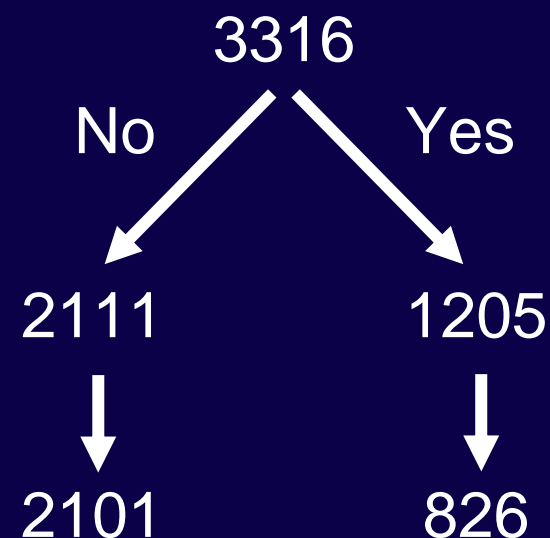
# CUSTOM: Decision to Purchase

Participated in purchase decision

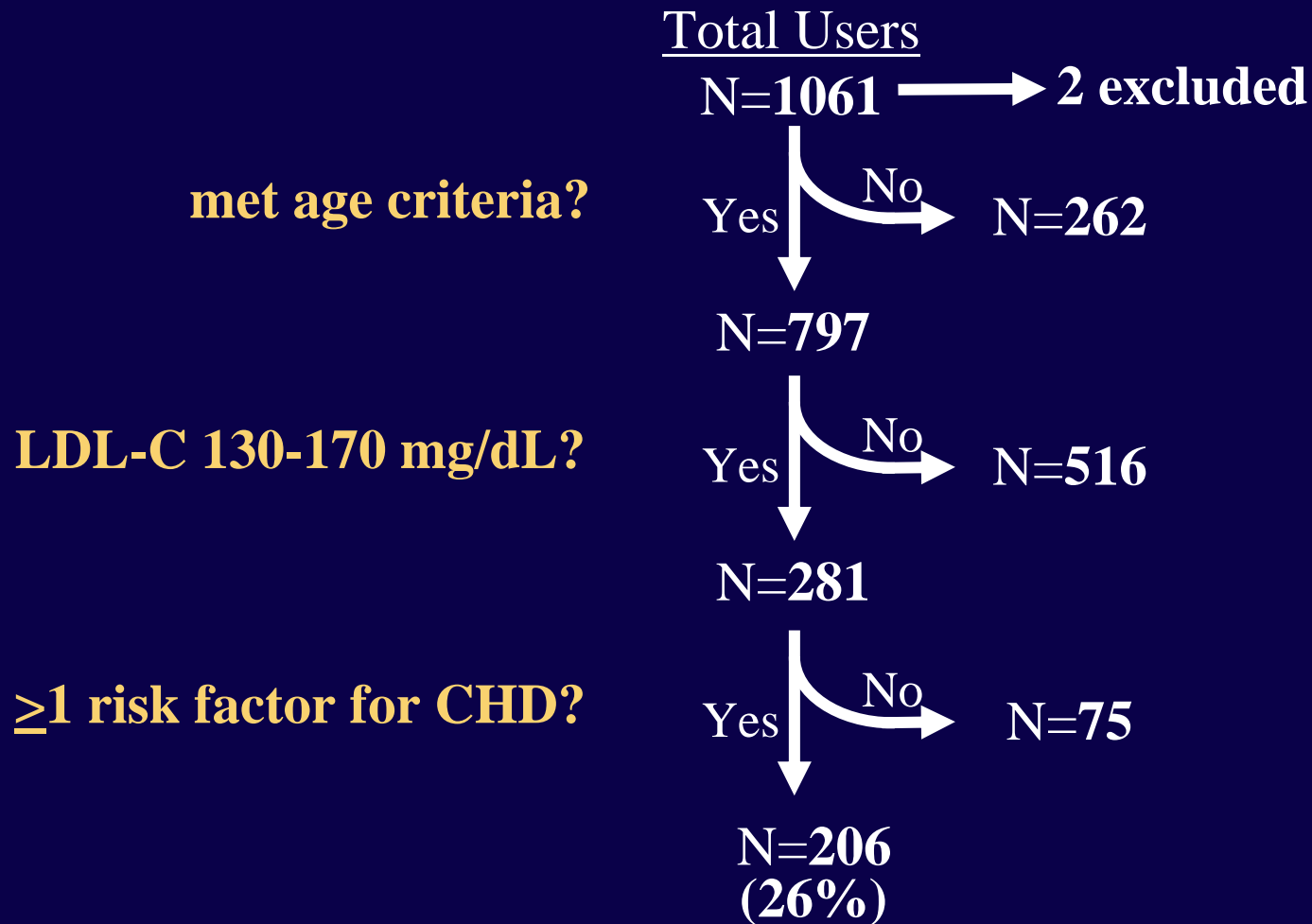
Purchased Mevacor OTC

Needed more information

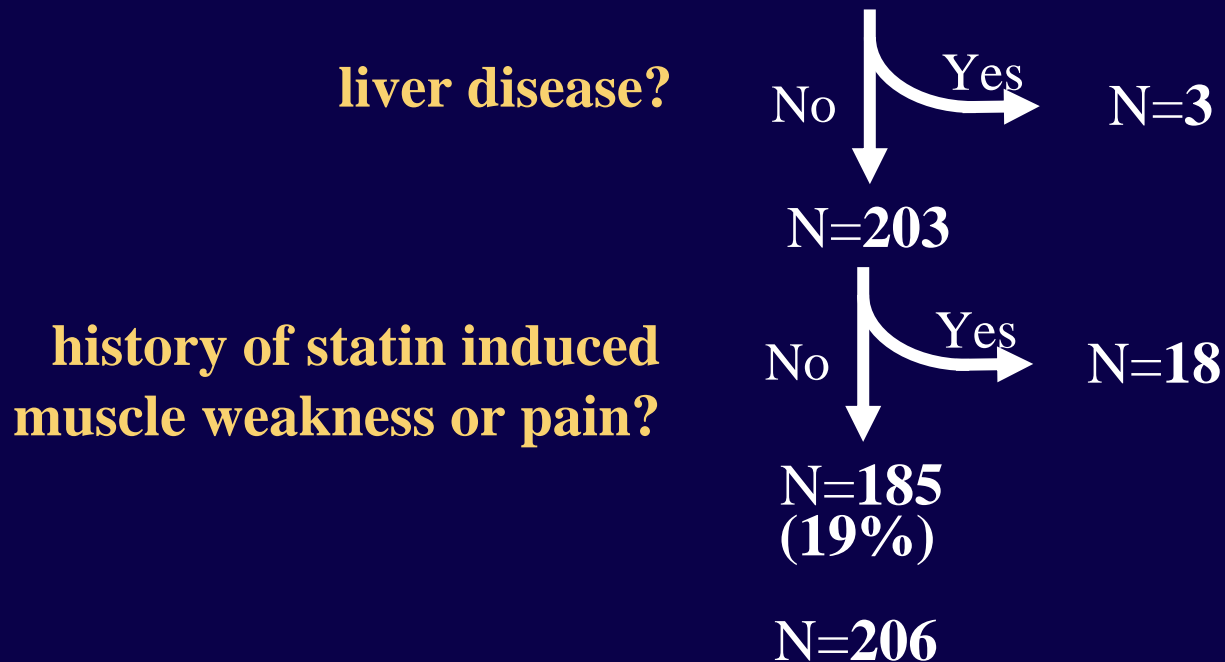
- To obtain cholesterol
- To talk to a doctor
- Personal health information
- Study related information



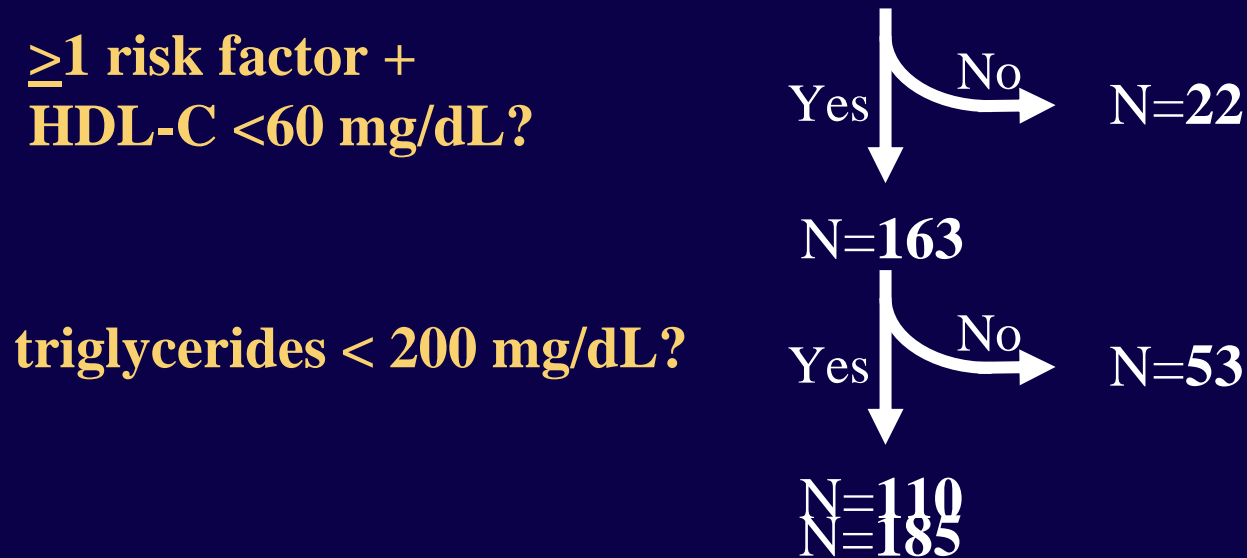
# Self-Selection of Users Based on the Label Criteria



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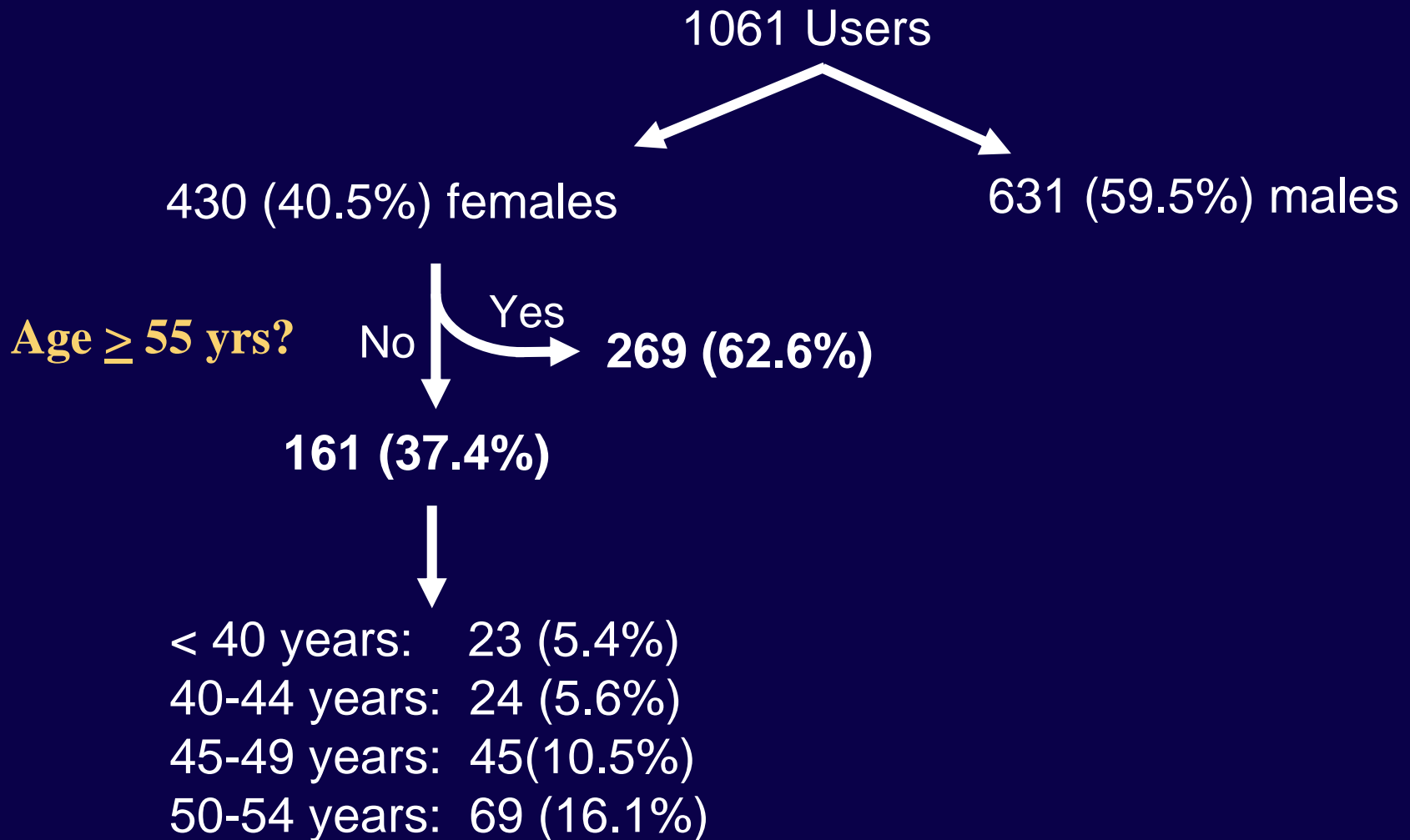


# Self-Selection of Users Based on the Label Criteria



**10% of all Users fit the label criteria**

# Self-Selection Demographics



# Use of Mevacor in Women under 50

- 21.5% of all women Users were < 50 years
  - Many of these women are likely of child bearing potential
- Because during the first trimester of pregnancy women may not realize that they are pregnant, it is important to understand the risk to the fetus if women of child bearing potential are going to use the product in the OTC setting

# Did Users Know Their Cholesterol Values?

What did Consumers Think Their LDL-C Level Was	LDL-C (mg/dL) Measured at Purchase Visit				Total
	Missing	<130	130 to 170	>170	
Missing	15	0	10	2	27
Unknown	66	55	103	94	318
< 130 mg/dL	10	87	16	9	122
130 -170 mg/dL	19	54	250	44	367
> 170 mg/dL	18	13	26	168	225
Total	128	209	405	317	1059

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<b>Missing</b>	15	0	10	2	<b>27</b>
<b>Unknown</b>	66	55	103	94	<b>318</b>
<b>&lt; 130 mg/dL</b>	10	<b>87</b>	16	9	<b>122</b>
<b>130 -170 mg/dL</b>	19	54	<b>250</b>	44	367
<b>&gt; 170 mg/dL</b>	18	13	26	<b>168</b>	<b>265</b>
Total	128	209	405	317	1059



# Summary of the Users' Knowledge of Their LDL-C Values at the Initial Visit

- 30% (318/1059) did not know their LDL-C
- 47.7% (505/1059) correctly identified their LDL-C value
- 71% of Users who correctly identified their LDL-C <130 mg/dL chose to use Mevacor OTC
- 75% of Users who correctly identified their LDL-C >170 mg/dL chose to use Mevacor OTC

# Did Users Meet the Label CHD Risk Factor Criteria?

## Risk Factors for CHD:

- Smoking
- Age
  - $\geq 45$  years men
  - $\geq 55$  years women
- Family history of CHD
- Hypertension
- Low HDL-C

Users with  $\geq 2$  risk factors  
(Age +  $\geq 1$  risk factor)

**57.3%**

Users with  $< 2$  risk factors

**42.7%**

# Sponsor's Definitions of Correct Self-Selection

## Original Definitions

- **AL:** According to Label
  - entirely consistent with label
- **NAL-MASM:** Not According to Label, Medically Acceptable for Self-Management; i.e., a favorable benefit to risk ratio (achieve LDL-C goal at 6 weeks)

## Modified Definition (a physician override)

- **AL-MASM:** According to Label, Medically Acceptable for Self-Management
  - AL and
  - not AL **but** consulted with a doctor

# Sponsor's Additional Analyses of Correct Self-Selection

Closely adhered to the label (post-hoc definition)

- Outside age criteria
- Absence of label risk factors
- LDL-C < 130 mg/dL
- LDL-C > 170 mg/dL
- HDL-C  $\geq$  60 mg/dL

But:

- Knew their lipid profile
- Did not have elevated triglycerides
- Did not substitute Mevacor OTC for a prescription lipid lowering medication, and
- Did not have diabetes, heart disease or stroke



# Sponsor's Additional Analyses of Correct Self-Selection (cont.)

## Failed to Closely Adhere to Label Benefit Criteria But Eligible for Statin Therapy (post-hoc definition)

- Did not know their lipid profile
- Had elevated triglycerides > 200 mg/dL
- Substituted Mevacor OTC for their Rx medication
- Had diabetes, heart disease, or stroke

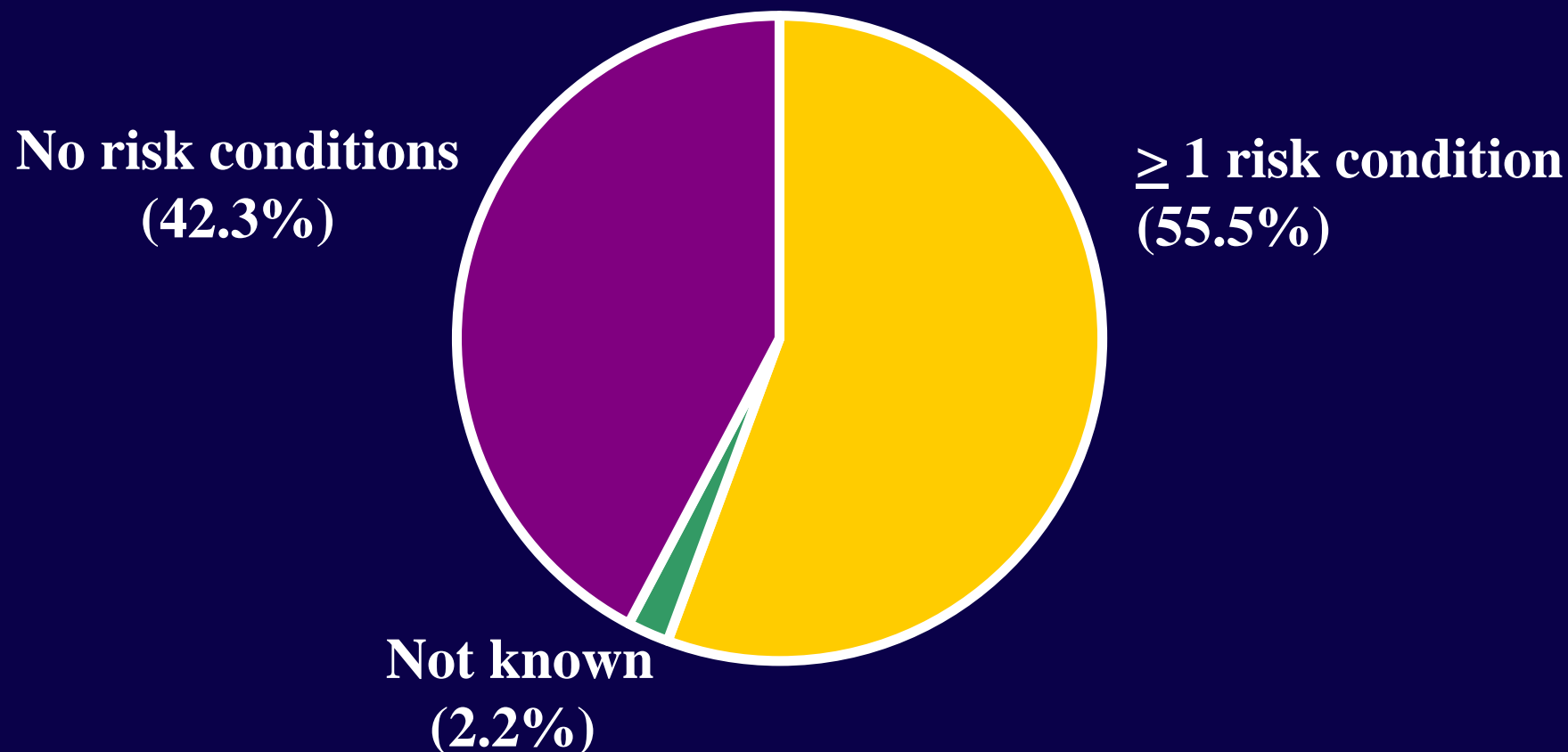
### But:

- were eligible for statin therapy by ATP III based on calculated > 10% 10-year risk for myocardial infarction or coronary death

# Sponsor's Results: Correct Self-Selection

Self-selected AL-MASM		484
– Without physician override (AL)	68	
– With physician override (MASM)	416	
Closely adhered to label		202
Did not adhere to label benefit criteria	357	
– Eligible for statin therapy		258
	Total	<hr/> 944

# Users with Relative Contraindications for Using Mevacor OTC According to Label

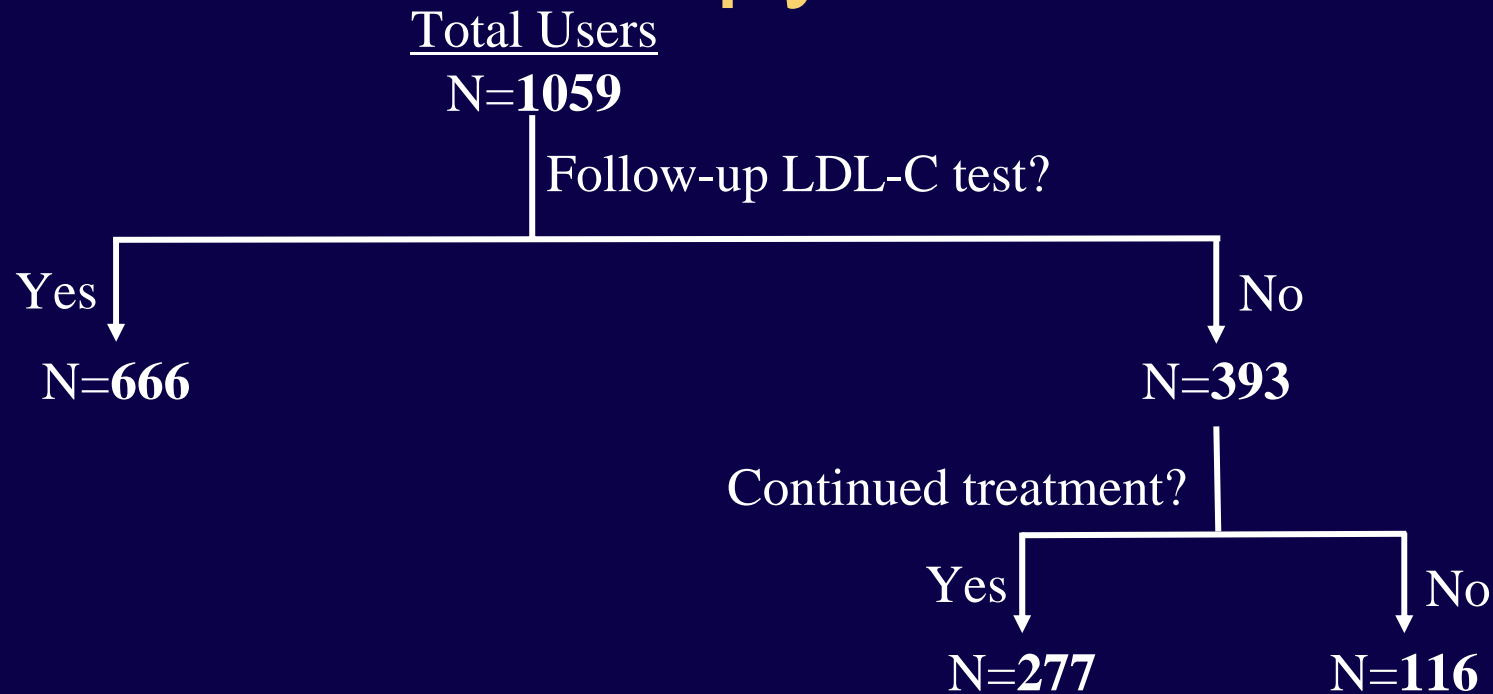


# Users with Relative Contraindications Who Did Not Consult a Physician

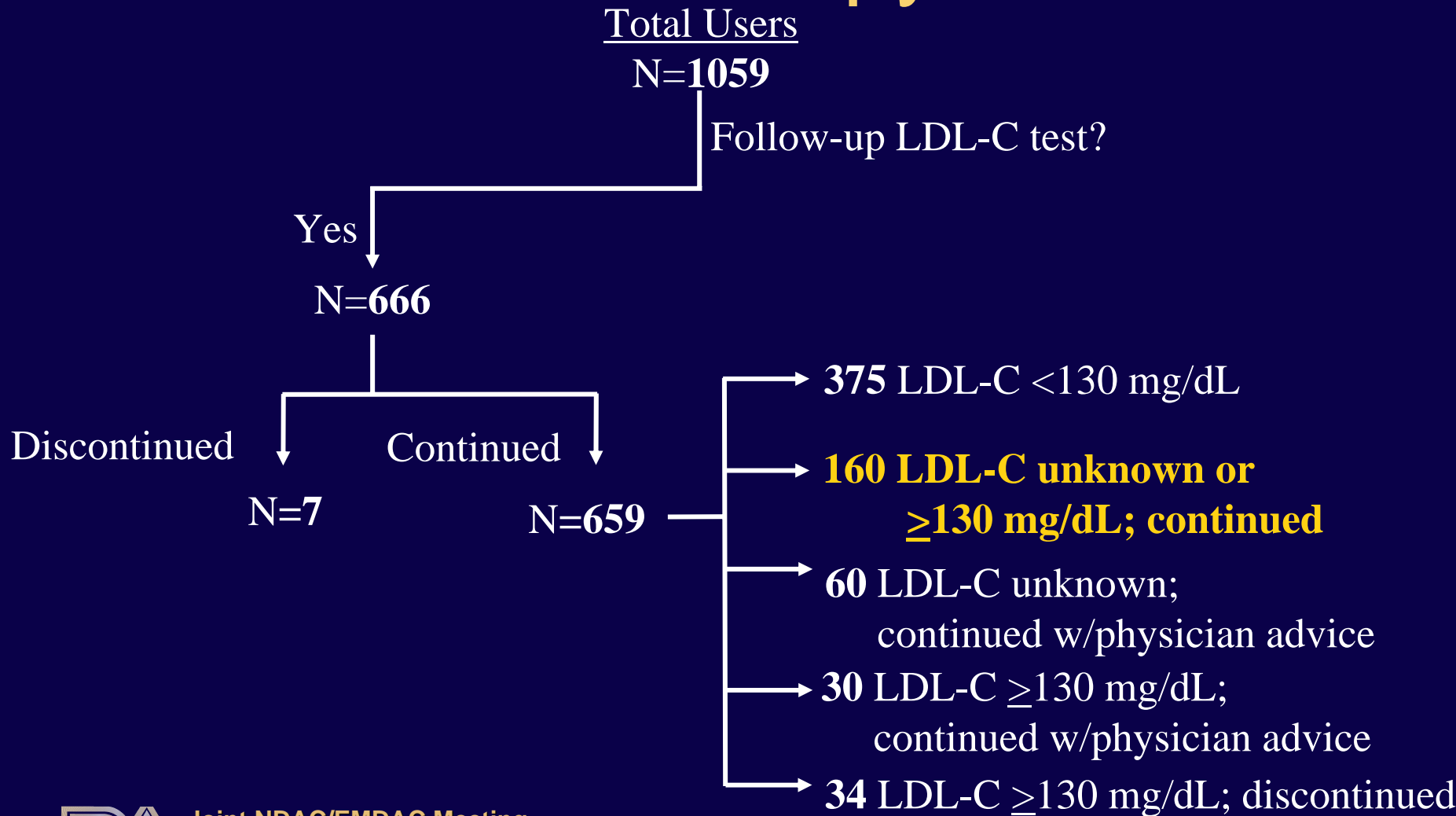
<u>Condition</u>	<u>Total Users</u>	<u>Did Not Consult Doctor</u>
Substituted for prescription lipid lowering medications	165	62 (37.5%)
High LDL-C or TG	435	281 (64.5%)
Taking potentially interacting drugs	32	12 (37.5%)
Diabetes	73	30 (41%)
CHD	89	37 (41.5%)
History of stroke	31	16 (51.6%)
History of previous muscle pain while on statin	86	53 (61.6%)



# Decisions Regarding Continuation of Therapy



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# Achievement of the LDL-C Goal at the End of the Study

- 548 of 878 Users with known LDL-C value had LDL-C < 130 mg/dL at the end of the study
  - 160 with LDL-C < 130 mg/dL at baseline
  - 39 LDL-C level at baseline unknown
  - 349 with LDL-C > 130 mg/dL at baseline

# Safety Data

- 17% of Users had drug-related adverse events
  - 1 serious allergic reaction to lovastatin
  - no other serious drug-related adverse events

# Summary

## (Cholesterol Knowledge)

- 69% of Purchasers needed more information to make a purchase or use decision
- 47.7% correctly identified their LDL-C
- 33% of Users did not know their LDL-C at the initial visit

# Summary (Self-Selection)

- 37% of women Users were < 55 years of age
- 26% of Users met the age and baseline LDL-C level 130-170 mg/dL
- 19% of Users met the age, LDL-C and risk factor for CHD criteria
- 10% of Users met all label eligibility criteria without a physician override

# Summary

## (CHD risks and contraindications)

- 42.7% of Users had  $<2$  CHD risk factors
- 55.5% of Users had  $\geq 1$  relative contraindication according to the label for the use of Mevacor

# Summary (Follow-up LDL-C)

- 63% of Users had a follow-up cholesterol test
- 35.6% of Users achieved the LDL-C goal on their follow-up testing
- Median reduction in LDL-C in the User population was 21%
- 548 (62%) of Users with known LDL-C value at the end of 6 months had an LDL-C <130 mg/dL
  - 199 Users started at an LDL-C <130 mg/dL or had missing baseline LDL-C



# Summary

- No new serious safety signals during the study
- Based on the CUSTOM results, it is likely to be used by:
  - Women of childbearing age
  - Consumers with contraindicated conditions
  - Consumers with no risk or low risk for CHD
  - Consumers at high risk for CHD