Lipid Guidelines: *The Importance of Non-Fasting Lipids in Cardiovascular Risk Stratification*

Lipid Guidelines:

The Importance of Non-Fasting Lipids in Cardiovascular Risk Stratification

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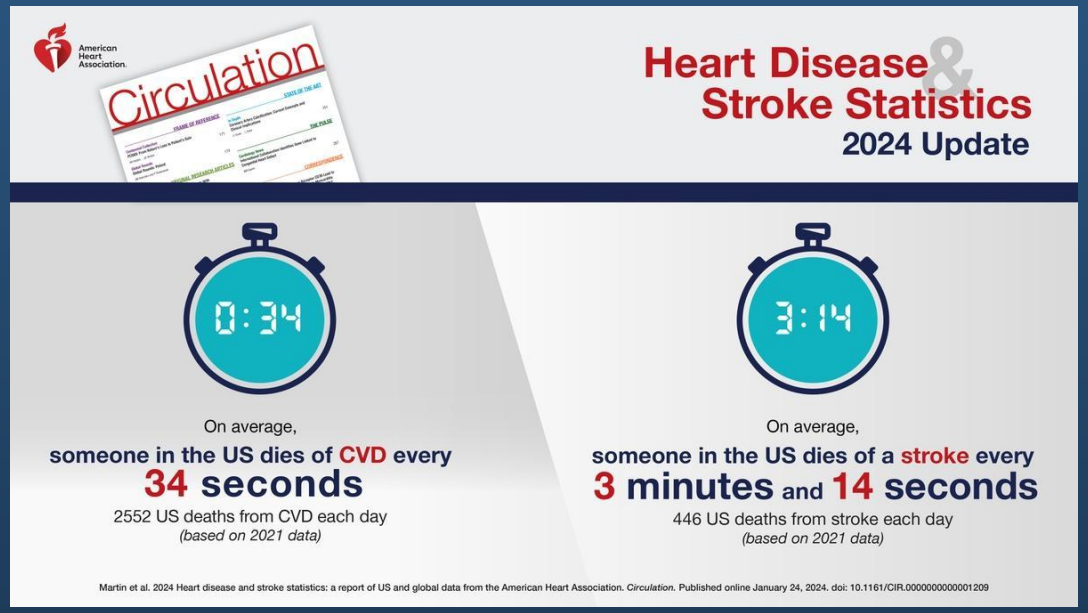
Global Burden of Cardiovascular Disease – *Key Facts*



- **CVDs are the number 1 cause of death globally:** more people die annually from CVDs than from any other cause.
- Over three quarters of CVD deaths take place in low- and middle-income countries.
- *Most cardiovascular diseases can be prevented* by addressing behavioural risk factors such as tobacco use, unhealthy diet and obesity, physical inactivity and harmful use of alcohol using population-wide strategies.
- People with cardiovascular disease or who are at high cardiovascular risk (due to the presence of one or more risk factors such as hypertension, diabetes, hyperlipidaemia or already established disease) need early detection and management using counselling and medicines, as appropriate.

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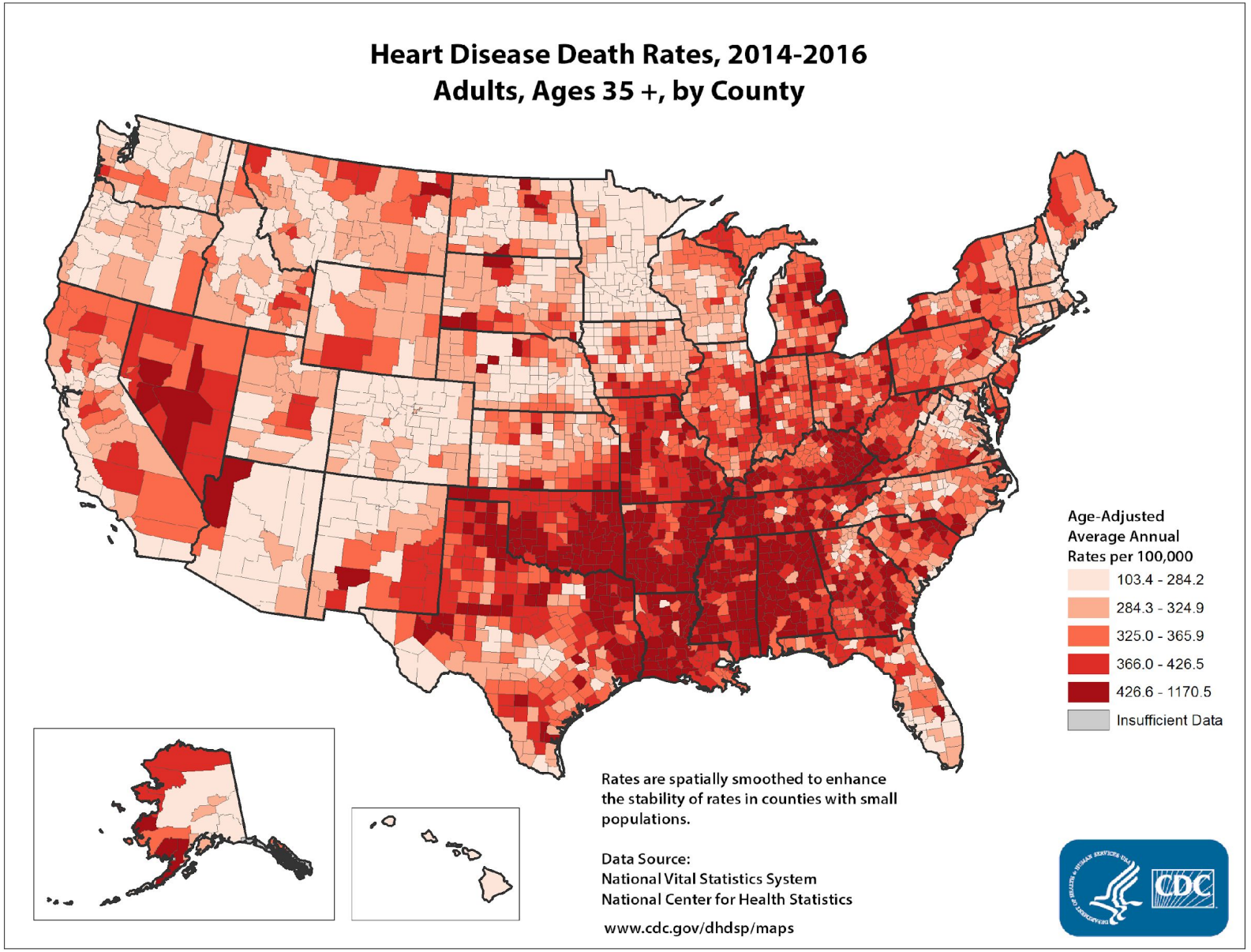

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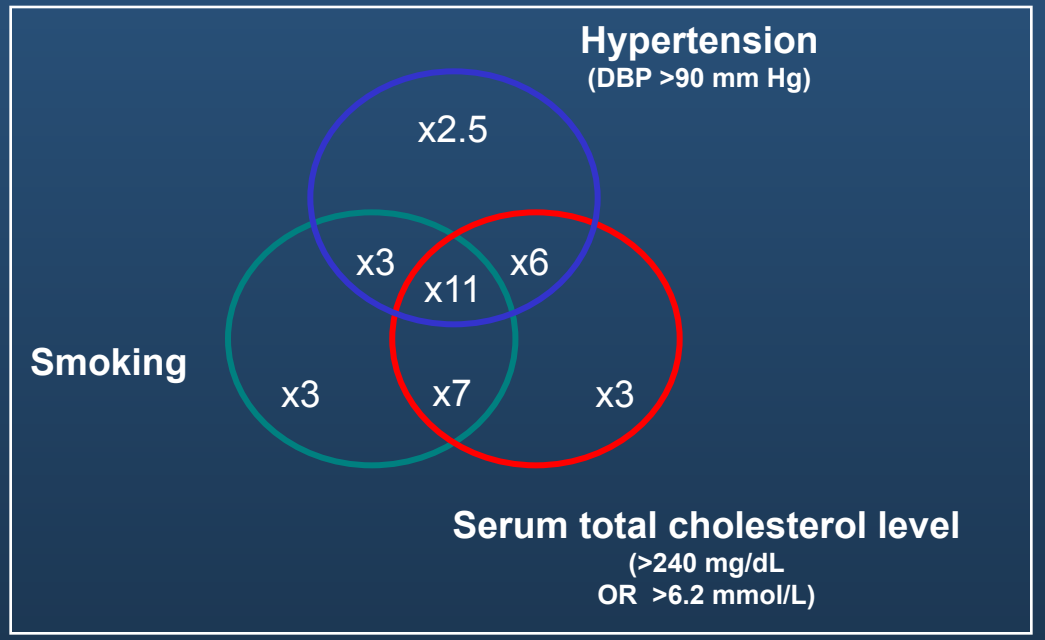
CVD DISEASE RISK FACTORS

Modifiable:

- Smoking
- Hypertension
- Diabetes mellitus
- Obesity
- Dietary factors
- Thrombogenic factors
- Sedentary lifestyle
- Dyslipidemia
  - Raised LDL-C
  - Low HDL-C
  - Raised TGs

Non-modifiable:

- Family history
- Age
- Gender



Adapted from Kannel WB et. al. *Am Heart J.* 1986. **12**:825-836.

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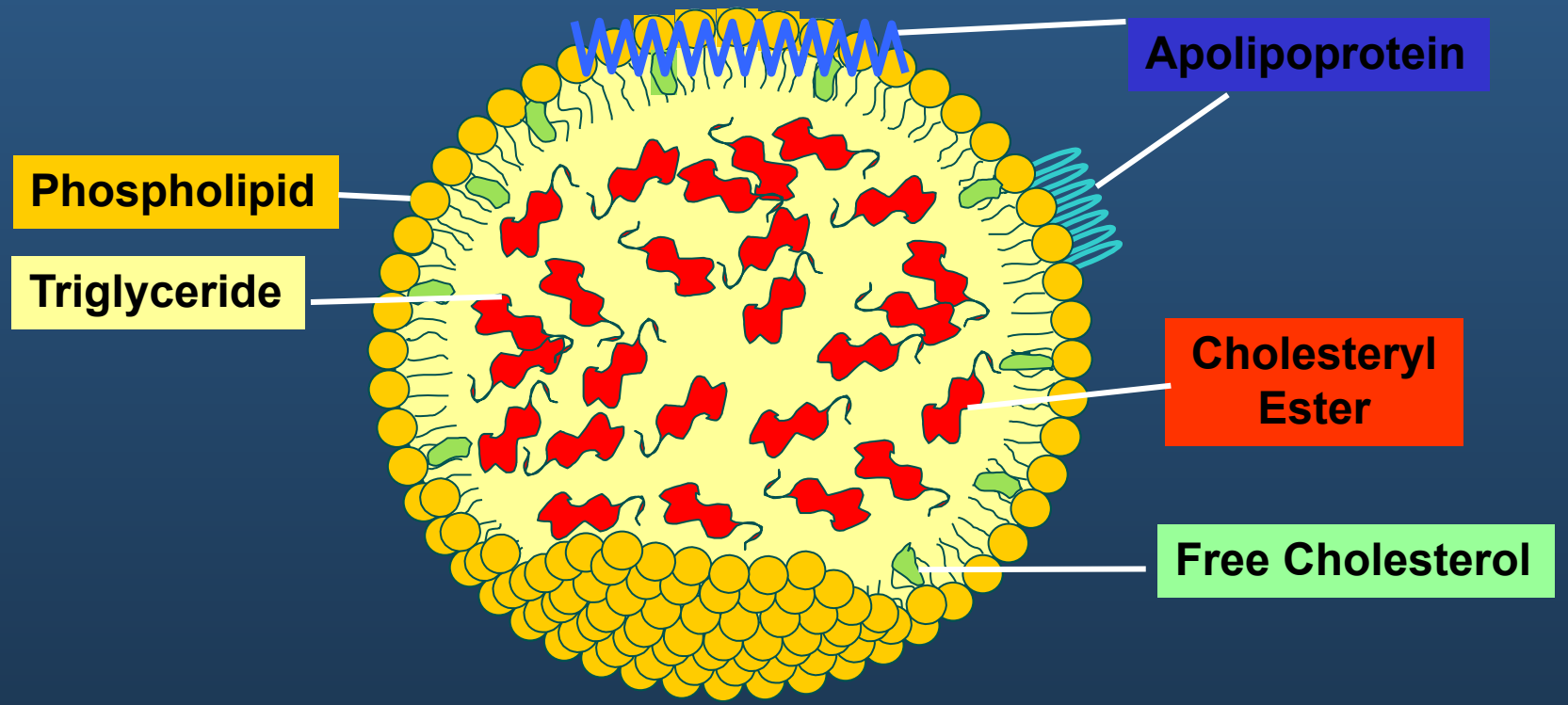
Lipoproteins

Spherical Microemulsion Particles



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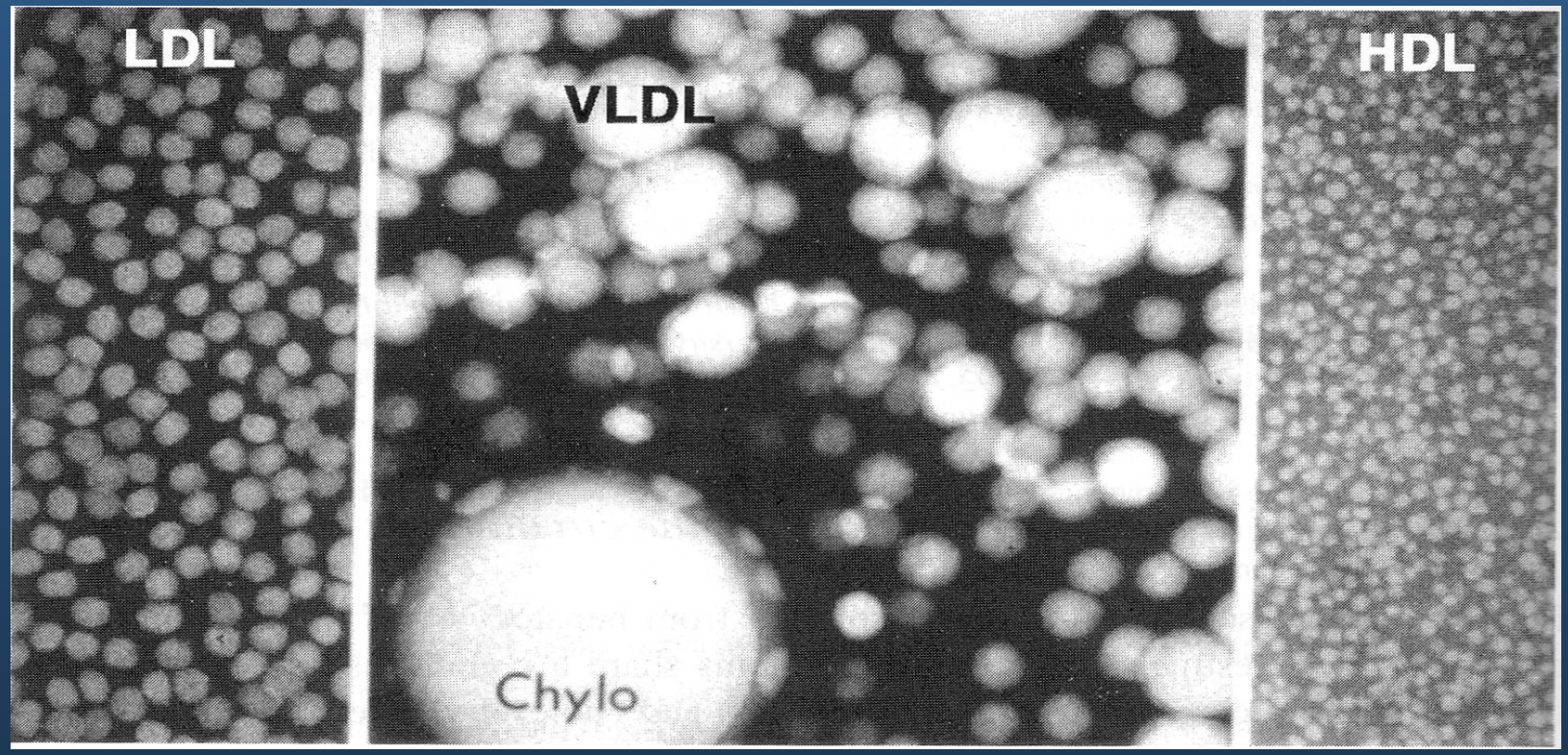
Major Lipoprotein Classes:

Chylomicron, VLDL, LDL, HDL



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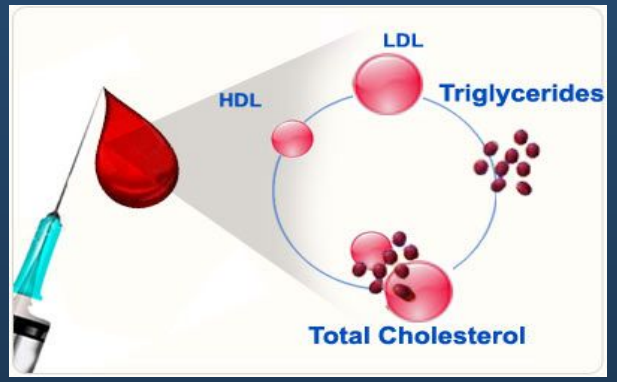
Biomarkers of Dyslipidemia and CHD Risk

Traditional risk markers

Total Cholesterol
LDL Cholesterol
HDL Cholesterol
Triglyceride



Non-Traditional risk markers

Non-HDL Cholesterol (calculated)
Apolipoprotein B
LDL particle size
C-reactive protein (CRP)
Lipoprotein(a)
Homocysteine
Fibrinogen
Plasminogen activator inhibitor
Cell adhesion molecules

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LDL cholesterol

- Remains the cornerstone of dyslipidemia therapy
- Strongly associated with atherosclerosis and CHD events
- *A 10% increase results in a 20% increase in CHD risk*
- Most patients with elevated LDLc untreated

National Centre for Health Statistics. National Health and Nutrition Examination Survey (III)

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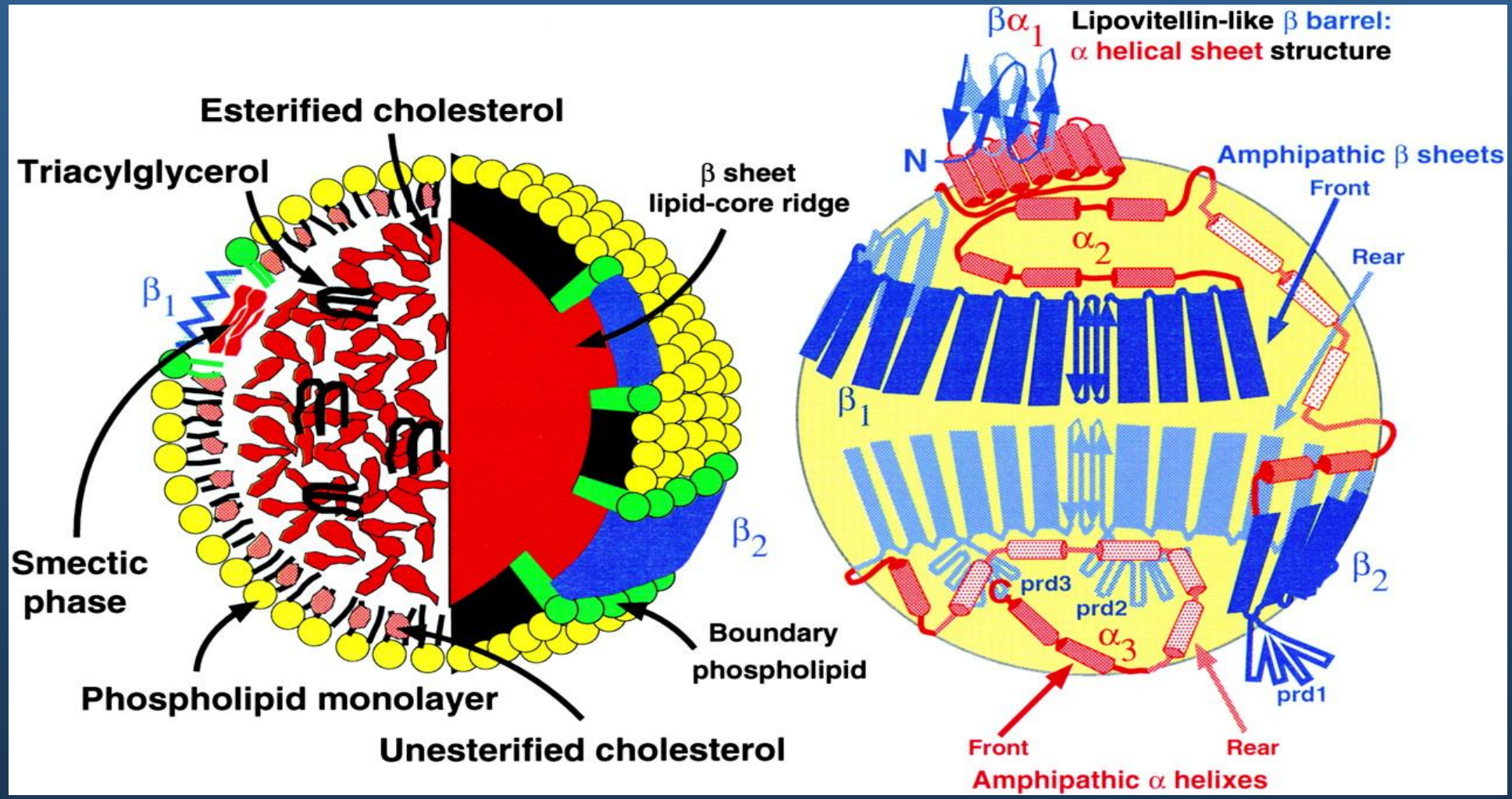
LDL Particle



Segrest, J. P. et al. J. Lipid Res. 42:1346-1367

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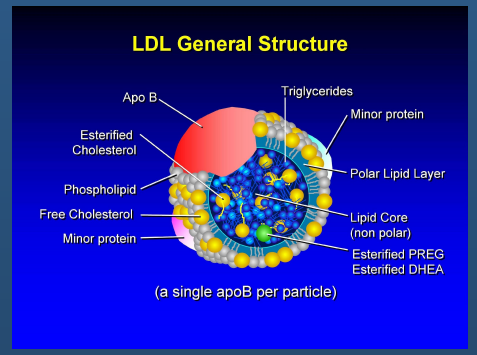
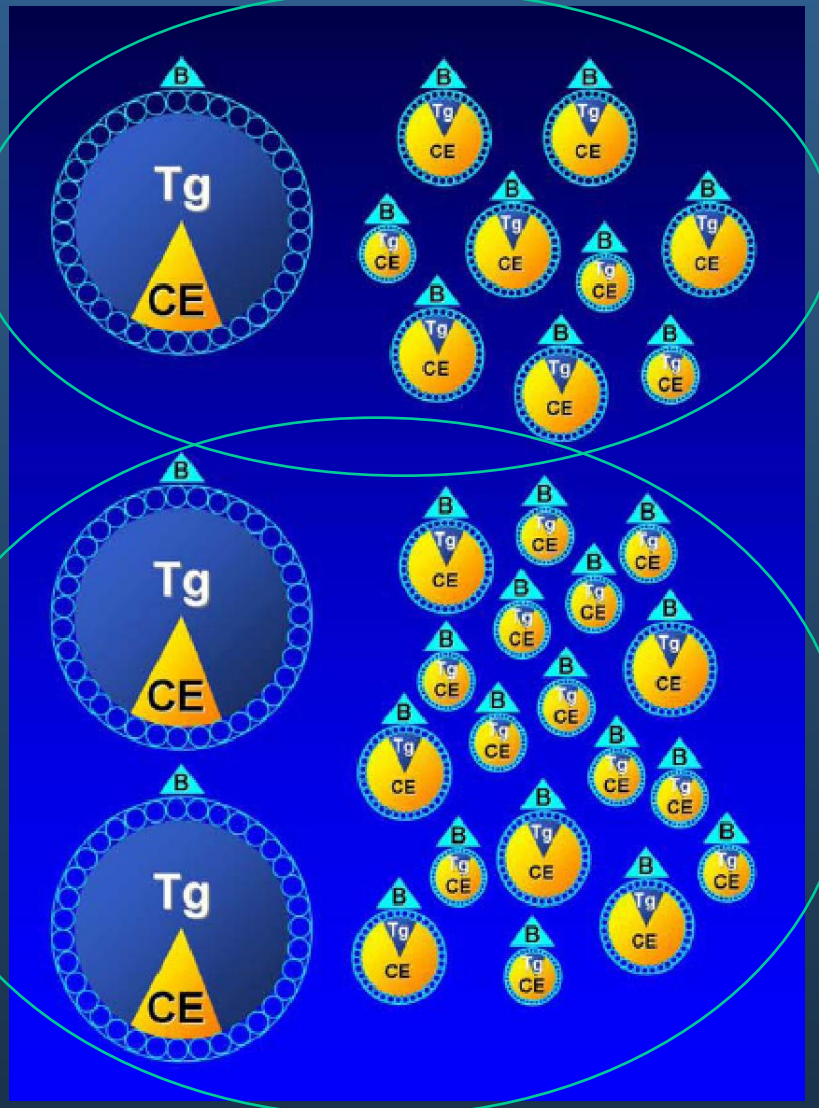
LDL Particles

- Each LDL particle has one molecule of ApoB protein
- ApoB Lipoprotein Particles in Healthy Subjects compared to those with Hypertriglyceridemic Hyper apoB Phenotype (the latter have higher number of LDL particles and higher plasma apoB)



Smaller/denser LDL particles = Higher CHD Risk



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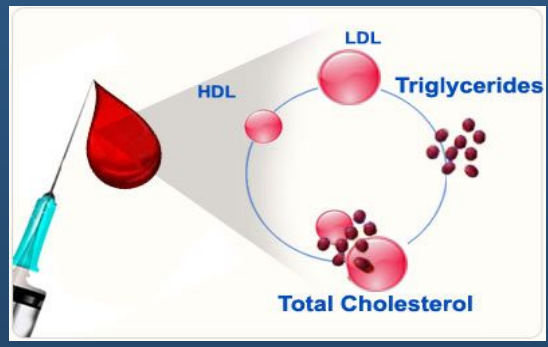
LIPID Guidelines

Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult



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Who to Screen

WHO TO SCREEN

Men ≥40 years of age; women ≥40 years of age (or postmenopausal)

Consider earlier in ethnic groups at increased risk such as South Asian or First Nations individuals

All patients with the following conditions regardless of age:

- Clinical evidence of atherosclerosis
- Abdominal aortic aneurysm
- Diabetes mellitus
- Arterial hypertension
- Current cigarette smoking
- Stigmata of dyslipidemia (arcus cornealis xanthelasma or xanthoma)
- Family history of premature CVD*
- Family history of dyslipidemia
- Chronic kidney disease**
- Obesity (BMI ≥30 kg/m^2)
- Inflammatory disease
- HIV infection
- Erectile dysfuntion
- Chronic obstructive pulmonary disease
- Hypertensive diseases of pregnancy

*Men <55 and women <65 yrs of age in first degree relative
**CKD: eGFR <60 ml/min/1.73 m2 or ACR >3 mg/mmol for at least 3 months duration

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How to Screen

HOW TO SCREEN

For all:

- History and physical examination
- Standard lipid panel (TC, LDL-C, HDL-C, TG)
- Non-HDL-C (will be calculated from profile)
- Glucose
- eGFR

Optional:

- ApoB
- Urine albumin:creatinine ratio (if eGFR <60 mL/min/1.73m², hypertension or diabetes)

LIPID TESTING CAN GENERALLY BE DONE NON-FASTING

RECOMMENDATIONS

- We recommend non-fasting lipid and lipoprotein testing which can be performed in adults in whom screening is indicated as part of a comprehensive risk assessment to reduce CVD events *(Strong Recommendation, High Quality Evidence)*.

- We suggest that for individuals with a history of triglyceride levels >4.5 mmol/L that lipid and lipoprotein levels be measured fasting *(Conditional Recommendation, Low Quality Evidence)*.

Practical tip: Compared to fasting lipid values, there will be minimal change with non-HDL-C, a slight decrease in LDL-C and small increase in triglyceride concentrations when individuals do not fast.

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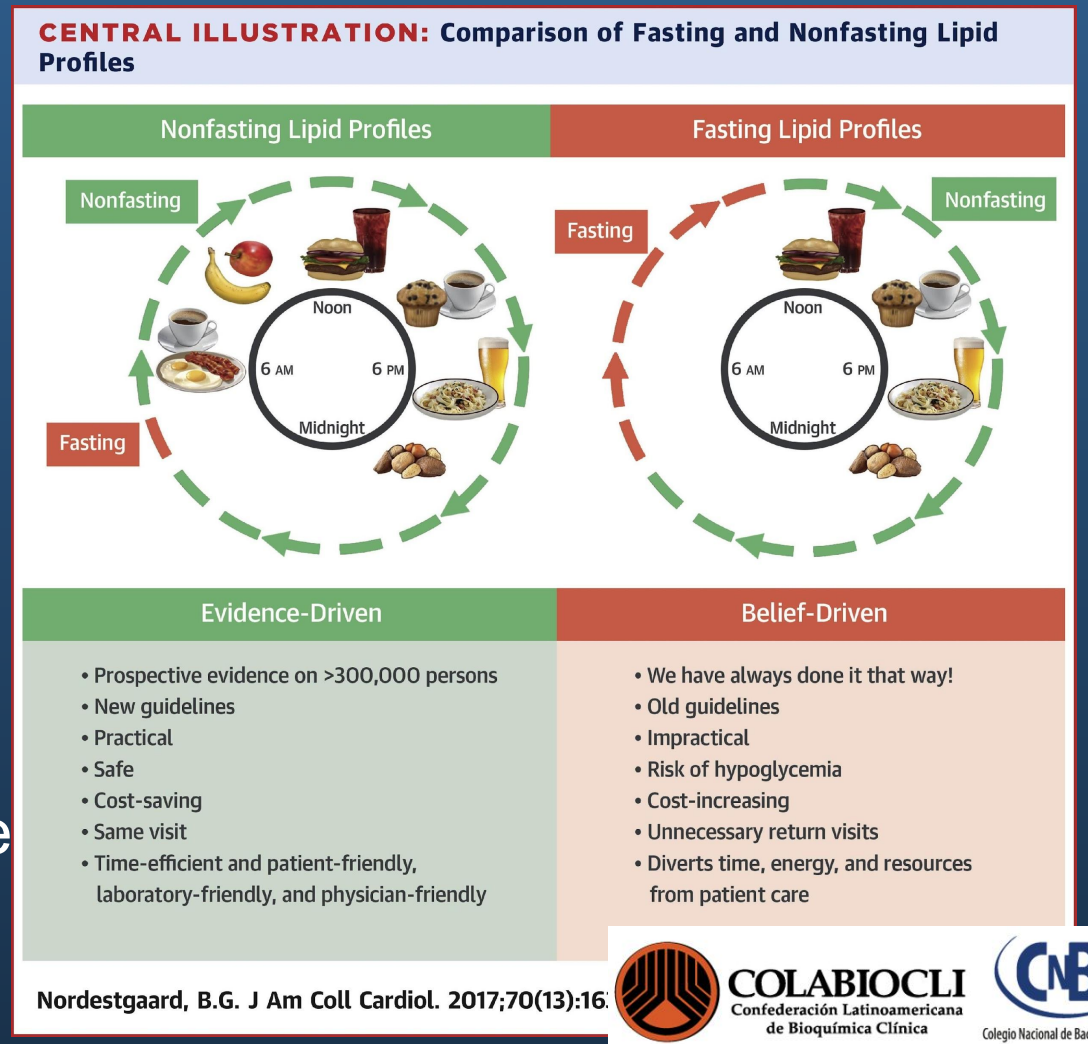
Fasting versus non-fasting Lipid Profiles

- Non-fasting lipids more representative of the normal state
- Increases convenience for patients
- Improve patient compliance
- Eliminates testing difficulty for patients who have trouble with prolonged fasting
- Samples received in lab throughout the day



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Clinical Guidelines: *Fasting or Non-Fasting?*

- Danish Society for Clinical Biochemistry (2009)
- UK National Institute of Excellent (NICE, 2014)
- Canadian Cardiovascular Society Guidelines (2016)
- European Atherosclerosis Society and the European Federation of Clinical Chemistry and Laboratory Medicine (EAS/EFLM, 2016)
- 2019 ACC/AHA Guideline on the Primary Prevention o Prev f Cardiovascular Disease

Non-Fasting Recommended

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2016 European Atherosclerosis Society and the European Federation of Clinical Chemistry and Laboratory Medicine (EAS/EFLM) Guidelines

Recommended Decision Limits/Cut-Offs

Abnormal Concentrations	Non-fasting (mmol/L)	Fasting (mmol/L)	Change
Triglycerides	≥2	≥1.7	▲
Total Cholesterol	≥5	≥5	No change
LDLc	≥3	≥3	No Change
Remnant Cholesterol	≥0.9	≥0.8	▲
HDLc	≤1	≤1	No Change
non-HDLc	≥3.9	≥3.8	▲
Apo B	≥1.0 g/L	≥1.0 g/L	No Change

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Canadian Society of Clinical Chemists
(CSCC) Working Group

Harmonized Lipid Reporting in Canada: *One Step Closer*

Harmonized Adult Lipid Reporting Recommendations

CCS Guidelines (2021)
NIH Equation Studies
CSCC Position Papers

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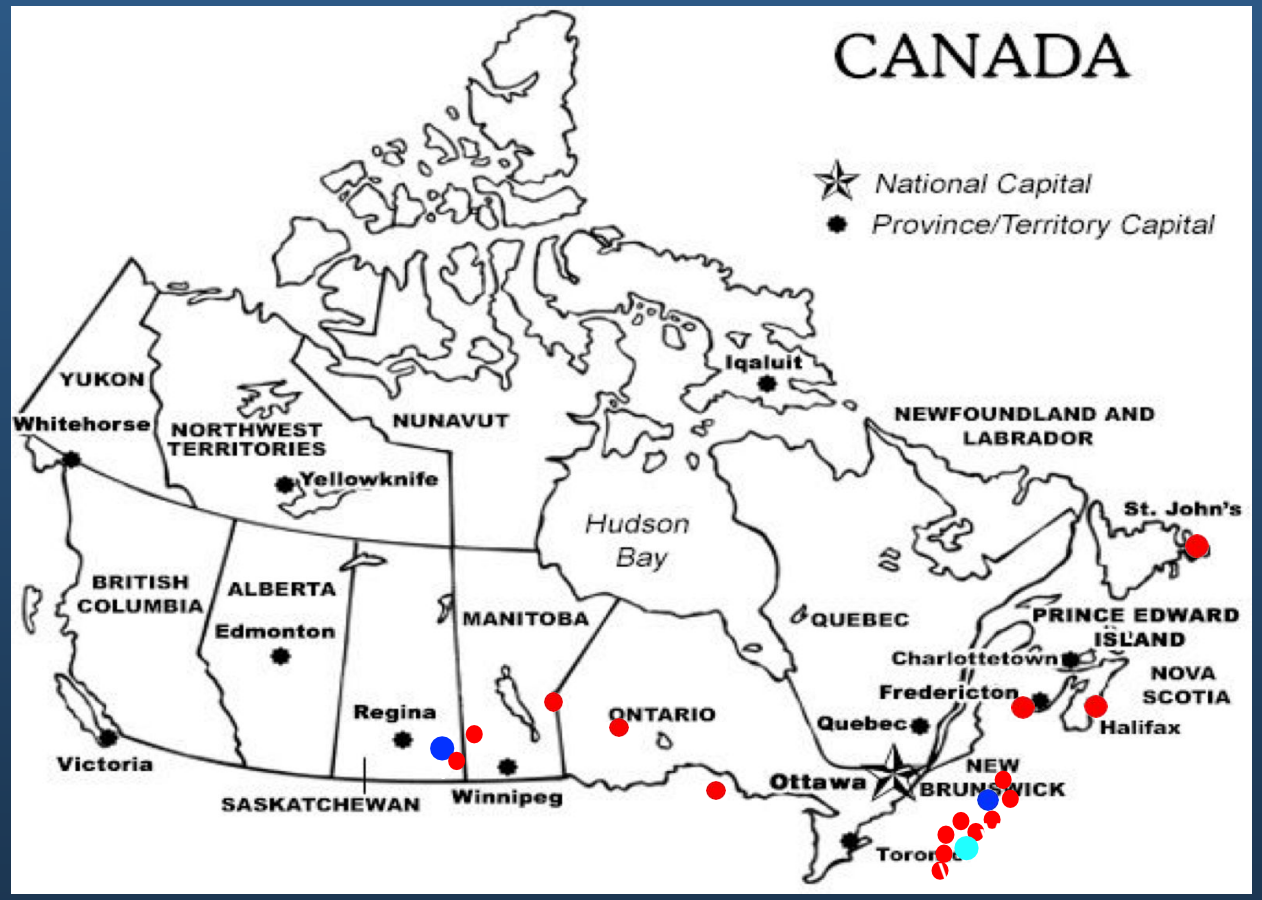
National Survey of Lipid Reporting Practices in Clinical Laboratories



Legend

- Single Laboratory
- 2 Laboratories
- 7 Laboratories

27 Laboratories responded to the survey

There was representation from all provinces with the exception of PEI, Nunavut, Yukon and Northwest Territories.

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Canadian Journal of Cardiology 38 (2022) 1180–1188

Guidelines

Canadian Society of Clinical Chemists Harmonized Clinical Laboratory Lipid Reporting Recommendations on the Basis of the 2021 Canadian Cardiovascular Society Lipid Guidelines

Nicole M.A. White-Al Habeeb, PhD,[a,‡] Victoria Higgins, PhD,[b,c,‡] Allison A. Venner, PhD,[d] Dana Bailey, PhD,[a] Daniel R. Beriault, PhD,[e,f] Christine Collier, PhD,[g] and Khosrow Adeli, PhD;[e,h] on behalf of the Canadian Society of Clinical Chemists Working Group on Reference Interval Harmonization

[a] Dynacare, Brampton, Ontario, Canada; [b] DynaLIFE Medical Labs, Edmonton, Alberta, Canada; [c] Department of Laboratory Medicine and Pathology, University of Alberta, Edmonton, Alberta, Canada; [d] Alberta Precision Laboratories and Department of Pathology and Laboratory Medicine, University of Calgary, Calgary, Alberta, Canada; [e] Department of Laboratory Medicine and Pathobiology, University of Toronto, Toronto, Ontario, Canada; [f] Department of Laboratory Medicine and Pathobiology, St Michael's Hospital, Toronto, Ontario, Canada; [g] Pathology and Laboratory Medicine, Royal Columbian Hospital, New Westminster, British Columbia, Canada; [h] Department of Pediatric Laboratory Medicine, The Hospital for Sick Children, Toronto, Ontario, Canada

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Box 1. CSCC recommendations for the laboratory reporting of lipids 2021

Recommendation 1. We recommend laboratories offer nonfasting and fasting lipid assessment.

Recommendation 2. We recommend laboratories offer a lipid panel consisting of total cholesterol, LDL-C, HDL-C, non-HDL-C, and triglycerides. ApoB and Lp(a) should be offered only as individually orderable tests.

Recommendation 3. We recommend laboratories adopt a lipid reporting format that includes lipid decision thresholds on the basis of lipid screening in primary prevention patients.

Recommendation 4. We recommend including minimal interpretive comments on the lipid report with reference to the 2021 CCS guidelines, where applicable.

Recommendation 5. We recommend that all laboratories should offer Lp(a), either as an in-house or send-out test, using assays that quantify apolipoprotein (a) [Apo(a)] in molar units (nmol/L), and that the assay is stated in the report.

Recommendation 6. We recommend implementation of the new NIH equation, rather than the Friedewald equation, for calculating LDL-C in all patients.

- Recommendation #1: Non-fasting vs. Fasting Assessments
  - Non-fasting is preferred for convenience, fasting required for triglycerides >4.52 mmol/L.
  - Record fasting hours on lab reports.

- Recommendation #2: Standard Lipid Panel
  - Components: total cholesterol, LDL-C, HDL-C, non-HDL-C, triglycerides.
  - ApoB and Lp(a) available as separate tests for additional risk stratification.

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Lipid Reporting Format

- Primary Prevention Decision Thresholds
  - LDL-C: Flag at ≥3.50 mmol/L for intermediate-risk; ≥5.00 mmol/L for low-risk.
  - Non-HDL-C: Flag at ≥4.20 mmol/L for intermediate-risk.
  - ApoB: Flag at ≥1.05 g/L, especially with triglycerides >1.50 mmol/L.

- Interpretive Comments
  - Reference the 2021 CCS Guidelines.
  - Include notes on triglycerides and LDL-C calculation limitations.

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Proposed Common Adult Lipid Reports

Analyte	Flagging Decision Limit
Total Cholesterol	<5.20 mmol/L
HDL-C	(M) >1.00 mmol/L
	(F) >1.30 mmol/L
LDL-C	<3.5 mmol/L
Triglycerides	<1.7 mmol/L
Non-HDL-C	<4.3 mmol/L
ApoB	<1.20 g/L
Hours fasting	Record hours fasted (h)

Table 1. Adult Flagging Limits

Risk Level	Initiate Treatment	Primary Target	Alternate Target
High (FRS ≥ 20%)	Consider treatment in all patients	<2.0 mmol/L or >50% decrease in LDL-C	Non-HDL-C <2.6 mmol/L ApoB <0.8 g/L
Intermediate (FRS 10%-19%)	Consider treatment if: LDL-C ≥3.5 mmol/L or Non-HDL-C ≥4.3 mmol/L or apoB ≥ 1.2 g/L or ≥ risk factor	<2.0 mmol/L or >50% decrease in LDL-C	
Low (FRS < 10%)	Consider treatment if: 1) LDL-C ≥ 5.0 mmol/L 2) Familial hypercholesterolemia	>50% decrease in LDL-C	
Refer to 2016 CCS Guidelines (Link to Framingham Risk Score calculator will be provided by local lab) If TG >1.5 mmol/L, use non-HDL-C or apoB treatment target (rather than LDL-C) If TG > 4.5 mmol/L, LDL-C will be canceled. Repeat testing in the fasted state.			

Table 2. Adult Interpretive Comments

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Recommended Adult (>18 years) Lipid Report

Analyte	Decision Limit	Result Comment
Total Cholesterol	<5.2 mmol/L	Treatment thresholds and targets based on the 2016 CCS Guidelines For patients ≥40 years, estimate risk using the modified Framingham Risk Score (FRS): **Low Risk (FRS < 10%)** Treatment advised if LDL-C ≥ 5.0 mmol/L Treatment target: ≥ 50% reduction LDL-C **Intermediate Risk (FRS 10 - 19%)** Treatment advised if LDL-C ≥ 3.5 mmol/L OR Non-HDL-C ≥4.3 mmol/L OR ApoB ≥ 1.2 g/L OR Men≥50 and women≥60 yrs with ≥1 additional CV risk factor Treatment targets: LDL-C ≤ 2.0 mmol/L OR decrease by ≥50% OR Non-HDL-C ≤2.6 mmol/L OR ApoB ≤ 0.8 g/L **High Risk (FRS ≥20% or presence of high risk features)** Treatment advised in all patients Treatment targets: LDL-C ≤2.0 mmol/L OR decrease by ≥50% OR Non-HDL-C ≤ 2.6 mmol/L OR ApoB ≤ 0.8 g/L Note: If non-fasting, triglycerides <2.0 mmol/L acceptable. Triglycerides >1.5 mmol/L, recommend to use non-HDL-C or ApoB as treatment target of choice If Triglycerides >4.5 mmol/L, recommend to measure lipids and lipoproteins fasted
HDL-C	>1.0 mmol/L	
LDL-C	<3.5 mmol/L	
Triglycerides	<1.7 mmol/L	
Non-HDL-C	<4.3 mmol/L	
Fasting (hours)	Record (h)	

ApoB	<1.2 g/L	Treatment thresholds and targets based on the 2016 CCS Guidelines **If ≥1.2 g/L** Treatment advised if Framingham Risk Score is Intermediate of High Treatment target for ApoB ≤ 0.8 g/L **If < 1.2 g/L** Treatment target for ApoB ≤ 0.8 g/L

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New NIH Equation for LDL-C

LDL-C = TC/0.948 – HDL-C/0.971 – (TG/8.56 + [TG x Non-HDL-C]/2140 – TG^2/16100) – 9.44

Advantages Over Friedewald Equation

- More accurate, especially in non-fasting samples and high triglycerides.
- Better estimation at low LDL-C levels (e.g., <1.80 mmol/L)

Implementation

- Transition to NIH equation with proper clinician communication.
- Clearly state LDL-C calculation method on reports.

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Harmonized Pediatric Lipid Reporting Recommendations

Canadian Society of Clinical Chemists (CSCC)

Khoury, M., et al. (2022). CCS/CPCA Clinical Practice Update on Pediatric Dyslipidemia.
Higgins, V., et al. (2021). Lipid Reporting Practices in Canadian Laboratories.
NHLBI Expert Panel (2011). Integrated Guidelines for Cardiovascular Health in Children.

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Pediatric Lipid Testing/Interpretation

Pediatric Dyslipidemia – Early Detection and Management:

- The prevalence of pediatric obesity has increased, leading to early-onset dyslipidemia, a key risk factor for atherosclerosis and CVD.
- Early detection and management of dyslipidemia in children are critical to prevent cardiovascular disease later in life.
  - Atherosclerosis begins in childhood, and untreated dyslipidemia can persist into adulthood.

Need for Harmonization:

- Despite CCS and CPCA guidelines, there is a lack of standardized lipid reporting in Canadian laboratories.
- CSCC's Working Group on Reference Interval Harmonization (hRI-WG) aims to standardize pediatric lipid reporting across Canadian laboratories.

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Key Recommendations

Recommendation #1:

- Offer both non-fasting and fasting lipid assessments. Non-fasting testing is convenient and reflects total atherogenic particle burden.
- Include a lipid panel with total cholesterol, LDL-C, HDL-C, non-HDL-C, and triglycerides. Lp(a) and ApoB available as individually orderable tests.
- Flag total cholesterol, LDL-C, and non-HDL-C at ≥95th percentile, HDL-C at <10th percentile based on CCS/CPCA/NHLBI guidelines and CALIPER validation.

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Interpretation and Flagging

Percentile-based Flagging:

- Flag total cholesterol, LDL-C, non-HDL-C at ≥95th percentile, HDL-C at <10th percentile.
- Implement NIH equation for more accurate LDL-C calculations in non-fasting samples.
- Provide interpretive comments and flagging based on percentile thresholds, ensuring accurate clinical decision-making.

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Proposed Common Pediatric Lipid Reports

Analyte	Age Range (years)	Lower Decision Limit (2.5th percentile)	Borderline High (75th percentile)
Total Cholesterol	2-<18	2.90 mmol/L	4.54 mmol/L
LDL-C	2-<10 M	1.22 mmol/L	2.43 mmol/L
	2-<10 F	1.52 mmol/L	2.54 mmol/L
	10-<19	1.18 mmol/L	2.61 mmol/L
Triglycerides	2-<18	0.50 mmol/L	1.44 mmol/L
Non-HDL-C	2-<10 M	1.79 mmol/L	3.01 mmol/L
	2-<10 F	2.07 mmol/L	3.24 mmol/L
	10-<19	1.68 mmol/L	3.19 mmol/L
ApoB	2-<6	0.41 g/L	0.72 g/L
	6-<18	0.31 g/L	0.63 g/L
HDL-C	2-<4	1.63 mmol/L	1.04 mmol/L
	4-<13	1.88 mmol/L	1.17 mmol/L
	13-<18 M	1.77 mmol/L	1.05 mmol/L
	13-<18 F	1.86 mmol/L	1.19 mmol/L

Table 3. Pediatric Flagging Limits

Analyte	Age Range (years)	High (95th percentile)	Decision limits based on CALIPER reference data (*Clin Chem 2012;58:854-868; Clin Chim Acta 2018;486:129-134*)
Total Cholesterol	2-<18	5.25 mmol/L	
LDL-C	2-<10 M	3.04 mmol/L	
	2-<10 F	3.16 mmol/L	
	10-<19	3.22 mmol/L	
Triglycerides	2-<18	2.04 mmol/L	
Non-HDL-C	2-<10 M	3.62 mmol/L	
	2-<10 F	3.98 mmol/L	
	10-<19	3.88 mmol/L	
ApoB	2-<6	0.87 g/L	
	6-<18	0.80 g/L	
HDL-C	2-<4	0.93 mmol/L	
	4-<13	1.05 mmol/L	
	13-<18 M	0.93 mmol/L	
	13-<18 F	1.02 mmol/L	

Table 4. Pediatric Interpretive Comments

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Pediatric Lipid Reporting – *Summary*

- CSCC's harmonized recommendations aim to standardize pediatric lipid reporting across Canada.
- Based on 2022 CCS/CPCA guidelines and validated with CALIPER data, implementation will enhance accuracy and improve clinical decision-making.
- Laboratories should adopt these guidelines and engage with the CSCC toolkit for proper implementation.

Khoury, M., et al. (2022). CCS/CPCA Clinical Practice Update on Pediatric Dyslipidemia.
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NHLBI Expert Panel (2011). Integrated Guidelines for Cardiovascular Health in Children.

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