Harmonized Lipid Reporting for Clinical Laboratories based on the 2021 Canadian Cardiovascular Society Lipid Guidelines

CSCC 2022 Roundtable

June 8, 2022

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Outline

- Discuss the 2021 Canadian Cardiovascular Society (CCS) Lipid Guidelines – what's new?
- List the six recommendations for harmonized lipid reporting proposed by the CSCC hRI-WG
- Discuss the advantages and disadvantages of the proposed LIS approaches for their laboratory and main clinical users
- Develop a plan to locally implement harmonized lipid reporting based on consideration of anticipated challenges
- Collaborate with the CSCC hRI-WG to provide insight and updates on their experience of the implementation process

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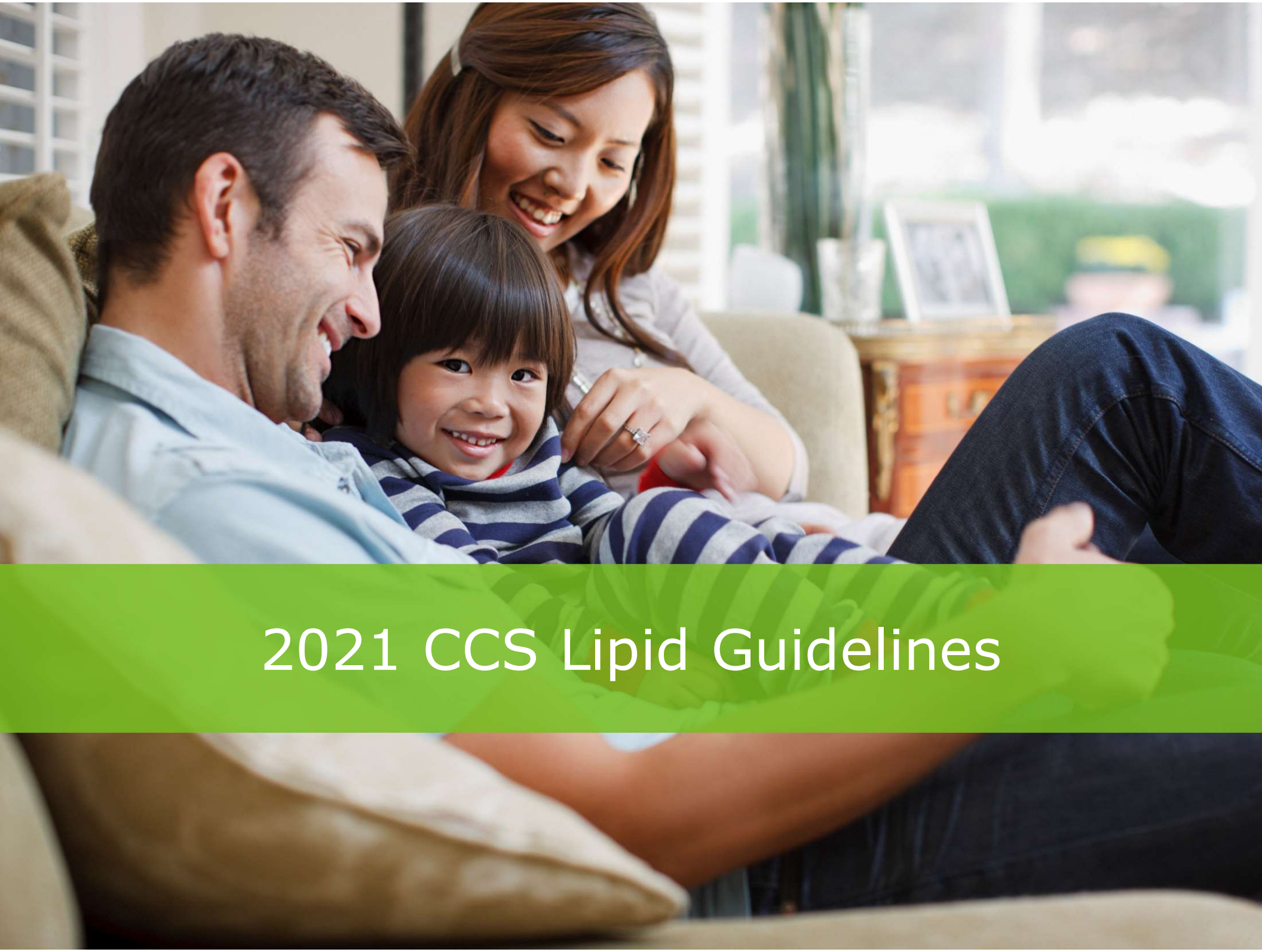
CSCC Reference Interval Harmonization (hRI) Working Group

CSCC hRI Working Group

- **Main Objective:** Establish evidence-based harmonized and/or common reference intervals (where possible) and support their implementation in clinical laboratories across Canada

- 2018 Lipid reporting survey reported significant differences exist in lipid reporting across Canada
  - Decision limits vs. reference intervals
  - Decision limit cutoffs
  - Source of decision limits (most are not using recent CCS guidelines)
  - Interpretative comments

It is essential to harmonize lipid reporting across Canada to ensure appropriate and uniform implementation of lipid and cardiovascular guidelines



2021 CCS Lipid Guidelines

2021 Canadian Cardiovascular Society (CCS) Lipid Guidelines – what's new?

- We recommend that for any patient with triglycerides >1.5 mmol/L, non-HDL-C or ApoB be used instead of LDL-C as the preferred lipid parameter for screening

- We recommend measuring Lp(a) level once in a person's lifetime as a part of the initial lipid screening
- For all patients in the setting of primary prevention with a Lp(a) ≥50 mg/dL (or ≥100 nmol/L), we recommend earlier and more intensive health behavior modification counselling and management of other ASCVD risk factors

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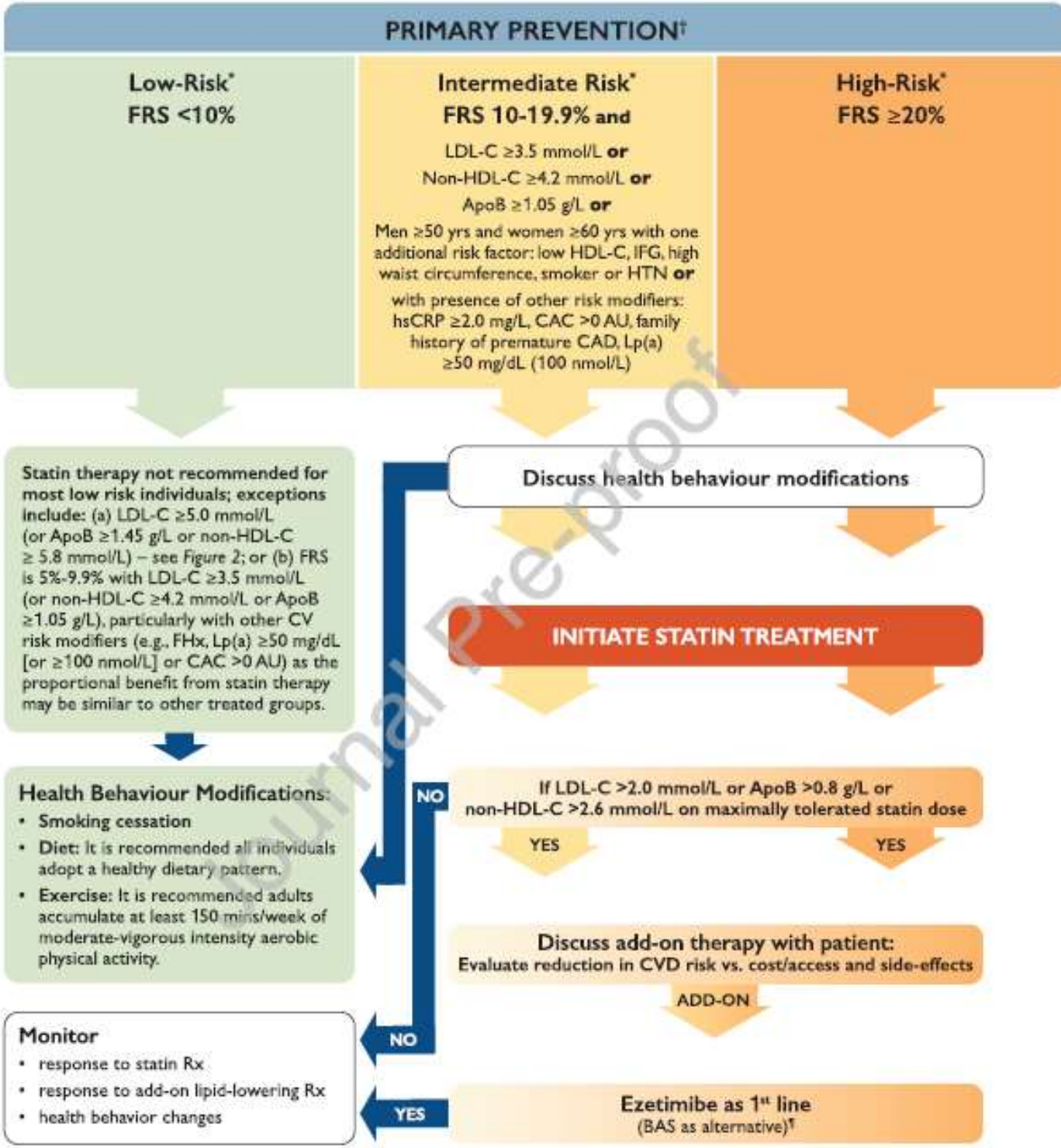
2021 CCS Lipid Guidelines

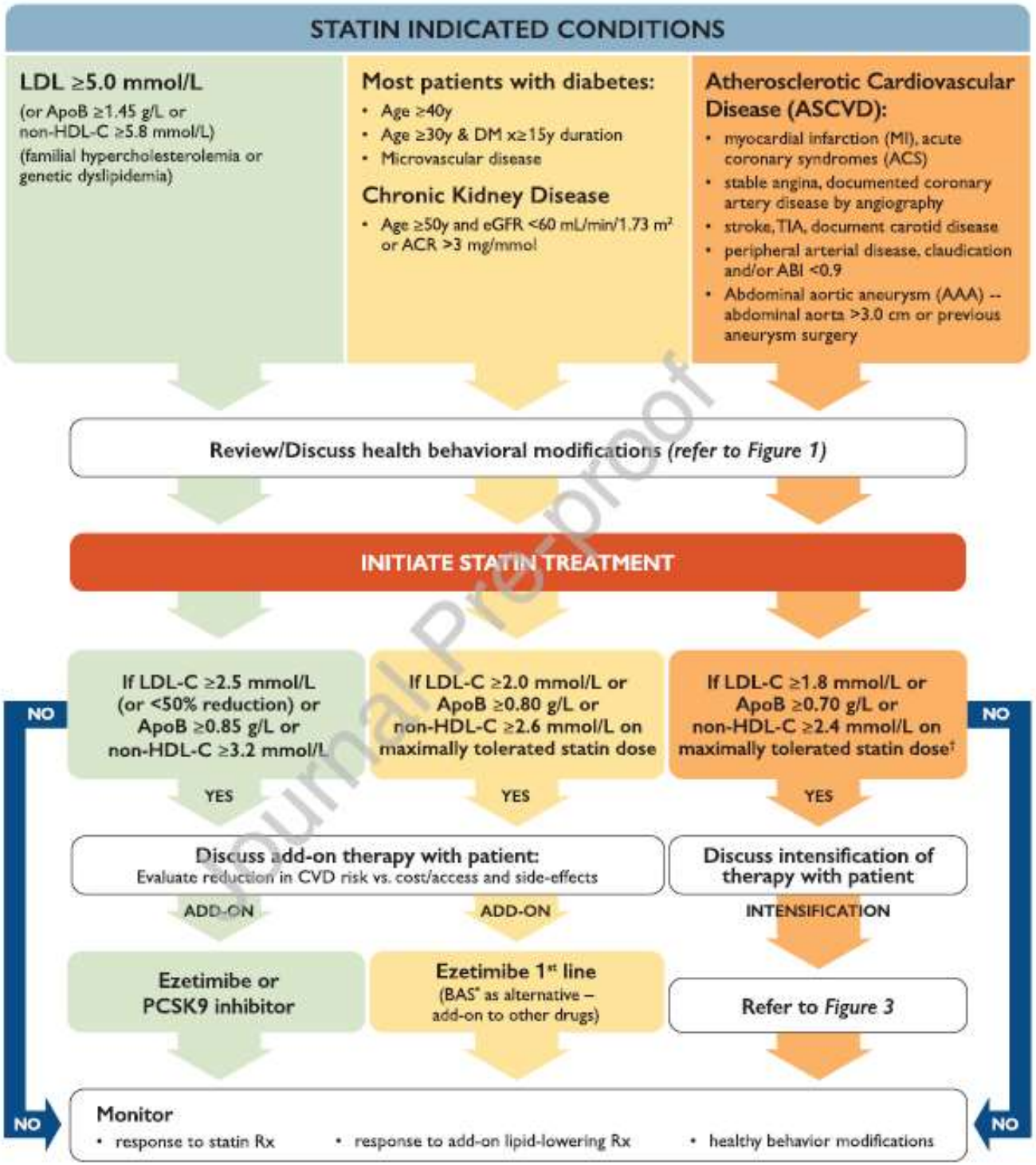
Figure 1. Treatment approach for Primary Prevention (without a statin indicated condition)



Pearson GJ, et al. Canadian Journal of Cardiology 2021;S0828-282X(21)00165-3

2021 CCS Lipid Guidelines

Figure 2. Treatment approach for patients with a statin indicated condition



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2021 CCS
Lipid Guidelines

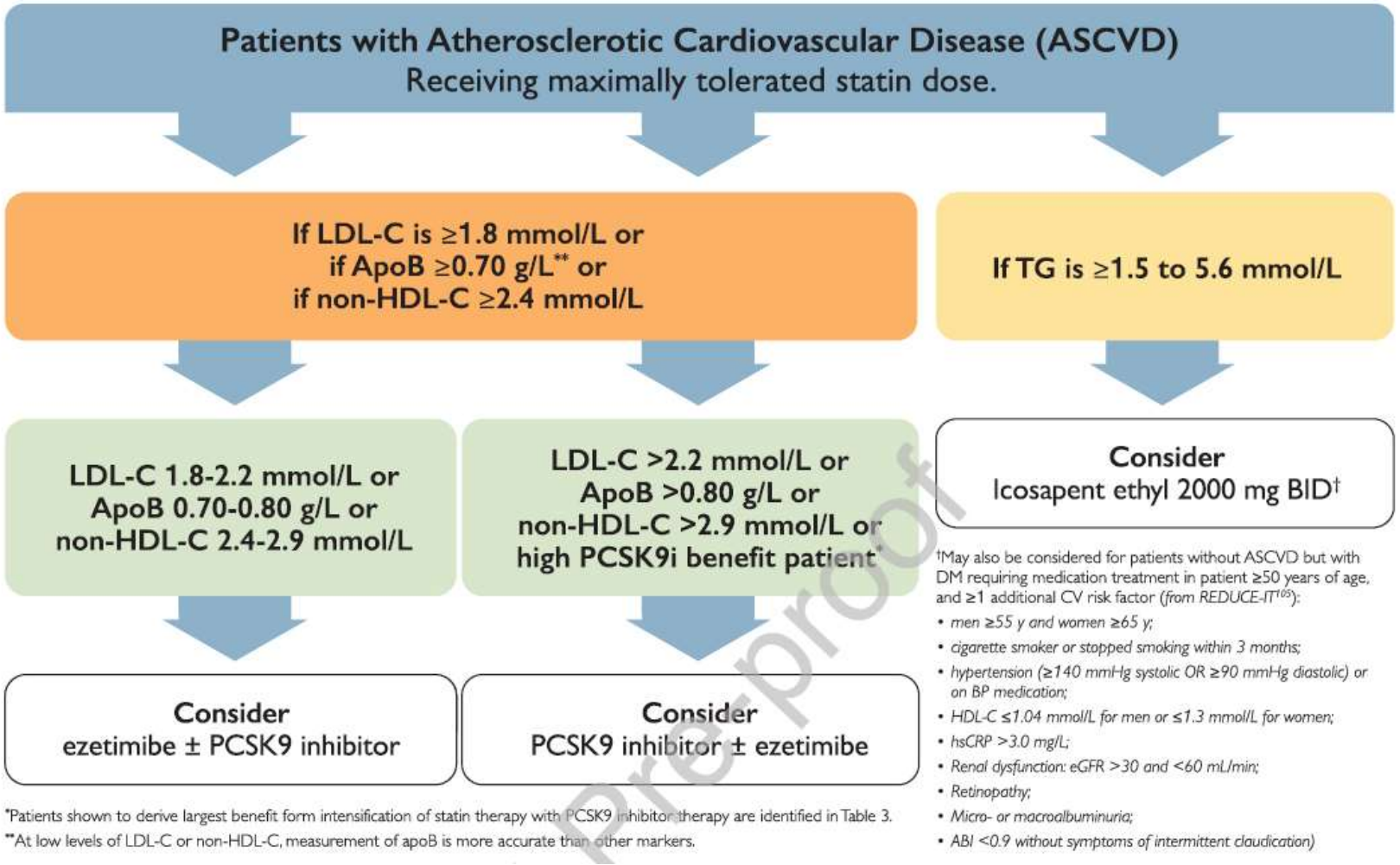

Figure 3. Treatment intensification approach for patients with Atherosclerotic Cardiovascular Disease (ASCVD)

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Pearson GJ, et al. Canadian Journal of Cardiology 2021;S0828-282X(21)00165-3

CSCC Harmonized Clinical Lipid Reporting Recommendations

CSCC Harmonized Lipid Reporting

- Lipid hRI team drafted CSCC lipid reporting recommendations largely based on CCS 2021 Lipid Guidelines
- Volunteers for review; CSCC ListServ; Cardiologists, lipidologists, endocrinologists, clinicians, family physicians
- Developed a survey to gather feedback/suggestions with 30 respondents
- Reviewed/incorporated responses based on consensus within the Lipid hRI team

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

- 2016 CCS Guidelines for the Management of Dyslipidemia for the Prevention of CVD in the Adult introduced the use of nonfasting lipid determination for CVD risk assessment screening
- The ability to predict CVD events has been shown to be identical for both fasting and nonfasting patients
- Nonfasting lipid determination has several practical advantages over fasting lipid determination, including the increased convenience for patients and laboratories.
- Recommended that all laboratories offer both fasting and nonfasting
- Number hours fasting, reported by the patient, in hours, should be included on the report at the time of collection

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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.

- It is recommended to screen for dyslipidemia in adults at risk for CVD using a standard lipid profile as per the 2021 CCS Guidelines. However, each lipid parameter should also be available to order individually.
- ApoB may also be used as the primary target when monitoring dyslipidemia. ApoB should be routinely offered (either in-house or as a send-out test).
- Lp(a) should be offered in-house or as a send out test.

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

- Lipid decision limits and interpretation for screening in primary prevention patients and monitoring patients after initiation of lipid-lowering therapy differs.
- While patients are being followed on lipid-lowering therapy, clinicians are more likely to trend patient results over time, rather than rely on lipid report flags.
- Therefore, it may be more beneficial to both healthcare providers and patients to include report flags that alert clinicians to exceeded thresholds based on lipid screening, rather than monitoring.

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

- The 2021 CCS Guidelines report various treatment thresholds for LDL-C, non-HDL-C and ApoB depending on primary vs. secondary prevention, the presence of different CVD risk factors and different statin-indicated conditions
- Lipid Screening
  - Non-HDL-C, LDL-C, and ApoB decision limits for **low and intermediate risk patients in a primary prevention setting** and referring to the 2021 CCS guidelines for additional information

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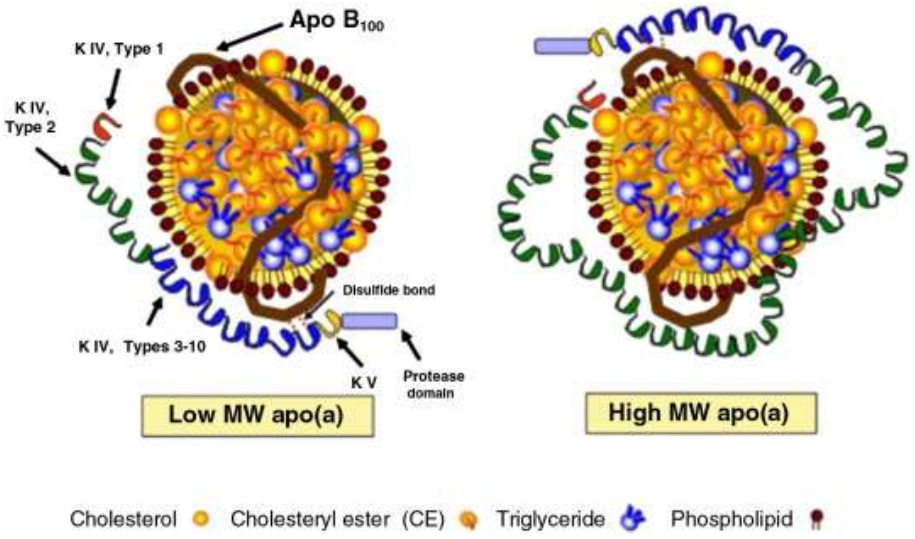
Recommendation #5. We recommend that all laboratories should offer Lp(a) either as an in-house or as a send out test using an assay that quantifies apo(a) in molar units (nmol/L). The assay used to measure Lp(a) should be stated on the report.

- Lp(a) is an LDL-like particle with a single apoB100 protein covalently linked to a single apo(a). Apo(a) is a highly heritable biomarker independently associated with CVD.
- Apo(a) exhibits high molecular weight heterogeneity between individuals and also exhibits variation within an individual
- Standardization of Lp(a) is challenging as immunoassays overlook variation in apo(a) size, leading to inaccurate Lp(a) "mass" results
- Genetic risk of *LPA* gene variants have been shown to be fully captured by measuring Lp(a) "particle number" (i.e., in nmol/L)
- Therefore, laboratories should select Lp(a) assays with calibration traceable in nmol/L to the WHO/IFCC SRM-2B reference material.



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

$$LDL - C = Total\ Cholesterol - (HDL - C) - \left(\frac{Triglycerides}{2.2}\right)$$

VLDL-C

in mmol/L

Factor is 5 in mg/dL
TG:VLDL-C = 5:1

- Limitations of the Friedewald equation
  - Small cohort – 448 subjects
  - Underestimation of LDL-C in samples containing chylomicrons (overestimation of VLDL)
  - Underestimated low LDL-C concentration
  - Triglycerides >4.5 mmol/L (ratio of TG/VLDL not valid)
  - Overestimation of LDL-C in patients with type III hyperlipoproteinemia

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

- NIH Equation
  - Estimate LDL-C in samples with high triglycerides (up to 9.04 mmol/L)
  - Estimate LDL-C samples with low LDL-C (down to 0.5 mmol/L)

NIH LDL-C Equation:

VLDL-C

$$LDL-C = \frac{Cholesterol}{0.948} - \frac{HDL-C}{0.971} - \left(\frac{Triglycerides}{3.74} + \frac{Triglycerides\ x\ Non-HDL-C}{24.16} - \frac{Triglycerides^2}{79.36}\right) - 0.244$$

Factors shown for parameters in mmol/L

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Sampson M, et al. JAMA Cardiology 2020

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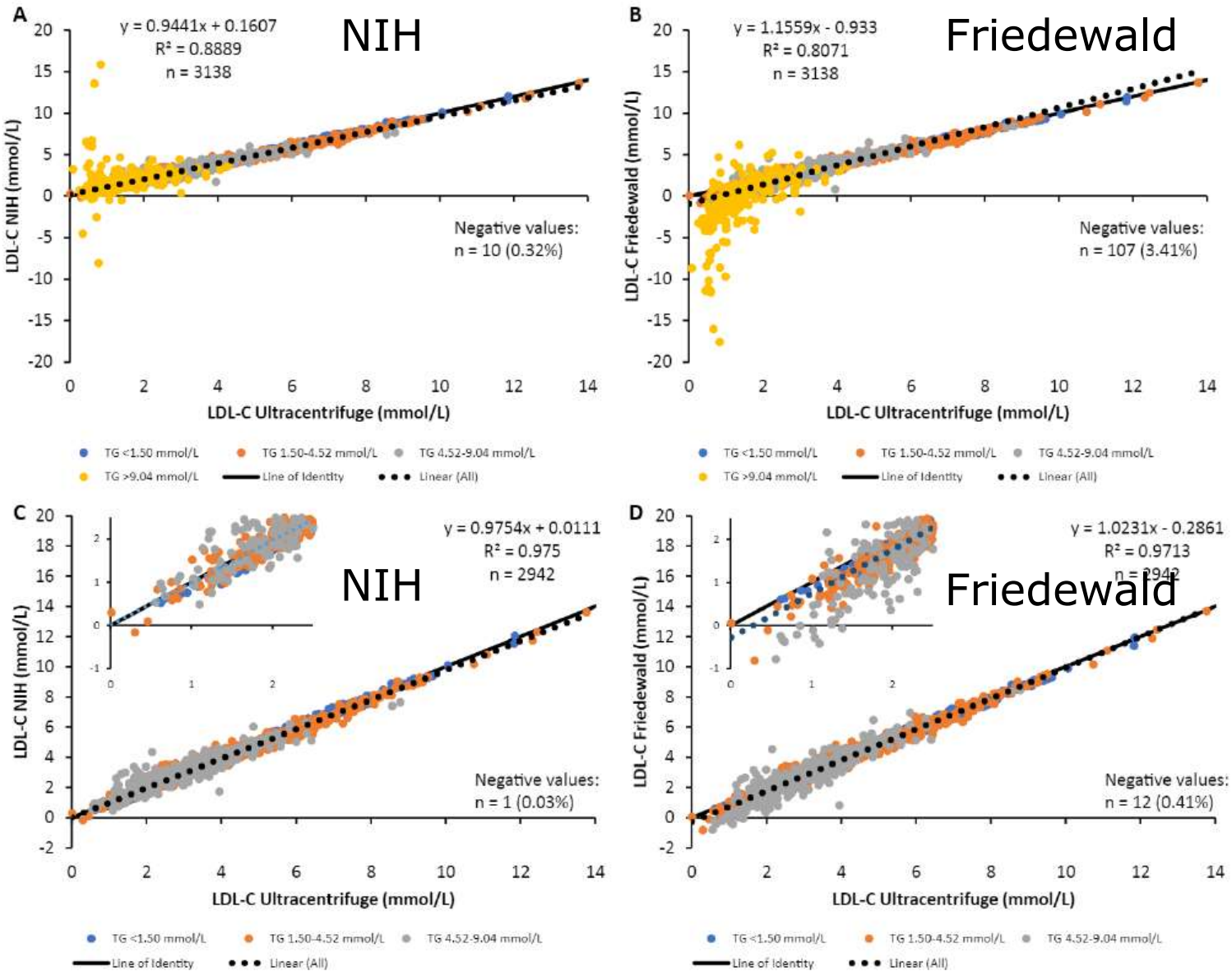

Patients with type III hyperlipoproteinemia were excluded

Patients with type III hyperlipoproteinemia and TG>9.04 mmol/L were excluded

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Higgins V, et al. Clin Biochem 99(2022):60

Implementing the harmonized lipid report

Implementation of the CSCC Harmonized Lipid Report

- **Recommendation #1**. We recommend laboratories offer both 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 based on 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.

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Analyte	Flagging Limit	Always Comments	Conditional Comments
Lipid Panel			
Total Cholesterol	≥5.20 mmol/L	Total cholesterol and HDL-C used for risk assessment and to calculate non-HDL-C.[a]	N/A
HDL-C	Males: <1.00 mmol/L Females:<1.30 mmol/L	HDL-C limits indicate risk for metabolic syndrome.	N/A
Non-HDL-C	≥4.20 mmol/L		If non-HDL-C ≥4.20 mmol/L: "If non-HDL-C ≥4.20 mmol/L in primary prevention setting for low risk patients with FRS 5-9.9% or intermediate risk patients, consider therapy. Therapy also suggested in low risk patients with non-HDL-C ≥5.8 mmol/L"
LDL-C	≥3.50 mmol/L	LDL-C was calculated using the ** equation. Refer to 2021 CCS guidelines for additional LDL-C and non-HDL-C thresholds based on risk stratification. 2021 CCS Guidelines. Can J Cardiol. 2021; S0828	If LDL-C ≥3.50 mmol/L: "If LDL-C ≥3.50 mmol/L in primary prevention setting for low risk patients with FRS 5-9.9% or intermediate risk patients, consider therapy. Therapy also suggested in low risk patients with LDL-C ≥5.00 mmol/L." If triglycerides ≥1.50 mmol/L: "Triglycerides exceed 1.50 mmol/L. For dyslipidemia assessment, refer to apoB or non-HDL-C instead of LDL-C". If triglycerides >4.52 mmol/L AND using Friedewald equation, cancel LDL-C and add comment to LDL-C result: "LDL-C cannot be calculated. Triglycerides exceed 4.52 mmol/L. Recollect in a fasting state or refer to non-HDL-C or apoB." If triglycerides >9.04 mmol/L AND using the NIH LDL-C calculation, cancel LDL-C and add comment to LDL-C result: "LDL-C cannot be calculated. Triglycerides exceed 9.04 mmol/L. Recollect in a fasting state or refer to non-HDL-C or apoB."
Triglycerides	≥1.70 mmol/L	If nonfasting, triglycerides <2.00 mmol/L acceptable.	
Fasting (hours)			

Lipid parameters ordered outside lipid panel			
ApoB	≥1.05 g/L	Refer to 2021 CCS guidelines for additional ApoB thresholds based on risk stratification. 2021 CCS Guidelines. Can J Cardiol. 2021; S0828 ApoB was measured using *** method.	If ApoB ≥1.05 g/L: "If ApoB ≥1.05 g/L in primary prevention setting for low risk patients with FRS 5-9.9% or intermediate risk patients, consider therapy. Therapy also suggested in low risk patients with ApoB ≥1.45 g/L "
Lp(a)	≥100 nmol/L	Lp(a) was measured using **** method.	If Lp(a) ≥100 nmol/L: "Earlier and more intensive clinical management recommended when Lp(a) ≥100 nmol/L."

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CSCC Toolbox for the Implementation of the NIH Equation

- Communication Template
- Transition Reporting Comments
- Key Verification Conditions and Verification Template

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"News and Events"

"eNews"

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Communication Template

- **Key Message**

  - Effective [DATE], LDL-C will be reported as calculated by the NIH LDL-equation instead of the Friedewald LDL-C equation.
  - *Current Friedewald LDL-C Equation (SI units):* $LDL\text{–}C = TC - HDL\text{–}C - \frac{TG}{2.2}$
  - *New NIH LDL-C equation (SI units):*
    - $LDL - C = \frac{TC}{0.948} - \frac{HDL\text{–}C}{0.971} - \left(\frac{TG}{3.74} + \frac{TG \times Non\text{–}HDL\text{–}C}{24.16} - \frac{TG^2}{79.36}\right) - 0.244$

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Communication Template

- **Background**
  - Friedewald equation has traditionally been used to calculate LDL-C, was developed in 1972 and is not valid in patients who are non-fasting, have triglycerides >4.5 mmol/L or have type III hyperlipoproteinemia; it is inaccurate when LDL-C <1.5 mmol/L
  - NIH equation was developed in 2020 and validated in a Canadian population; it accurately estimates LDL-C when patients are non-fasting and when triglycerides are up to 9.0 mmol/L
  - NIH equation should not be used for patients with type III hyperlipoproteinemia and is inaccurate when LDL-C <0.5 mmol/L
  - NIH equation correlates well with Friedewald equation for most patients, but correlates better with β-quantification (LDL-C reference method) when triglycerides are high and LDL-C is low
  - Reporting LDL-C as calculated by the NIH equation is in accordance with the Harmonized Lipid Reporting Recommendations from the CSCC Harmonized Reference Interval Working Group (CSCC hRI-WG)

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Communication Template

- **Why this is important**
  - The NIH equation provides a more accurate estimation than the Friedewald equation for LDL-C:
    - In the non-fasting state, which is becoming more common when ordering the lipid panel
    - When triglycerides are high (between 4.5 and 9.0 mmol/L), which is becoming more common with the increased prevalence of dyslipidemia
    - When LDL-C is low (between 0.5 – 1.5 mmol/L), which is becoming more common with more aggressive LDL-C targets

References

1. *Friedewald, et al. Estimation of the concentration of low-density lipoprotein cholesterol in plasma, without use of the preparative ultracentrifuge. Clinical Chemistry 1972;18(6):499-502*
2. *Sampson M, et al. A new equation for calculation of low-density lipoprotein cholesterol in patients with normolipidemia and/or hypertriglyceridemia. JAMA Cardiology 2020;5(5):540-548*
3. *Higgins V, et al. Validating the NIH LDL-C equation in a specialized lipid cohort: Does it add up? Clinical Biochemistry. 2022;99:60-68*
4. *White-Al Habeeb N & Higgins V, et al. Harmonized Lipid Reporting for Clinical Laboratories based on the 2021 Canadian Lipid Guidelines. Canadian Journal of Cardiology. 2022;S0828-282X(22)00215-X*

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Transition Reporting Comments

Circumstance	Comment
Prior to change, with unknown implementation date	LDL-C result is based on the Friedewald LDL-C equation. The laboratory will be changing to the new NIH LDL-C equation that has improved accuracy when triglycerides are high and/or LDL-C is low.
Prior to change, with known implementation date	LDL-C result is based on the Friedewald LDL-C equation. As of [DATE], the laboratory will change to the new NIH LDL-C equation that has improved accuracy when triglycerides are high and/or LDL-C is low.
After change	LDL-C result is based on the NIH LDL-C equation.

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Key Verification conditions and template to verify correct calculation by NIH LDL-C Equation

- **Key verification conditions**

Condition	Expected Result
LDL-C LoD of 0.50 mmol/L	LDL-C results 0-0.49 mmol/L are reported as <0.50 mmol/L
Triglycerides >4.52 mmol/L	LDL-C result is reported
Triglycerides >9.04 mmol/L	LDL-C result is not reported. The comment "Unable to calculate" is added to the report.
At least one component parameter not available	LDL-C result is not reported. The comment "Unable to calculate" is added to the report.

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Key Verification conditions and template to verify correct calculation by NIH LDL-C Equation

- **Template for testing**

Age (years)	Sex	Total Cholesterol (mmol/L)	HDL-C (mmol/L)	Triglycerides (mmol/L)	NIH LDL-C Equation Calculation (mmol/L)
10	Male	2.30	0.60	5.20	<0.50
10	Female	2.30	0.60	5.20	<0.50
10	Male	3.90	0.60	5.00	1.55
10	Female	3.90	0.60	5.00	1.55
10	Male	7.10	0.70	1.00	6.00
10	Female	7.10	0.70	1.00	6.00
10	Male	4.20	0.50	10.2	Unable to calculate
10	Female	4.20	0.50	10.2	Unable to calculate
10	Male	Not available	0.80	1.30	Unable to calculate
10	Female	Not available	0.80	1.30	Unable to calculate
10	Male	3.90	Not available	1.30	Unable to calculate
10	Female	3.90	Not available	1.30	Unable to calculate
10	Male	3.90	0.80	Not available	Unable to calculate
10	Female	3.90	0.80	Not available	Unable to calculate
40	Male	2.30	0.60	5.20	<0.50
40	Female	2.30	0.60	5.20	<0.50
40	Male	3.90	0.60	5.00	1.55
40	Female	3.90	0.60	5.00	1.55
40	Male	7.10	0.70	1.00	6.00
40	Female	7.10	0.70	1.00	6.00
40	Male	4.20	0.50	10.2	Unable to calculate
40	Female	4.20	0.50	10.2	Unable to calculate
40	Male	Not available	0.80	1.30	Unable to calculate
40	Female	Not available	0.80	1.30	Unable to calculate
40	Male	3.90	Not available	1.30	Unable to calculate
40	Female	3.90	Not available	1.30	Unable to calculate
40	Male	3.90	0.80	Not available	Unable to calculate
40	Female	3.90	0.80	Not available	Unable to calculate

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Implementation Challenges

Anticipated Challenges/Considerations

- Communication with HCP
- LIS Capabilities
  - Interpretative comments
- Flagging limits for total cholesterol and HDL-C
  - Some HCP may be hesitant due to lack of clinical action based on result
- Lower reporting range 0.5 mmol/L
  - If you have no lower reporting limit, may require discussion with HCP
- NIH Equation
  - Middleware may be sufficient for Friedewald equation, however due to increased complexity of the NIH equation, may have to move to LIS e.g. Beckman, Siemens (Central Link)

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Implementation experiences

- hRI-WG would like to work with labs to gain further insight and experience on implementation
- Discussion

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Acknowledgements

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Thank you!

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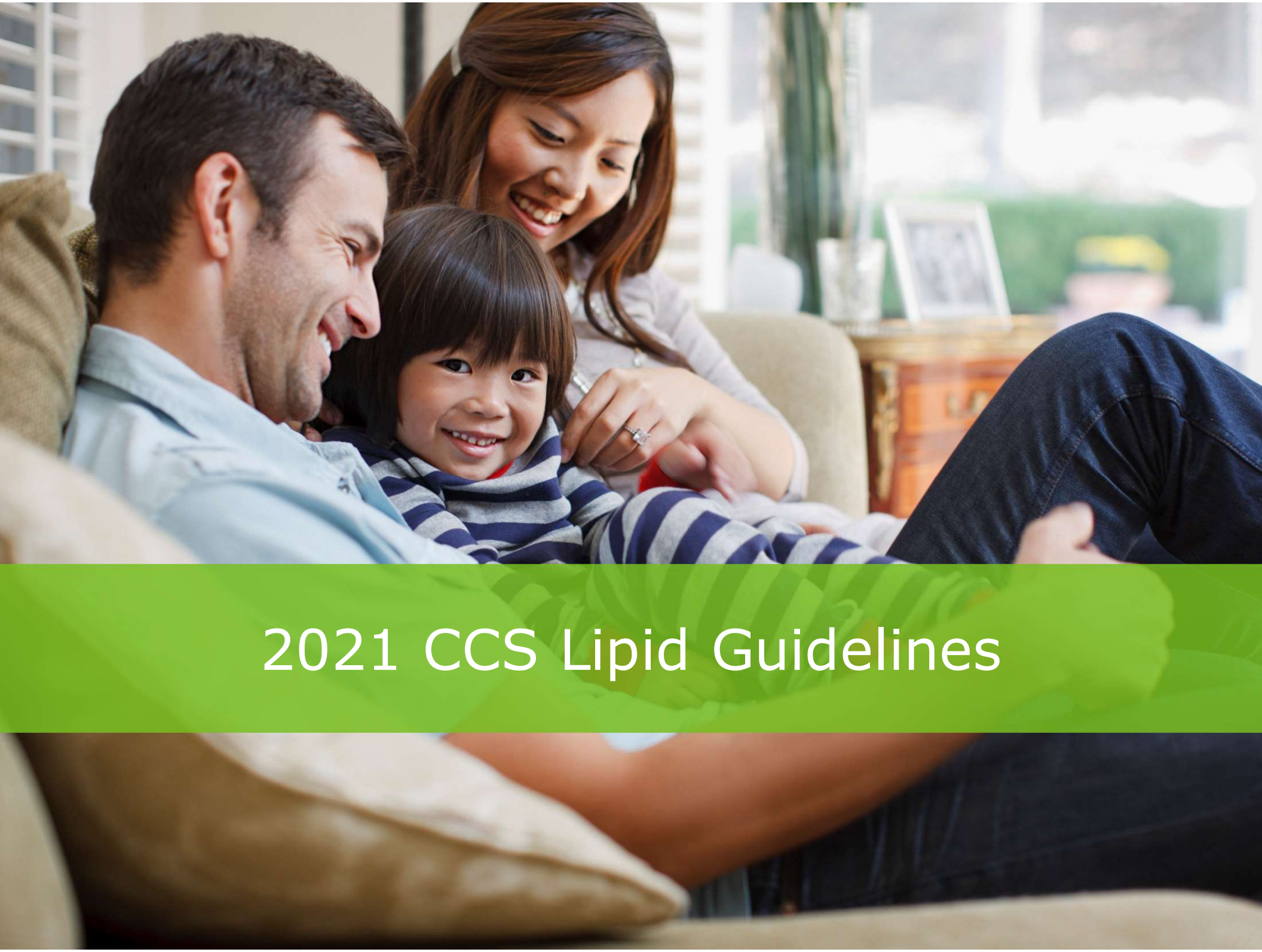

2021 CCS Lipid Guidelines

Who and how to screen for dyslipidemia

WHO

- Men & women ≥40y (or postmenopausal women)
  - Consider earlier in ethnic groups at ↑ risk (South Asian, indigenous)
- All patients with any of the following conditions, regardless of age:
  - Clinical evidence of atherosclerosis
  - Abdominal aortic aneurysm
  - Diabetes mellitus
  - Arterial hypertension
  - Current cigarette smoking
  - Stigmata of dyslipidemia
  - FHx of premature CVD*
  - FHx of dyslipidemia
  - CKD (eGFR ≤60 mL/min/1.73m^2 or ACR ≥ 3 mg/mmol)
  - Obesity (BMI ≥ 30 kg/m^2)
  - Inflammatory diseases (RA, SLE, IBD)
  - HIV infection
  - Erectile dysfunction
  - COPD
  - Hx of hypertensive disorder of pregnancy

*Men <55y and women <65y in first-degree relative

HOW

- For all
  - Hx and physical examination
  - Standard lipid profile*: TC, LDL-C**, HDL-C, non-HDL-C, TG
  - FPG or A1c
  - eGFR
  - Lp(a) (once in patient's lifetime, with initial screening)
- Optional
  - ApoB
  - Urine ACR (if eGFR <60 mL/min/1.73m^2, hypertension, or diabetes)

*Nonfasting lipid testing is recommended in most adults for screening; however, for individuals with Hx of TG >4.5 mmol/L, measuring of fasting lipid levels are recommended

**It is now generally preferable to follow non-HDL-C or ApoB levels over LDL-C when interpreting lipid results, particularly when TG ≥1.5 mmol/L

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Pearson GJ, et al. Canadian Journal of Cardiology 2021;S0828-282X(21)00165-3