Harmonized Lipid Reporting across Canada: Current Variability and Proposed Harmonized Lipid Report

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INTRODUCTION

- Despite published Canadian Cardiovascular Society (CCS) guidelines for dyslipidemia management, lipid reporting across Canadian laboratories remains highly variable
- The CSCC Harmonized Reference Interval (hRI) Working Group aims to address this gap by establishing harmonized lipid reporting and supporting implementation across the country

OBJECTIVES

(1) Assess current lipid reporting practices in Canadian clinical laboratories

(2) Propose common adult and pediatric lipid reports

METHODS

1. Survey development and dissemination

- Survey disseminated to Canadian laboratories in November 2018 to assess current adult and pediatric lipid reporting practices
- Triglycerides, total cholesterol, LDL-C, HDL-C, non-HDL-C, apoB
- Information collected:

1. General information/demographics
2. Decision limits (DLs)/reference intervals (RIs)
3. Source of DLs and RIs
4. Interpretive Comments
5. Non-fasting lipid reporting
6. Interest in harmonized reporting

2. Common Adult Lipid Report Development

Incorporated decision limits from:

- 2016 CCS Guidelines[1]
- National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) Guidelines[2]
- European Atherosclerosis Society (EAS) and European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Guidelines[3]

3. Common Pediatric Lipid Report Development

Age and sex-specific DLs based on CALIPER reference data[4,5]

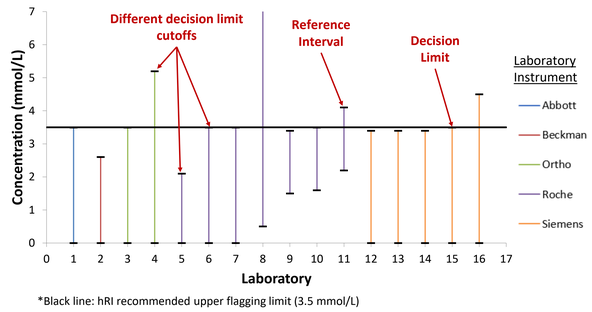
- Low: 2.5th percentile (HDL-C High: 97.5th percentile)
- Borderline high: 75th percentile (HDL-C Borderline low: 50th percentile)
- High: 95th percentile (HDL-C Low: 10th percentile)

RESULTS

Survey Responses

28 laboratories responded

- British Columbia (4), Alberta (2), Saskatchewan (1), Manitoba (1), Ontario (16), Quebec (1), New Brunswick (1), Nova Scotia (1), Newfoundland & Labrador (1)



*Black line: hRI recommended upper flagging limit (3.5 mmol/L)

Figure 1. LDL-C upper and lower limits reported for a 50 year male across 16 labs

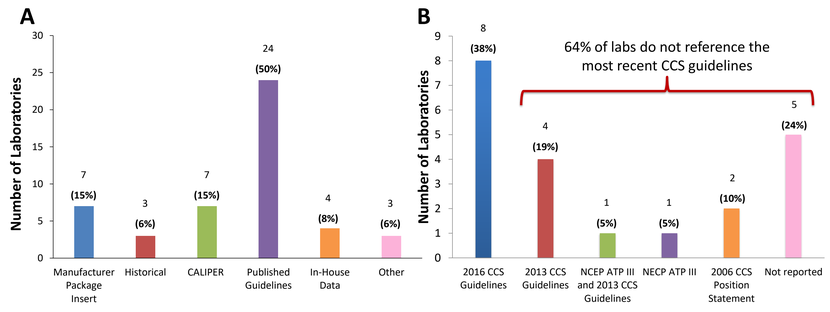


Figure 2. (A) Source of DLs and/or RIs and (B) reference included in interpretive comments

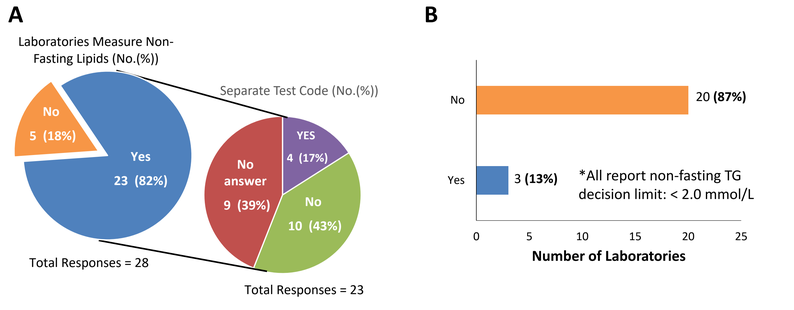
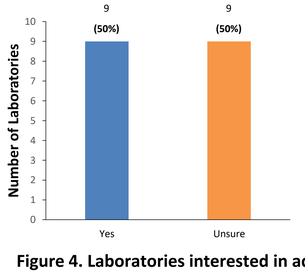


Figure 3. Laboratories that (A) measure non-fasting lipids and offer separate test codes, (B) report non-fasting triglyceride decision limits



*Note: Laboratories "unsure" with adopting a common lipid report including laboratories already involved in provincial lipid harmonization initiatives

Figure 4. Laboratories interested in adopting a common lipid report

RESULTS

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		
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 <2.0 mmol/L or >50% decrease in LDL-C	Non-HDL-C <2.6 mmol/L ApoB <0.8 g/L
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

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)
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

Decision limits based on CALIPER reference data (*Clin Chem 2012;58:854-868; Clin Chim Acta 2018;486:129-134*)

Table 4. Pediatric Interpretive Comments

CONCLUSIONS

- Assessment of current lipid reporting practices supports the need for harmonized lipid reporting
- Proposed common adult and pediatric lipid reports align with current clinical recommendations for dyslipidemia
- Harmonized lipid reporting aims to promote laboratory harmonization and improve patient care

ACKNOWLEDGEMENTS

We would like to thank all the laboratories who participated in the survey and all colleagues who have provided expert feedback on our proposed lipid reports.

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