

External Quality Assurance and Performance Assessment of Prenatal Screening in Ontario – A NEW reporting tool

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Objective

To develop a prenatal screening laboratory quality report that can be generated directly from Ontario's BORN (Better Outcomes Registry & Network) Information System and provide timely and accurate information to assist the external quality assurance activities of prenatal screening for Down syndrome (DS) and Open Neural Tube Defect (ONTD) in Ontario, Canada.

Methods

Established in 2009, BORN Ontario manages an advanced registry that collects critical data about pregnancy, birth and childhood in the province and provides reliable, secure and comprehensive information on maternal and child care. One of the mandates of BORN is Quality Assurance (QA) of prenatal screening in Ontario. BORN receives a data feed from five provincial screening centres on a weekly basis. Information collected includes maternal demographics, pregnancy related information, screening marker values and Multiples of the Median (MoM) and screening tests results. It also collects information on follow up diagnostic tests and pregnancy outcomes from prenatal genetics centres, maternal fetal medicine centres and hospitals in Ontario. A web-based quality report was developed using real time data collected in BORN to provide information on screening values and positive rates, and assess median MoM values of each biochemical marker. The report compares modality specific positive rates with expected positive rates adjusted for maternal age. The monthly median MoM of biochemical markers are assessed using a scoring system. Information generated can be laboratory specific or provincial as appropriate. Access to the report is centrally managed by BORN Ontario.

Results

The reporting tool has significantly reduced the QA report preparation time from about a week to a few minutes. The monthly QA data is now available on the 15th day of the following month, two weeks sooner than the manual report. The new report has a flexible reporting period and additional quality indicators including the summaries of median MoM of analytes and positive rates over the entire reporting period. It also enables the comparison of observed positive rates with the theoretical values. The report is reviewed by the provincial prenatal screening QA group on a monthly basis to assess screening centres' quality and performance. Each screening centre has access to the report for their site for internal QA, and provincial information for comparison and reference. The report reflects real-time information captured in BORN and is updated continuously.

Conclusion

The report is an essential tool for external quality assurance of prenatal screening in Ontario. It provides timely feedback on the quality and performance of prenatal screening tests. It is sensitive in identifying potential quality issues and specifying areas that need improvement. The report provides information to enhance the performance of, and ensure the best quality of prenatal screening tests in Ontario.

Contents of the QA report

November 2013 to April 2014

PSO Lab A, PSO Lab B, PSO Lab C, PSO Lab D, PSO Lab E

Table of contents

1. Prenatal screening test volumes for Down Syndrome
- 2A. Prenatal screening summary for Down Syndrome
- 2B. Prenatal screening summary for ONTD
- 2C. Prenatal screening summary for Trisomy 18
3. Median score summary by laboratory
4. Positive rates flag summary by laboratory
5. Median of biochemical markers (Provincial)
6. Median of biochemical markers (Laboratory specific)
- 7A. Positive rates for Down Syndrome (Provincial)
- 7B. Positive rates for ONTD (Provincial)
- 7C. Positive rates for Trisomy 18 (Provincial)
- 8A. Positive rates for Down Syndrome (Laboratory specific)
- 8B. Positive rates for ONTD (Laboratory specific)
- 8C. Positive rates for Trisomy 18 (Laboratory specific)

Notes:

- Singleton
- All races
- Non-IDDM and IDDM

Positive rates summary

Down Syndrome Screening Summary Report

All Singleton, All races, IDDM/non-IDDM, All age groups

QUAD (AFP, uE3, hCG, DIA)
 Risk Cut-off $\geq 1:200$ at term
 Provincial expected PR: 5.0%

	Apr 2014						Nov 2013 - Apr 2014							
	Volume	%	% of Prov	Positives	PR%	95% CI PR	Expected Flag PR	Volume	%	% of Prov	Positives	PR%	95% CI PR	Expected Flag PR
Lab A	90	10.0	0.5	6	3.52	(1.51 - 11.82)	4.29	320	7.5	0.6	17	5.31	(2.86 - 7.77)	4.87
Lab B	200	22.3	1.9	7	3.50	(0.95 - 6.05)	4.74	960	22.4	1.9	40	4.17	(2.90 - 5.43)	4.83
Lab C	88	9.8	0.8	0	0.00	(0.00 - 0.00)	4.01	500	11.7	1.0	18	3.60	(1.97 - 5.23)	4.12
Lab D	220	24.5	1.6	8	3.64	(1.16 - 6.61)	5.23	800	18.7	1.8	38	4.75	(3.28 - 6.22)	4.83
Lab E	300	33.4	3.1	8	2.67	(0.84 - 4.49)	4.48	1,700	39.7	3.4	68	4.00	(3.07 - 4.93)	4.62
Province	898	100.0	7.9	29	3.23	(2.07 - 4.39)	4.63	4,280	100.0	8.7	181	4.23	(3.63 - 4.83)	4.67

IPS (AFP, uE3, hCG, NT, PAPP-A)
 Risk Cut-off $\geq 1:200$ at term
 Provincial expected PR: 2.5%

	Apr 2014						Nov 2013 - Apr 2014							
	Volume	%	% of Prov	Positives	PR%	95% CI PR	Expected Flag PR	Volume	%	% of Prov	Positives	PR%	95% CI PR	Expected Flag PR
Lab A	900	13.2	10.2	23	2.56	(1.52 - 3.59)	2.48	4,899	13.3	10.0	133	2.71	(2.26 - 3.17)	2.52
Lab B	1,879	27.6	21.1	36	1.92	(1.30 - 2.54)	2.37	9,950	26.9	20.5	209	2.01	(1.82 - 2.38)	2.48
Lab C	850	12.5	9.6	21	2.47	(1.43 - 3.51)	2.14	4,200	11.4	8.9	106	2.53	(2.05 - 3.00)	2.14
Lab D	960	14.1	10.9	26	2.71	(1.68 - 3.74)	2.33	5,780	15.6	11.5	129	2.23	(1.85 - 2.61)	2.64
Lab E	2,220	32.6	24.8	53	2.39	(1.75 - 3.02)	2.47	12,120	32.8	24.9	296	2.44	(2.17 - 2.72)	2.47
Province	6,809	100.0	76.6	159	2.34	(1.98 - 2.69)	2.38	36,949	100.0	75.7	873	2.36	(2.21 - 2.52)	2.47

All FTS (NT, fbhCG/hCG, PAPP-A)
 Risk Cut-off $\geq 1:350$ at term
 Provincial expected PR: 7.8%

	Apr 2014						Nov 2013 - Apr 2014							
	Volume	%	% of Prov	Positives	PR%	95% CI PR	Expected Flag PR	Volume	%	% of Prov	Positives	PR%	95% CI PR	Expected Flag PR
Lab A	190	17.3	1.8	14	7.37	(3.65 - 11.08)	6.29	850	12.9	1.7	62	7.26	(5.55 - 9.04)	7.10
Lab B	211	19.2	1.3	11	5.21	(2.21 - 8.21)	7.46	919	13.9	1.3	38	6.18	(2.85 - 5.42)	6.61
Lab C	500	45.4	6.4	41	8.20	(5.80 - 10.60)	7.05	3,208	48.5	6.4	250	7.79	(6.87 - 8.72)	7.11
Lab D	200	18.1	3.6	18	9.00	(5.03 - 12.97)	9.42	1,634	24.7	3.2	160	9.78	(8.35 - 11.23)	9.39
Province	1,101	100.0	13.0	84	7.63	(6.06 - 9.20)	7.64	6,611	100.0	12.5	510	7.71	(7.07 - 8.36)	7.63

Median score summary

Median Score Summary by Laboratory

November 2013 to April 2014. All races, singleton

One-month review

Lab A	Apr 2014	Mar 2014	Feb 2014	Jan 2014	Dec 2013	Nov 2013
MS AFP	-50	0	+25	0	+25	+50
uE3	-25	-50	+50	-25	-25	+25
hCG	+50	-75	+50	+75	-25	-25
DIA	-275	+25	+150	+25	+225	0
fbhCG	+25	+125*	+125*	+200	-200	+50
PAPP-A	-75	-50	-50	-100	+75	+100
AF AFP	+75*	+75*	-25*	+25*	-125*	-75*

* Indicates volume <100
 One-month Score=Month's absolute difference from 1.00/Acceptable Limit (4)*100%
 Benchmarks: $\leq |150|$

When using MoM: Scores of MSH are based on adjusted values that are used in risk calculations
 When using Adjusted MoM: Scores for AF-AFP are based on MoM values.

Six-month accumulative review

Lab A	Apr 2014	Mar 2014	Feb 2014	Jan 2014	Dec 2013	Nov 2013
MS AFP	9	10	10	8	5	8
uE3	9	10	17	11	8	7
hCG	22	21	17	16	8	9
DIA	24	16	22	23	21	20
fbhCG	28	29	43	31	43	28
PAPP-A	12	16	10	10	14	14
AF AFP	30	28	27	20	21	17

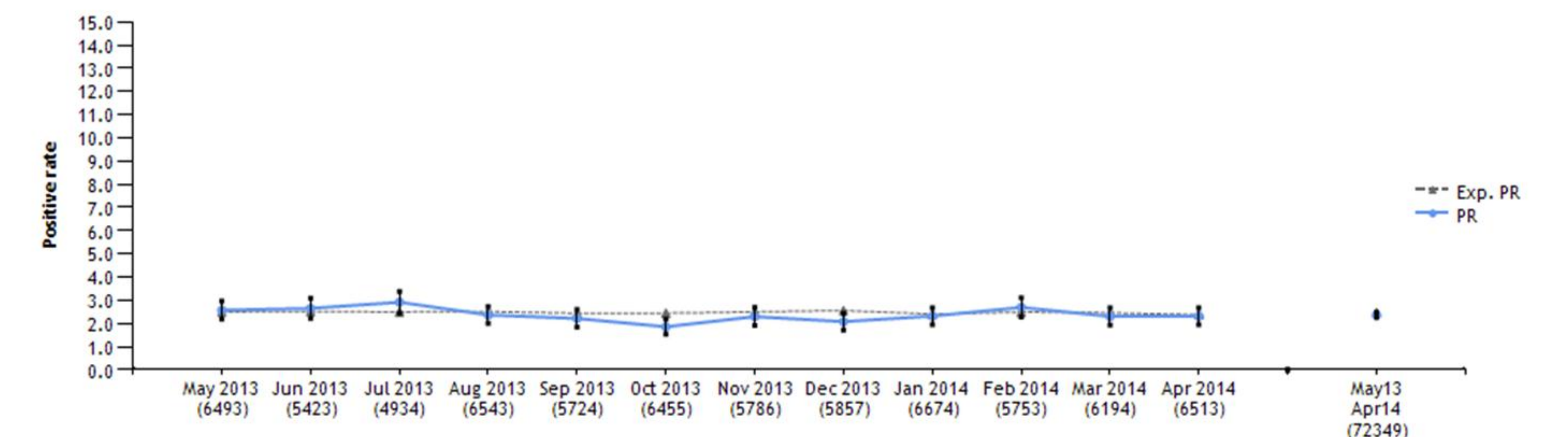
Six-month Score=Sum of variation of medians from 1.0 +1 (if on same side of 1.0 as the previous month and if no intervention was taken)
 Intervention: change in lot of reagent, median adjustment, and weight adjustment
 Benchmarks: ≤ 30

Positive rates

IPS Down Syndrome Positive Rate Report (Provincial)

May 2013 to April 2014. (AFP, uE3, hCG, DIA) with 95% confidence interval (CI)

All singleton. Risk Cut-off $\geq 1:200$ at term

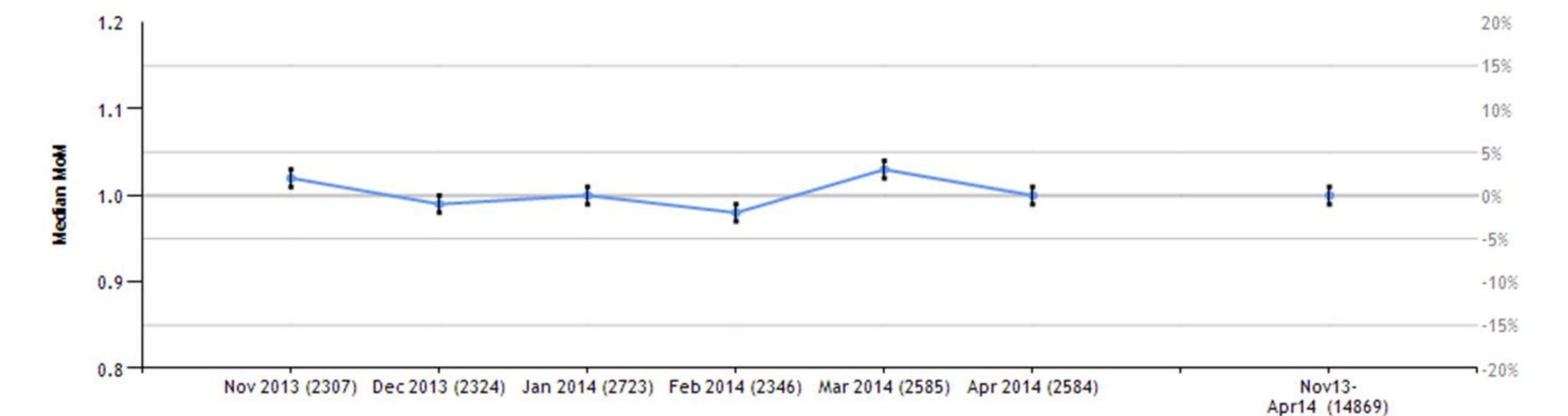


All Labs	Month (Volume)												
	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May 13
CI Upper	2.96	3.08	3.39	2.74	2.60	2.19	2.68	2.45	2.68	3.11	2.68	2.68	2.48
PR	2.57	2.66	2.92	2.37	2.22	1.86	2.30	2.08	2.32	2.69	2.31	2.32	2.37
CI Lower	2.19	2.23	2.45	2.00	1.84	1.53	1.91	1.72	1.96	2.28	1.93	1.95	2.26
Exp. PR	2.50	2.51	2.50	2.52	2.44	2.45	2.50	2.56	2.41	2.49	2.47	2.38	2.48
Flag													

Medians

MS AFP MoM Report (PSO Lab A)

November 2013 to April 2014. All races, singleton. FE AutoDelta, with 95% confidence interval (CI)



Lab A	Month (Volume)						
	Nov 2013	Dec 2013	Jan 2014	Feb 2014	Mar 2014	Apr 2014	Nov 13-Apr 14
CI Upper	1.03	1.00	1.01	0.99	1.04	1.01	1.01
Median	1.02	0.99	1.00	0.98	1.03	1.00	1.00
CI Lower	1.01	0.98	0.99	0.97	1.02	0.99	0.99
Excl. Pts	1	2	3	3	2	1	
Lab Changes							