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NHS Fetal Anomaly Screening Programme DQASS Cycle 25 report (October 2018 to March 2019)



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About PHE Screening

Screening identifies apparently healthy people who may be at increased risk of a disease or condition, enabling earlier treatment or informed decisions. National population screening programmes are implemented in the NHS on the advice of the UK National Screening Committee (UK NSC), which makes independent, evidence-based recommendations to ministers in the 4 UK countries. PHE advises the government and the NHS so England has safe, high quality screening programmes that reflect the best available evidence and the UK NSC recommendations. PHE also develops standards and provides specific services that help the local NHS implement and run screening services consistently across the country.

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Executive Summary

About DQASS

The Down's syndrome screening quality assurance support service (DQASS) is a service commissioned by Public Health England (PHE) to support the NHS Fetal Anomaly Screening Programme (FASP). The main aim of DQASS is to monitor and support the quality and effectiveness of Down's syndrome, Edwards' syndrome and Patau's syndrome screening in England. Laboratories providing NHS screening submit data every 6 months based on the DQASS schedule. The laboratory end-of-cycle report, published for the first time, includes aggregated results for all laboratories and allows comparison of performance cycle-on-cycle. This can be seen for individual markers and for the overall screening programme. These reports also provide summary statistics for the distribution of biochemical markers, including effects of factors such as ethnicity and smoking status. Laboratories receive their individual detailed laboratory report directly but we have decided to make these cycle reports more widely available.

Summary

Number of laboratories:	20
Number (%) of tests performed:	
First trimester	220 399 (87.1%)
Second trimester	32 750 (12.9%)
Overall screen positive rate:	2.8%

Commentary

This report summarises the results of cycle 25. Data for this cycle was submitted between October 2018 to March 2019.

Data submissions

The number of first trimester combined tests accounts for 87.1% of all tests while quad tests account for the remaining 12.9%. This is similar to the previous cycle.

Screen positive rates

The age-standardised screen positive rate (SPR) for the combined test is consistent with the previous cycle, whereas the SPR for the quad test has increased slightly (Figure 1).

The overall age-standardised SPR of 2.8% reflects the high proportion of combined tests.

Performance

Performance for the first trimester markers remains good. In particular, performance for Free β -hCG in the first trimester shows some improvement since the previous cycle. Performance for hCG and Inhibin also shows improvement, whereas, performance for Free β -hCG in the second trimester has deteriorated over this period.

All markers have more than 75% of median MoM values within $\pm 5\%$ of target (0.95 MoM - 1.05 MoM) (Figure 2).

With the exception of Free β -hCG in the second trimester, all biochemistry markers have less than 5% of median MoM values outside $\pm 10\%$ of target (0.9 MoM - 1.1 MoM) (Figure 2).

Meta-analysis

Standard deviations of log₁₀-MoM values are generally consistent with the previous cycle (Table 2).

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Estimates of smoking, ethnicity, diabetes and multiple pregnancy effects are generally consistent compared to previous cycles (Table 4). Due to small numbers of records, estimates for second trimester markers are based on data pooled since cycle 17.

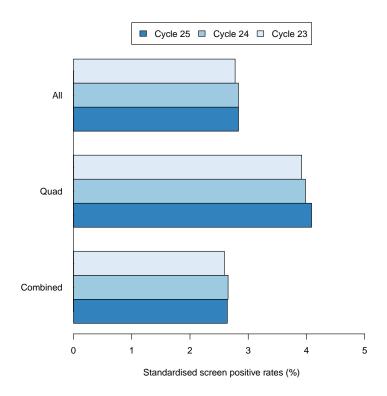


Figure 1: Standardised SPR by type of test, for the previous 3 cycles.

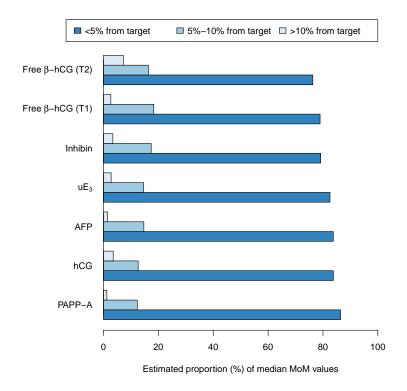


Figure 2: Overall performance by marker.

	Number screened in data supplied	Estimated annual number screened	Number screened positive	Estimated annual number screened positive	Standardised SPR (%)
Combined	220 399	425 889	6 342	12 251	2.6
Quad	32 750	65 078	1 541	3 053	4.1
All	253 149	490 967	7 883	15 304	2.8

Table 1: Number of screening tests included in submission, number screened positive and standardised SPR's for this cycle. Laboratories provided data over varying lengths of time so annualised figures are given. Standardised SPR's are estimated from the annualised figures.

Pareto diagrams

Figures 3 to 9 show the estimated proportions of all screening tests for which the median MoM value was outside 5% of target. The pale blue background represents the results from cycle 1. The black line represents the results from the previous cycle. Each horizontal bar represents the results for a screening laboratory in the current cycle.

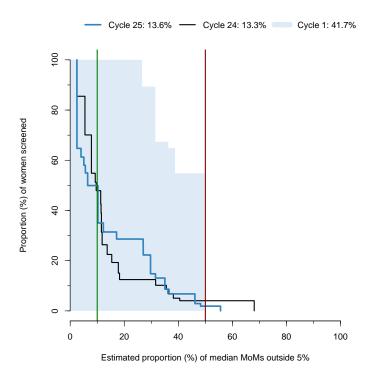


Figure 3: PAPP-A, estimated proportion of tests for which the median MoM value was more than 5% from target.

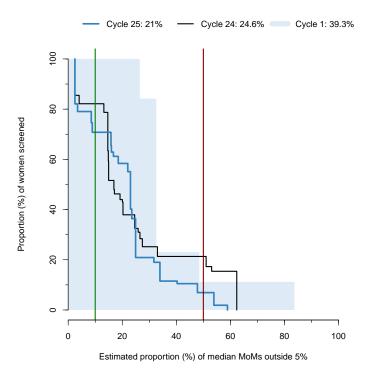


Figure 4: Free β -hCG (first trimester), estimated proportion of tests for which the median MoM value was more than 5% from target.

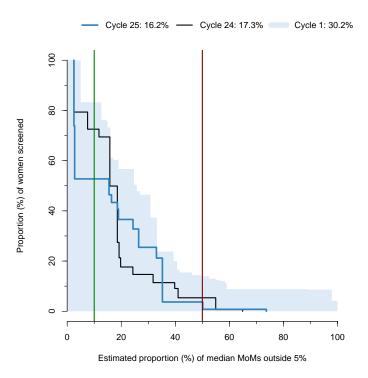


Figure 5: AFP, estimated proportion of tests for which the median MoM value was more than 5% from target.

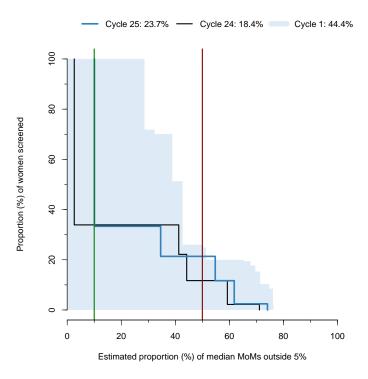


Figure 6: Free β -hCG (second trimester), estimated proportion of tests for which the median MoM value was more than 5% from target.

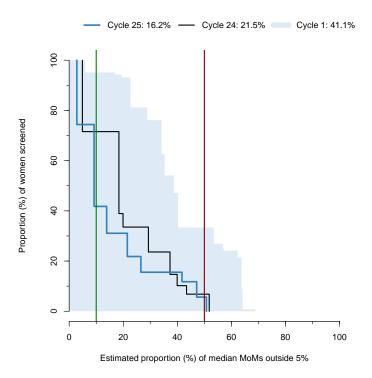


Figure 7: hCG, estimated proportion of tests for which the median MoM value was more than 5% from target.

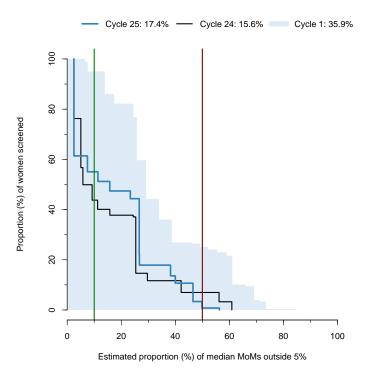


Figure 8: uE_3 , estimated proportion of tests for which the median MoM value was more than 5% from target.

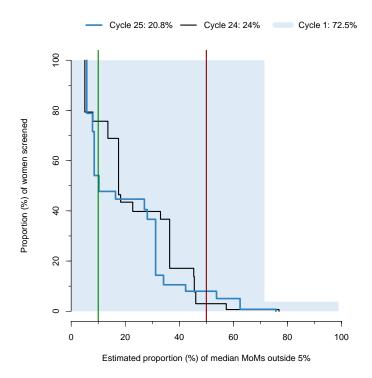


Figure 9: Inhibin, estimated proportion of tests for which the median MoM value was more than 5% from target.

Meta-analysis

Parameter estimates

Tables 2 to 3 give random effects meta-analysis estimates of standard deviations and correlations of the log_{10} MoM distributions, with 95% confidence intervals.

	Number of laboratories	Number of records	Estimate	95% CI
First trimester	•			
NT	13	157 330	0.0878	(0.0864, 0.0892)
PAPP-A				
Delfia	11	89 542	0.2363	(0.2346, 0.238)
Kryptor	2	17 765	0.2229	(0.2176, 0.2282)
Roche	7	103 301	0.227	(0.2246, 0.2295)
Free β -hCG				
Delfia	11	89 579	0.2506	(0.2488, 0.2524)
Kryptor	2	17 780	0.2443	(0.2313, 0.2572)
Roche	7	103 343	0.2634	(0.261,0.2657)
Second trimes	ster			
AFP				
Beckman	1	1 368	0.1476	(0.1423, 0.1533)
Delfia	8	16 533	0.1421	(0.141,0.1432)
Kryptor	1	984	0.1342	(0.1285,0.1404)
Roche	3	12 763	0.1484	(0.1464, 0.1505)
Free β -hCG				
Delfia	3	8 920	0.252	(0.2447, 0.2593)
Kryptor	1	990	0.2671	(0.2558, 0.2794)
Roche	1	238	0.2709	(0.2486, 0.2977)
hCG				
Beckman	1	1 368	0.2227	(0.2147, 0.2314)
Delfia	5	7 644	0.2193	(0.2162,0.2224)
Roche	2	12 541	0.217	(0.2115, 0.2225)
uE_3				
Beckman	5	15 112	0.1242	(0.1236, 0.1249)
Delfia	8	16 505	0.1083	(0.104,0.1126)
Inhibin				
Beckman	9	21 210	0.1797	(0.1767, 0.1826)
Delfia	4	10 480	0.1781	(0.1756,0.1806)

Table 2: Standard deviations of log₁₀ MoM values.

Please note, standard deviations do not take account of the separation between means and they should not be used to make conclusions about differences in screening performance.

	Number of laboratories	Number of records	Estimate	95% CI
First trimester				
NT & PAPP-A	13	129 247	0.0028	(-0.0027,0.0082)
NT & Free eta -hCG	13	129 247	-2e-04	(-0.0083,0.0079)
PAPP-A & Free eta -hCG	20	182 746	0.2316	(0.2248, 0.2383)
Second trimester				
AFP & Free eta -hCG	5	10 065	0.1232	(0.0773,0.1687)
AFP & hCG	8	21 351	0.1594	(0.1463, 0.1725)
AFP & uE ₃	13	31 416	0.1221	(0.1085, 0.1355)
AFP & Inhibin	13	31 416	0.1765	(0.1657, 0.1872)
Free β -hCG & uE ₃	5	10 065	-0.0555	(-0.097,-0.0139)
Free eta -hCG & Inhibin	5	10 065	0.4772	(0.4263, 0.5251)
hCG & uE₃	8	21 351	-0.0302	(-0.0518,-0.0086)
hCG & Inhibin	8	21 351	0.5433	(0.5023, 0.5818)
uE ₃ & Inhibin	13	31 416	-0.0056	(-0.0222,0.011)

Table 3: Correlation coefficients for \log_{10} MoM values.

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Smoking, ethnicity, diabetes and multiple pregnancy effects

Ethnicity groups are combinations of several laboratory-defined groups, as follows:

Black Afro-Caribbean, Black, Black African, Black Caribbean, Black Other

East Asian Chinese, East Asian, Oriental

South Asian Asian, Bangladeshi, Indian, Pakistani, South Asian

		Ethnic origin				
	Smokers	Black	East Asian	South Asian	Diabetes	Multiple pregnancy
First trimester						
PAPP-A						
Number of estimates	20	20	18	20	14	20
Number of records	23 068	9 983	3 591	19 254	853	3 389
Estimate	0.8092	1.5818	1.0304	0.9738	0.8737	2.2221
95% CI	(0.797, 0.8216)	(1.5466, 1.6178)	(1.007, 1.0542)	(0.9597, 0.9881)	(0.8427, 0.9059)	(2.1571,2.2891)
Free β-hCG						
Number of estimates	20	20	18	20	14	20
Number of records	23 070	9 979	3 596	19 272	852	3 392
Estimate	0.9537	1.1828	1.087	0.9184	1.0019	1.9204
95% CI	(0.9424, 0.9652)	(1.1594,1.2068)	(1.0613,1.1133)	(0.9045, 0.9325)	(0.9578,1.048)	(1.8822,1.9593)
Second trimester						
AFP						
Number of estimates	117*	116*	103*	117*	107*	89*
Number of records	46 170	25 900	6 333	34 714	1 446	2 238
Estimate	1.0194	1.1395	0.9878	0.9509	0.9368	2.083
95% CI	(1.0159,1.0228)	(1.1302,1.1488)	(0.9765, 0.9992)	(0.9461,0.9557)	(0.9161,0.958)	(2.0456,2.1212)
Free β -hCG						
Number of estimates	45*	44*	36*	45*	35*	33*
Number of records	12 417	4 860	1 434	7 928	489	403
Estimate	0.8251	1.1613	1.0732	0.9378	0.9606	2.2464
95% CI	(0.8143, 0.836)	(1.141,1.182)	(1.0403,1.1071)	(0.9208, 0.9551)	(0.908, 1.0163)	(2.0846, 2.4208)
hCG						
Number of estimates	72*	72*	67*	72*	72*	56*
Number of records	33 921	21 090	4 904	26 839	958	1 808
Estimate	0.7422	1.1817	1.1035	1.0206	0.9621	2.1207
95% CI	(0.7367, 0.7478)	(1.1722,1.1912)	(1.0876,1.1196)	(1.0125,1.0288)	(0.9222,1.0037)	(2.058,2.1853)
uE_3						
Number of estimates	117*	116*	103*	117*	107*	89*
Number of records	46 259	25 916	6 328	34 729	1 446	2 206
Estimate	0.9556	0.9603	1.1064	1.0711	0.9318	1.6828
95% CI	(0.952, 0.9591)	(0.9548, 0.9659)	(1.0968,1.1161)	(1.0653,1.0769)	(0.9171,0.9468)	(1.6575,1.7084)
Inhibin						
Number of estimates	117*	116*	103*	117*	107*	89*
Number of records	46 331	25 905	6 331	34 710	1 450	2 208
Estimate	1.4289	1.006	1.0739	1.0646	0.9255	2.2311
95% CI	(1.4169,1.4409)	(0.9998,1.0122)	(1.0627,1.0853)	(1.059,1.0702)	(0.904, 0.9475)	(2.1764,2.2873)

Table 4: Effects of smoking, ethnicity, diabetes and multiple pregnancy on each biochemical marker, on the MoM scale, with 95% confidence intervals.

^{*} These estimates are pooled from cycle 17 onwards due to small numbers of records.