Combined Screening for Trisomy 21 – Frequently asked Questions

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Summary

On 10th May 2012 representatives of the NHS Fetal Anomaly Screening Programme (FASP) met with the Ultrasound Advisory Group of the Society and College of Radiographers (SCoR) to discuss combined screening for Trisomy 21. The following are a series of 'Frequently Asked Questions' on which the discussions were based and are published with the agreement of FASP.

Combined Screening for Trisomy 21 – Frequently asked Questions

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Question 1

Can FASP give information on the spread of red/amber/green flags on either side of the reference curve? What proportions of red flags are there for over-measurement compared to under-measurement? It is our understanding that the great majority are for under-measurement.

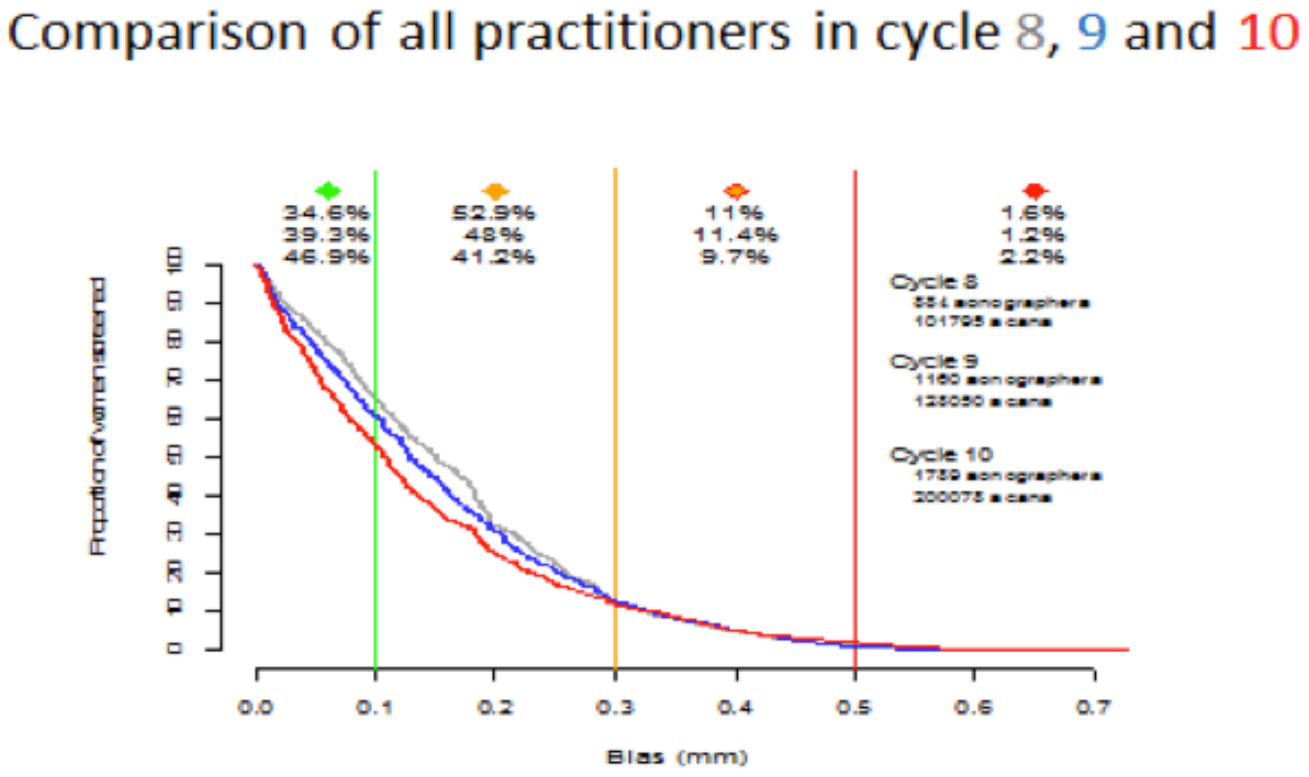
Answer: Below is a table outlining the number (and proportion) of sonographers in each bias category. Figures are based only on those ultrasound practitioners contributing 25 scans or more in the reporting cycle.

	Under-measuring			**Over-measuring**		
	Red* < -0.5mm	Amber < -0.1mm	Green < 0mm	Green >=0mm	Amber > 0.1mm	Red* > 0.5mm
Cycle 8 Apr-Sept 2009 (884 ultrasound practitioners, 101795 scans)	19 (2.5%)	455 (59.3%)	161 (21%)	93 (12.1%)	39 (5.1%)	0 (0%)
Cycle 9 Oct	22 (2.2%)	564 (57.3%)	217 (22%)	128 (13%)	53 (5.4%)	1 (0.1%)

2009-Mar 2010 (1160 ultrasound practitioners, 128050 scans)						
Cycle 10 Apr-Sept 2010 (1789 ultrasound practitioners, 200078 scans)	20 (1.5%)	694 (50.4%)	375 (27.2%)	228 (16.5%)	61 (4.4%)	0 (0%)
Cycle 11 Oct 2010-Mar 2011 (numbers of practitioners and scans not available yet)	5 (0.3%)	629 (40.5%)	551 (35.5%)	298 (19.2%)	69 (4.4%)	0 (0)%)

*NB. Bias range for red flags changed to 0.4mm (positive or negative from FMF reference curve) as of April 1st 2012 – DQASS Cycle 12

The Down's Syndrome Screening Quality Assurance Support Service (DQASS) are able to give specific information to ultrasound practitioners about positive and negative bias, spread and trend relative to the FMF reference curve. This graph gives the proportion of flags over four cycles.



Question 2

Some sonographers have questioned the validity of the reference curve but we are told that it is correct. Some sonographers have worked in centres which contributed to the reference curve data and have commented that the technique used was not as detailed as that now specified by the screening programme. Can FASP comment on this?

Answer: The technique to measure and obtain the Nuchal Translucency (NT) has always been specified by the Fetal Medicine Foundation (FMF) and this has not changed. FASP has developed some further specific anatomical guidance to help ultrasound practitioners ensure that they obtain the best possible section of the fetus to obtain the measurement. However the FMF rules to obtain the best section are used within this guidance and still apply. Some ultrasound practitioners have suggested that the calliper placement technique (inner to inner) used in contributing to the data on which the FMF reference curve is based leads to a bias of 0.2mm. This is much less than the biases that lead to red flags and was the technique used and recommended by FMF, on which the reference curve is based. Furthermore, the curve is based on close to 40,000 normal pregnancies.

Question 3

Are the plots on pages 20-24 of the 'Manual for Ultrasound Service Providers' (Version 2, 2012) based on real data? Some sonographers have commented that they would not recognise this spread from their experience in their own departments.

Answer: Yes. Individuals who do not have spread deviation in their own measurements may not recognise it. Spread usually occurs when ultrasound practitioners are new to measuring NTs, share their FMF or DQASS unique ID code with another practitioner or if practitioners are not supported to make adjustments to their technique to improve their measurements. The graphics were produced using simulated data that are typical of routine data reviewed by DQASS.

Question 4

Has the recommended technique been changed to try and counter under-measurement? Gain especially is turned down to the point that images could not have been assessed by FMF via their accreditation process. Is technique being adjusted to meet the expectations?

Answer: No. (See also comments on Question 2.) The FMF have always recommended turning down the gain. In the experience of the Regional Obstetric Screening Co-ordinator's (ROSCOS) some ultrasound practitioners have turned down the gain a little too much so all the anatomical features required to measure the NT could not be seen. The new image guidance tool (link not functional as of 2015-07-20

has been developed to address this by giving specific examples.

Question 5

Ultrasound at the frequencies used cannot measure to an accuracy of 0.1mm yet the DQASS QA scheme is based on this. Can DQASS provide the scientific rationale given that it seems to be in conflict with the basic physics of ultrasound?

Answer: NHS FASP appreciates the limitations of the ultrasound equipment, however the recommendation to measure to one decimal point is based on the research available and more importantly to ensure clinical practice is standardised throughout England. DQASS comment that they only assess whether the median distance of observed NT values from the FMF curve is within +/- 0.1mm, not that measurements are accurate to one decimal point.

Question 6

At what stage are the CRL/NT pairs entered on to the DQASS system and by whom? Reports suggest that mistakes have been made in this process which can affect the flag status of sonographers. It is recognised that FASP recommend that sonographers keep their own records and the Society and College of Radiographers would endorse this.

Answer: Data with NT, CRL and ultrasound practitioner unique ID code is provided to DQASS by the screening laboratory, usually as an Excel spreadsheet, exported from their risk calculation software.

There are three software products being used by laboratories in the UK: ViewPoint by GE Healthcare, LifeCycle/Elipse by PerkinElmer and Alpha by Logical Medical Systems (LMS).

When ViewPoint software is used by the laboratory the patient record is electronic, so there is little or no scope for transcription errors.

Where LifeCycle is used patient details are sent to the laboratory by individual centres using a blood sample request form. Laboratory staffs enter the data into their software manually. There is scope here for errors to be made.

We have been told by some hospitals that they have started using ID stamps for sonographers to use to make information on request forms clearer to the laboratory.

Unfortunately, it is impossible to state that transcription errors will never occur when data is being transferred manually, although it is unlikely that it would be to such a degree that sonographer flag status would be affected.

Ultrasound practitioners should be aware that not all women on whom they measure an NT will go on to complete the test. Some women for many reasons fail to attend for the blood test even when this is offered on the same day in the same location. DQASS have provided an Excel tool on the FASP website for ultrasound practitioners to use to monitor and record all their paired measurements if they wish.

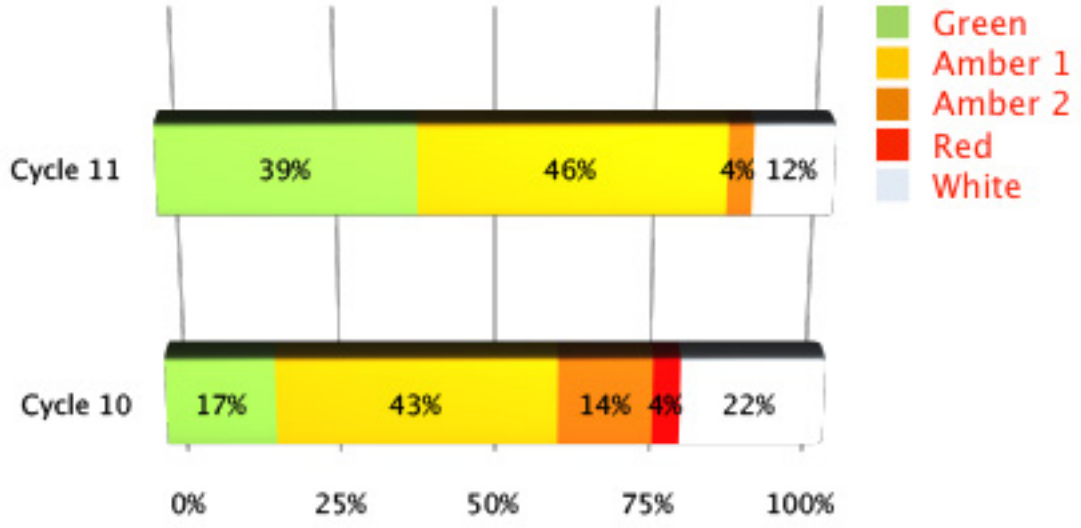
Question 7

Although individual sonographers are not identified, Trust managers, regional screening co-ordinators and commissioners are aware of the overall flag status of departments and this can have implications. Can sonographers be confident that the flag status really is due to technique and that there are not other factors operating? Commissioners and higher Trust management may not always fully understand the meaning of the various flags.

Answer: This is correct and we appreciate that red flags have implications not only for the screening test performance for individual women but also the ultrasound practitioner. In the Manual for Ultrasound Practitioners: measuring the NT and CRL as part of combined screening for Trisomy 21 in England (July 2012)

we have specified a number of reasons why practitioner measurements may have a red flag. There may for example be bias due to equipment. This may be evident from, as an example, all sonographers working at a particular site showing similar bias in NT; one sonographer working at different sites will see differences in the points of their distribution plot. However in the experience of the ROSCO group, flag status does appear to be predominantly related to poor technique. Minor adjustments to the ultrasound equipment to optimise the quality of the image achieved assists with improvements in measurement technique. It has always been the intention of NHS FASP to support practitioners to make improvements; however it is difficult for us to influence how individual managers or commissioners of services may react to these results. As an example, a Trust in the North West received three red flags in cycle 9 and 10 but with support and individual training those practitioners received green flags within a few weeks. The feedback was that their experience was a positive one. In cycle 12, the same department had 10 practitioners; 8 with green flags and 2 with amber flags.

Example demonstrating improved technique with support. Graph comparing final cycle 10 and 11 data for a North West Trust



Question 8

Agency sonographers obtain their flag status via DQASS but how are their images assessed? They may not return to a particular department.

Answer: It is the responsibility of each Trust/ultrasound department they work in to ensure these practitioners have their images assessed. DQASS collate all their measurement data from a variety of local screening providers. If the Screening Support Sonographer (SSS) or superintendent from each department informs them, DQASS have a notification form for the SSS to complete to inform them of such circumstances and have systems in place to report results for a sonographer to all hospitals that they have been told they are working at.

Question 9

Where independent providers hold a contract for the delivery of NHS first trimester screening are all the FASP QA procedures followed?

Answer: It is recommended that they should be. One NHS Trust has commissioned and uses practitioners wholly provided from a private company. These sonographers are reported on in exactly the same way as contracted staff.

Quesion 10

The potential for Work Related Musculo-skeletal Disorders (WRMSD) has been raised by many sonographers and the Society of Radiographer's Health and Safety Officer has been involved in several cases.

Answer: We appreciate that it isn’t always possible to obtain the measurements required for the T21 test in one appointment and we would wish practitioners to be mindful of their own and the patient’s safety by not prolonging the ultrasound examination to longer than 20 minutes. During training sessions the ROSCO’s have promoted the use of micro breaks during the scanning time and getting the women to move around if the examination proves difficult; this should help to alleviate WRMSD issues.

Question 11

How far away in terms of detection rate and false positive rate is the quadruple test (with the new cut-off of 1:150 at term)? This is much easier from an ultrasound

perspective; the necessary ultrasound dating can be done in a ten minute time slot. It would also potentially allow for increased use of Assistant Practitioners at a time of sonographer shortage.

Answer: A dating scan requires a highly trained professional to undertake the biometry measurement as these are used to standardise the laboratory Multiples of the Median for the quadruple test. Poor technique and inaccurate measurements can also lead to inaccuracies in gestational age assignment and screening test performance. NHS FASP is currently reviewing the evidence for the detection of structural fetal anomalies in the first trimester, which, should this be recommended as a national standard, would render the use of Assistant Practitioners as an inappropriate and inadequately trained choice of personnel to undertake the dating scan.

The Table below demonstrates modelled screening performance based on a cut-off of 1 in 150 and the maternal age distribution of England & Wales 2000-2002, using FMF parameters (combined test) or SURUSS (Serum Urine and Ultrasound Screening Study) parameters (quad test). Performance for the quad test using free beta-hCG is similar to that using total hCG.

Maternal Age	**Combined test**		**Quad test (total hCG)**	
	FPR (%)	**DR (%)**	**FPR (%)**	**DR (%)**
20 and under	1.1	73	1.6	56
21	1.1	73	1.7	56
22	1.1	73	1.7	56
23	1.2	73	1.7	57
24	1.2	74	1.8	57
25	1.2	74	1.9	58
26	1.3	75	2	58
27	1.4	75	2.1	59
28	1.5	76	2.3	61
29	1.6	77	2.6	62
30	1.8	78	2.9	63
31	2	79	3.3	65
32	2.3	80	3.9	68
33	2.7	82	4.7	70
34	3.2	83	5.7	73
35	3.8	85	7	75
36	4.6	86	8.6	78
37	5.6	88	10.7	81
38	7	89	13.3	84
39	8.7	91	16.5	87
40	10.8	92	20.3	89
41	13.3	93	24.9	91
42	16.4	95	30	93
43	20.2	96	35.8	95
44	24.6	96	42.1	96
45	29.6	97	48.7	97

Question 12

Do published FASP costings include the increased length of scan (20 minutes), repeat examinations after having been scheduled at the wrong time or having been a difficult fetal position; SSS time; ROSCO costs and time; training costs to reach the required standard and the general costs associated with administering what is a complex and very operator dependent screening test?

Answer: The decision analytic model developed by NHS FASP in conjunction with the PENTag (Exeter) has the capability to factor in a number of the variables described above.

Question 13

How is the possible use of free fetal DNA as a test for Down's syndrome proceeding?

Answer: The bank of maternal, paternal and fetal samples from pregnancies at risk of single gene disorders and aneuploidy now includes around 2000 samples. Currently these samples are being used in London, Salisbury and other laboratories around the country to investigate the development of specific non-invasive tests as well as best practice in sample processing.

Non-invasive testing will not be implemented in the NHS as a screening or diagnostic programme until the results from the RAPID (Reliable Accurate Prenatal non-Invasive Diagnosis) trial as well as a formal evaluation of the benefits and harms of the technology have been carried out.

Question 14

Can you comment on concerns about the sustainability of the ultrasound provision in view of the shortage of sonographers and the demands from other areas of the service? Many sonographers are only part time as far as obstetrics is concerned.

Answer: We appreciate the pressures and demands on the ultrasound services, however the screening tests are based on best practice guidance and evidence and have been demonstrated to be beneficial to health care services and women. We also know from a study in 2007 (An audit of antenatal ultrasound scans from 22 hospital in England and Wales during 2007: Report on behalf of the NHS Fetal Anomaly Screening Programme, P Boyd et al. 2009), that departments are undertaking a large number of post-anomaly scans (275) and professionals performing these scans deemed 17% of these as 'unnecessary'. This accounted for 11% of all non-routine obstetric scans in this study.

Question 15

Why can't NT/CRL pairs from twins be included in the audit programme?

Answer: Data from twins was not previously included in order to be consistent with DQASS laboratory audits. As of April 2012, DQASS are including data from twins in analyses. This will give a more accurate representation of sonographers' measurement performances and reduce the number of white flags (for less than 25 scans) allocated.

DQASS do not receive data about twins in a way that is consistent across all laboratories, owing to software. DQASS believe they have now overcome these inconsistencies.

Question 16

Can you confirm that there will no longer be funding for the ROSCOS?

Answer: That is correct. Funding for the ROSCO posts has now been withdrawn. There are plans for a national Screening Support Sonographers meeting in January 2013, date and venue to be confirmed shortly.

Question 17

Is there any firm data yet as to current detection and false positive rates for Down's syndrome?

NHS FASP and DQASS cannot yet provide data on the Trisomy 21 detection rates (screening test

performance should meet 90%*) due to a lack of joined-up local/national IT systems that are able to link to pregnancy outcome data. However, data on the screen positive rate (screening test performance should meet 2%*) is described below and supplied by DQASS, along with figures on the reduction in the number of invasive tests, supplied by the Association of Clinical Cytogeneticists.
*Ref: *Screening for Down's syndrome: UKNSC Policy Recommendations 2011 – 2014 Model of Best Practice*

DQASS Cycle 9 - from October 2010 to March 2011: 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.

	Number screened in data supplied	**Estimated annual number screened**	**Number screened positive**	**Estimated annual number screened positive**	**Standardised SPR (%)**
Combined	157,666	289,616	4,299	7,846	2.2
Double	4,077	8,106	183	364	4.5
Integrated	2,467	4,745	72	135	2.4
Quad	50,735	95,306	2,127	3,988	4.1
Triple	44,779	88,209	2,022	3,972	4.8
All	259,724	485,982	8,703	16,305	3.1

Table below demonstrates data for invasive procedures undertaken from 2003 to 2011 following a positive Down's syndrome (DS) screening result

Type of invasive procedure subsequent to a DS screen	**2003/4**	**2004/5**	**2005/6**	**2006/7**	**2007/8**	**2009/10**	**2010/1**
Amniocentesis	28,700	24,349	22,625	14,733	12,932	6795	6353
CVS	8,268	7,980	7,819	4,781	4,681	3669	4195
TOTAL	**36,968**	**32,329**	**30,444**	**19,514**	**17,613**	**10464**	**10548**