

Antenatal Screening for Down Syndrome and other Conditions

Guidelines for nuchal translucency
(NT) and crown rump length
(CRL) measurements



National Screening Unit

The National Screening Unit (NSU) of the Ministry of Health is responsible for the development, implementation and management of four national screening programmes and one quality improvement initiative:

- Antenatal screening for Down syndrome and other conditions (quality improvement initiative)
- Newborn Metabolic Screening Programme
- Universal Newborn Hearing Screening and Early Intervention Programme
- Breastscreen Aotearoa
- National Cervical Screening Programme.

Acknowledgements

These guidelines have been developed in consultation with radiology expert advisors.

The NSU thanks these advisors and the many individuals and groups who contributed to the development of this handbook.

Content within these guidelines is derived and modified from the United Kingdom Fetal Anomaly Screening Programme with permission.

Endorsements

These guidelines are endorsed by the New Zealand branch of the Royal Australian and New Zealand College of Radiologists (RANZCR) and the New Zealand branch of the Australasian Society for Ultrasound in Medicine (ASUM).

Citation: Ministry of Health. 2015. *Antenatal Screening for Down Syndrome and other Conditions: Guidelines for nuchal translucency (NT) and crown rump length (CRL) measurements*. Wellington: Ministry of Health.

Published in November 2015
by the Ministry of Health
PO Box 5013, Wellington 6145, New Zealand

ISBN 978-0-947491-34-5 (print)
ISBN 978-0-947491-35-2 (online)
HP 6297

This document is available at www.health.govt.nz



MANATŪ HAUORA



This work is licensed under the Creative Commons Attribution 4.0 International licence. In essence, you are free to: share ie, copy and redistribute the material in any medium or format; adapt ie, remix, transform and build upon the material. You must give appropriate credit, provide a link to the licence and indicate if changes were made.

Contents

Key messages	v
Introduction	1
Abbreviations used in this document	1
1 Background	2
2 Best practice criteria	3
2.1 Image guidance tools	3
2.2 Tips for achieving high quality NT measurements	6
2.3 Tips for achieving high quality CRL measurements	7
2.4 Obtaining high quality images	7
3 Image review	10
3.1 Scoring images	10
4 External quality improvement initiatives	17
4.1 Fetal Medicine Foundation requirements	17
4.2 Feedback to radiology	17
4.3 Bias, spread, trend	19
4.4 The flag system	23
4.5 Recommended actions	24
5 Internal quality assurance activities	26
5.1 Role of radiology practices – best practice guidance	27
5.2 Role of reporting radiologists – best practice guidance	28
5.3 Role of ultrasound practitioners – best practice guidance	29
Appendix 1	30
NT image score sheet	30
CRL image score sheet	31
Appendix 2	32
Action plan template	32

List of Tables

Table 1:	Image guidance tool for best practice NT	3
Table 2:	Image guidance tool for best practice CRL	4
Table 3:	Grading images using the image guidance tools for NT and CRL	10
Table 4:	Relevance of bias, spread and trend	22
Table 5:	Flag status definitions for bias	23
Table 6:	Flag status definitions for spread	23
Table 7:	Flag status definitions for trend	24
Table 8:	Flag status for less than 25 scans	24
Table 9:	Factors that may affect quality	25
Table 10:	Quality assurance activities for radiology practices	27
Table 11:	Quality assurance activities for radiologists	28
Table 12:	Quality assurance activities for ultrasound practitioners	29

List of Figures

Figure 1:	Example NT scan feedback report	18
-----------	---------------------------------	----

List of Images

Image 1:	Caliper placement for NT measurement	5
Image 2:	Caliper placement for CRL measurement	6
Image 3:	Comparison of frequency	7
Image 4:	Magnification setting	8
Image 5:	Gain setting	9
Image 6:	Transvaginal scan	9
Image 7:	NT scan image reviewed and assessed as good	11
Image 8:	NT scan image reviewed and assessed as acceptable	12
Image 9:	NT scan image reviewed and assessed as poor	13
Image 10:	CRL scan image reviewed and assessed as good	14
Image 11:	CRL scan image reviewed and assessed as acceptable	15
Image 12:	CRL scan image reviewed and assessed as poor	16

Key messages

- Combined first trimester antenatal screening for Down syndrome and other conditions involves a maternal blood test taken between 9w0d – 13w6d gestation (ideally at 9 to 10 weeks) and an ultrasound scan to provide nuchal translucency (NT) and crown-rump length (CRL) measurements between 11w2d – 13w6d when the CRL is between 45–84mm (ideally performed around 12 weeks when the CRL is greater than 56mm).
- Precise NT and CRL measurements are essential for high quality risk results for antenatal screening for Down syndrome and other conditions.
- The National Screening Unit (NSU) of the Ministry of Health is responsible for monitoring and reporting on national screening initiatives. This includes monitoring NT and CRL measurements.
- Feedback to radiology practitioners provides information on the quality of NT and CRL measurements and assists with best practice review.
- Feedback will be provided to radiology practices, reporting radiologists and individual practitioners. To provide this feedback, all radiology reports provided for antenatal screening for Down syndrome and other conditions require the name and Fetal Medicine Foundation (FMF) number of the person performing the scan as well as the name of the person reporting the scan.
- The feedback provides radiology with a green, amber or red flag status based on the quality of NT and CRL measurements.
- The aim of the feedback is to ensure that all women receive a high quality risk result for antenatal screening for Down syndrome and other conditions.

Introduction

The purpose of these guidelines is to support radiology practitioners to provide high quality nuchal translucency (NT) and crown-rump length (CRL) ultrasound measurements as part of antenatal screening for Down syndrome and other conditions.

These guidelines provide detail on best practice measurements, the quality assurance processes within each radiology practice and detail on the feedback process aimed at assisting radiology providers in delivering high quality ultrasound services as part of first trimester combined antenatal screening for Down syndrome and other conditions in New Zealand.

Accurate and precise NT and CRL measurements are essential for high quality risk results for women who chose to have antenatal screening for Down syndrome and other conditions. The measurements are used within the calculation, which generates the risk report that is provided to women. Although there are other factors included within the risk calculation, the quality of the NT measurement has a significant impact on the quality of the risk calculation. The CRL measurement also plays a key role in standardising the maternal serum results against an accurate gestational age, which is pivotal in generating a high quality risk result.

The National Screening Unit (NSU) of the Ministry of Health is responsible for antenatal screening for Down syndrome and other conditions. Monitoring of this screening has identified that there is variation in the quality of NT and CRL measurements throughout New Zealand. This has led to the provision of feedback to support quality improvements of NT and CRL measurements. This assists all women receiving a reliable, high quality risk result for antenatal screening for Down syndrome and other conditions.

The feedback process is part of the NSU's work to continuously improve the quality of antenatal screening for Down syndrome and other conditions and is similar to feedback provided to radiology practitioners in Australia, England, Canada and some of the United States of America.

Abbreviations used in this document

AFP	Alpha- fetoprotein
βhCG	Beta-human chorionic gonadotrophin
CRL	Crown rump length
FMF	Fetal Medicine Foundation
NT	Nuchal translucency
PAPP-A	Pregnancy associated plasma protein
μE ₃	Unconjugated oestriol

1 Background

Quality improvements to antenatal screening for Down syndrome and other conditions were introduced in New Zealand in 2010 to bring this screening into line with international best practice. While all pregnant women are advised about this screening, it remains optional. Screening is made available so that women who wish to have this information about their baby are able to find out during pregnancy and plan accordingly.

These guidelines should be read in conjunction with the *Antenatal Screening for Down Syndrome and Other Conditions Guidelines for Health Practitioners 2013* found at www.nsu.govt.nz

Health practitioners providing ultrasound services to women have an obligation to provide services specified under the Primary Maternity Services Notice 2007, issued pursuant to Section 88 of the Public Health and Disability Act 2000, Section DC5 can be found at: www.health.govt.nz/publications/section-88-primary-maternity-services-notice-2007

Further information about the Fetal Medicine Foundation can be found at: <https://fetalmedicine.org/> Monitoring reports for this screening and other information can be found at www.nsu.govt.nz Further information about the general principles of screening can be found at: www.nsu.govt.nz The NSU e-learning modules are available at: www.learnonline.govt.nz

2 Best practice criteria

2.1 Image guidance tools

To provide the most accurate NT and CRL measurements, the ultrasound image should meet most or all of the 12 criteria outlined in Tables 1 (NT) and 2 (CRL).

Images 1 (NT) and 2 (CRL) provide graphical images of best quality NT and CRL measurements.

Table 1: Image guidance tool for best practice NT

Sections	Image guidance for best practice NT
Midline section	<ol style="list-style-type: none">1. Horizontal sagittal section of the fetus extending from crown to include at least the upper section of the heart.*2. Head in line with the body with the NT visible along the length of the neck.3. Echogenic tip of nose.4. Rectangular shape of the palate.5. Translucent diencephalon.6. Frontal process of the maxilla not visible.
Position	<ol style="list-style-type: none">7. Pocket of fluid, at least equivalent in size to the width of the palate, visible between the fetal chin and chest.8. Angle of the palate relative to the horizontal between 30° and 60°.9. Nasal tip level with, or below, the anterior chest wall.
Magnification	<ol style="list-style-type: none">10. Section fills over 60% of the screen.
Caliper placement	<ol style="list-style-type: none">11. Calipers placed on the upper and lower edges of the NT – the skin lines that define the nuchal fluid (see Image 1).12. Widest part of the NT is measured.

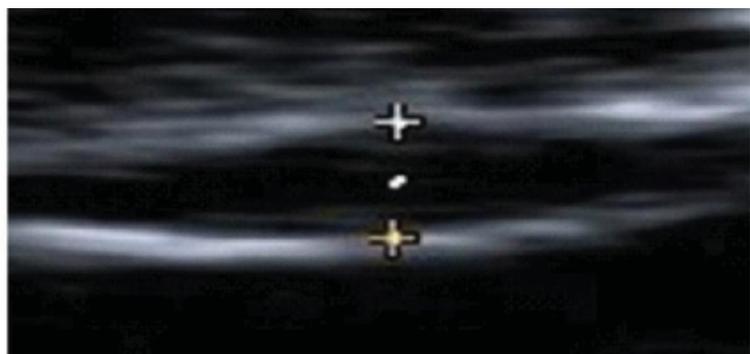
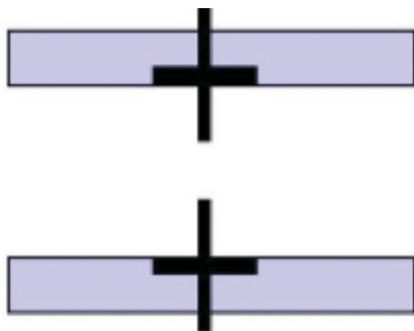
* This assumes that the fetus is supine. The image components can still be applied when the fetus is prone, although it may not be possible to score component 3 (echogenic tip of nose). Therefore, when the fetus is prone, an image score of 'good' may not be achievable (see Table 3 page 10).

To provide the most accurate CRL measurements, the ultrasound image should meet most or all of the 12 criteria outlined in the image guidance tool in Table 2.

Table 2: Image guidance tool for best practice CRL

Sections	Image guidance for best practice CRL
Midline section	<ol style="list-style-type: none">1. Sagittal section of the fetus with the head in line with the full length of the body.2. Echogenic tip of nose.3. Rectangular shape of the palate.4. Translucent diencephalon.5. CRL axis between 0° and 30° to the horizontal.6. Clearly defined crown and rump.
Position	<ol style="list-style-type: none">7. Pocket of fluid, at least equivalent in size to the width of the palate, visible between the fetal chin and chest.8. Fetal palate angle between 30° and 60° relative to horizontal.9. Nasal tip level with, or above the anterior abdominal wall.
Magnification	<ol style="list-style-type: none">10. Entire CRL section fills over 60% of the screen.
Caliper placement	<ol style="list-style-type: none">11. Correct caliper placement on outer borders of crown and rump (see Image 3).12. Longest measurement of the fetus is taken.

Image 1: Caliper placement for NT measurement



The NT image should be obtained with a sagittal view of the fetus in a neutral position. The fetus should be horizontal on the screen with the image including from the crown to at least the upper section of the heart. The head should be in line with the body with the NT visible along the length of the neck. A pocket of fluid, at least equivalent in size to the width of the palate should be visible between the fetal chin and chest. The image should fill approximately 60 percent of the screen.

The calipers should be placed on the upper and lower edges of the NT – the skin lines that define the nuchal fluid. The widest part of the NT is measured.

Image 2: Caliper placement for CRL measurement



The CRL image should be obtained with a sagittal view of the fetus in a neutral position, horizontal on the screen. Both crown and rump should be clear of the uterine wall for accurate measurements to be obtained. The calipers should be placed at the crown and rump of the fetus.

2.2 Tips for achieving high quality NT measurements

- Ensure midline sagittal view of the fetus.
- The frontal process of the maxilla should not be visible.
- Use the highest frequency transducer available, which may be linear, curvilinear or transvaginal scan (see Section 2.4.1, Images 3A and 3B, 6A and 6B).
- Ensure appropriate depth and magnification, demonstrating head and upper thorax in field of view (see Section 2.4.1, Images 4A and 4B).
- Use appropriate gain settings (see Section 2.4.1, Images 5A and 5B).
- Adjust the dynamic range.
- Focus in the correct location.
- Measure on the lines that define the NT.
- Measure the NT at least twice and record the maximum measurement that meets the criteria.
- Archive the image showing the reported NT.
- Watch www.youtube.com/watch?v=yJs1OxjtPu8

2.3 Tips for achieving high quality CRL measurements

- Ensure sagittal view of the fetus in a neutral position, horizontal on the screen.
- Place calipers at the crown skin above the parietal bone and rump (skin inferior to the tip of the sacrum).
- Use appropriate depth and magnification settings.
- Measure the CRL at least twice and the maximum best measurement that meets the criteria should be recorded.
- Archive the image showing the reported CRL.

NB: To be accepted for Antenatal screening for Down syndrome and other conditions the CRL must be between 45–84 mm.

2.4 Obtaining high quality images

Obtaining high quality images may require making the required adjustments of frequency, depth, gain settings, high definition zoom and occasional use of a transvaginal (TV) approach as shown in the following comparisons.

2.4.1 Comparisons of settings

Frequency setting

The following two images taken of the same fetus demonstrate the difference between an NT image obtained using a high frequency transducer Curvilinear C4-8 (Image 3A) versus a low frequency transducer Curvilinear C1-5 (Image 3B).

Comparison of frequency

C4-8

Image 3A



C1-5

Image 3B



In Image 3B, the intracranial landmarks are difficult to identify and the lines that define the NT are thick, resulting in an underestimation of the NT. The best frequency setting is a high frequency transducer (Curvilinear C4-8) as used in Image 3A.

Magnification setting

The two images taken of the same fetus in this section, demonstrate the difference between an NT image obtained with the use of correct magnification (Image 4A) versus incorrect magnification (Image 4B).

Image 4A



Image 4B



Correct magnification ensures the head and upper thorax are in field of view.

Gain setting

The scans below are images of the same fetus.

Image 5A was obtained using a high frequency transducer with the fetus in the correct position. Appropriate gain settings are used. Image 5B demonstrates the fetus in an incorrect position. The overall gain is set too high resulting in poor visualisation of intracranial landmarks and thicker lines which define the NT, resulting in an underestimation of the NT measurement.

In Image 5A the nasal bone is clear, the maxilla is not visible, the intracranial landmarks are able to be identified and the chin is in a neutral position.

In Image 5B, the maxilla is visible, the neck is flexed and the chin is too close to the chest and the nasal bone is not well seen.

Comparison of images demonstrating how adjusting the overall gain settings and fetal position can alter the NT measurement obtained.

Image 5A



Image 5B



Best quality images are obtained when the fetus is in the correct position and the scan is performed using a high frequency probe with appropriate gain setting.

Transvaginal scan

The use of a transvaginal scan (Image 6A) can help obtain an NT measurement when fetal position makes it unsatisfactory to obtain adequate images transabdominally (Image 6B).

The use of transvaginal scanning is recommended to assess the fetal anatomy and NT when adequate views are not obtainable by a transabdominal approach, for example when the uterus is retroverted or secondary to increased patient Body Mass Index (BMI).

Image 6A: Transvaginal scan



Image 6B: Poor fetal position (transabdominal)



3 Image review

To ensure that all scans are of a suitable quality and provide accurate results for the risk assessment for antenatal screening for Down syndrome and other conditions, regular image review within practices of NT and CRL measurements against the image guidance tool criteria is strongly recommended.

3.1 Scoring images

The reviews should involve checking each image against the twelve criteria outlined in each of the Image Guidance Tools for NT and CRL measurements and scoring them accordingly (Tables 1 and 2).

Sample score sheets can be found in Appendix 1.

This process will result in each image gaining an overall score out of 12. The image may then be graded according to the criteria outlined in Table 3.

Table 3: Grading images using the image guidance tools for NT and CRL

Number of criteria present	Overall score
All 12 present	Good
10 to 11 present (no more than two absent in any image review of each section see Tables 1 and 2)	Acceptable
9 to 11 present (three or more absent in an image review of each section see Tables 1 and 2) 8 or fewer present	Poor

In order for an ultrasound image to be considered ‘good’ or ‘acceptable’ at least 10 out of 12 criteria (83%) must be present. In sections of more than one criterion, there should be no more than two criteria in each section absent.

All images provided as part of antenatal screening for Down syndrome and other conditions must be good or acceptable.

In conducting an image review, three paired images are reviewed. If a practitioner scores ‘poor’ for all three pairs of images, it is recommended that he or she has an individualised training plan to support improvements to their imaging and measurement techniques as covered in this section.

Examples of scan images reviewed and assessed as good, acceptable and poor according to the image guidance tool are provided in Images 7, 8 and 9 (NT) and Images 10, 11 and 12 (CRL).

Image 7: NT scan image reviewed and assessed as good



Midline section						Position			Mag	Calipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
12/12 components present											Good	

Image 8: NT scan image reviewed and assessed as acceptable



Midline section						Position			Mag	Calipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
✓	✓	✓	✓	✓	x	✓	✓	✓	✓	✓	✓	
11/12 components present											Acceptable	
6. Frontal process of the maxilla is present.												

Image 9: NT scan image reviewed and assessed as poor



Midline section						Position			Mag	Calipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
✓	✓	✓	✓	✓	x	x	✓	x	✓	x	x	

7/12 components present

Poor

- 6. Frontal process of the maxilla is present.
- 7. No pocket of fluid under the chin.
- 9. Nasal tip below anterior chest wall.
- 11. Calipers are not correctly placed on the skin lines.
- 12. Widest part of the NT not measured.

Image 10: CRL scan image reviewed and assessed as good



Midline section						Position			Mag	Calipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
12/12 components present												Poor

Image 11: CRL scan image reviewed and assessed as acceptable



Midline section						Position			Mag	Calipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
✓	✓	✓	x	✓	✓	✓	✓	✓	✓	✓	✓	
11/12 components present											Acceptable	
4. Diencephalon absent.												

Image 12: CRL scan image reviewed and assessed as poor



Midline section						Position			Mag	Calipers		Overall
1	2	3	4	5	6	7	8	9	10	11	12	
x	✓	✓	✓	✓	x	✓	✓	✓	✓	x	x	

8/12 components present

Poor

1. The full length of the body is not present.
6. The rump is not clearly defined.
11. Calipers are not correctly placed on the rump.
12. The longest measurement has not been taken.

4 External quality improvement initiatives

4.1 Fetal Medicine Foundation requirements

All practitioners performing NT and CRL scan measurements for antenatal screening for Down syndrome and other conditions must:

1. hold the Fetal Medicine Foundation (FMF)¹ Certificate of Competence, which can be achieved by attending the FMF internet based course on the 11–13 weeks scan and submitting a logbook of three images demonstrating the measurement of NT, and
2. provide **NT images** annually as required by FMF for external image review: <https://fetalmedicine.org/>

Note: It is no longer a requirement to submit **NT data** annually to the FMF for audit as this information will be provided by the NSU feedback.

4.2 Feedback to radiology

The NSU quality improvement initiative includes a statistical service to provide radiology practices and DHB radiology departments with feedback on the quality of NT and CRL measurements provided as part of antenatal screening for Down syndrome and other conditions.

All scan reports for antenatal screening for Down syndrome and other conditions must include the name of the:

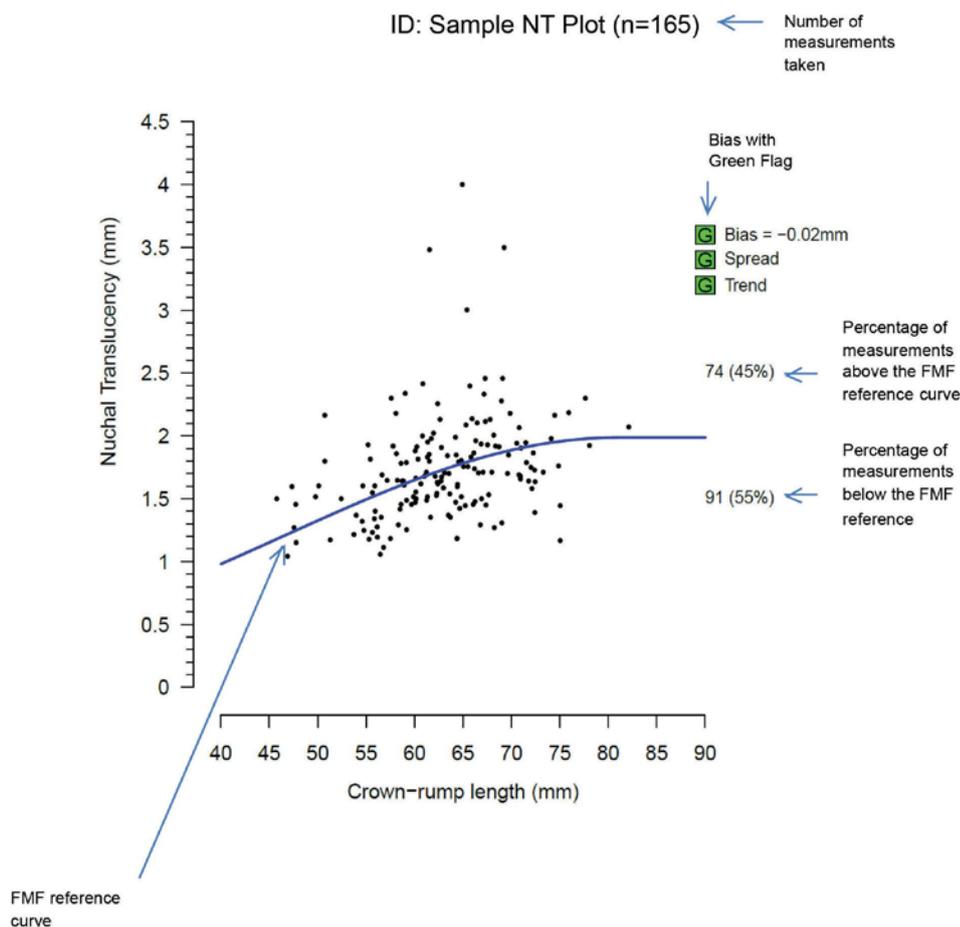
- ultrasound practitioner who performed and/or supervised the scan and their unique FMF ID number
- reporting radiologist
- radiology practice.

Feedback will be provided to each named radiology practice/department, reporting radiologist and practitioner performing NT scans.

The feedback, which will initially be provided for 2014 and 2015 data and for every 6 months thereafter, will include a graph of paired NT and CRL measurements against the FMF reference curve¹ (example in Figure 1) as well as a summary and explanation of the data.

¹ More information about the FMF can be found at: <https://fetalmedicine.org/>

Figure 1: Example NT scan feedback report



Each practice or department will receive:

- a graph for the total NT and CRL scan measurements submitted from the practice together with the list and bias confidence intervals for the flag status of individual radiologists and NT practitioners
- graphs for each reporting radiologist for distribution (sealed envelopes)
- graphs for each ultrasound practitioner for distribution (sealed envelope).

The feedback is designed to provide the radiology practice, reporting radiologist and individual ultrasound practitioners/sonographers with information and feedback on the quality of NT and CRL measurements that they have either performed or signed out from the practice or department.

4.2.1 The FMF reference curve

The data within each graph will be assessed to indicate performance against the FMF reference curve. The curve is a statistically validated benchmark used internationally to provide standardised measurements for comparison² in three areas.

1. Bias – The difference between paired NT and CRL measurements and those expected from the FMF reference curve.
2. Spread – The way measurements cluster along the FMF curve.

² Kagan et al. 2009. Effect of deviation of nuchal translucency measurements on the performance of screening for trisomy 21. *Ultrasound in Obstetrics and Gynaecology* 33:657–664.

- Trend – The shape and direction of the curve of NT and CRL measurements relative to the FMF reference curve.

Summary measures of bias, spread and trend will be presented on the reports together with flags to aid interpretation.

4.3 Bias, spread, trend

Each individual graph of paired NT and CRL measurements provided in the feedback will be accompanied by assessments of bias, spread and trend measured against the FMF reference curve. These are defined below.

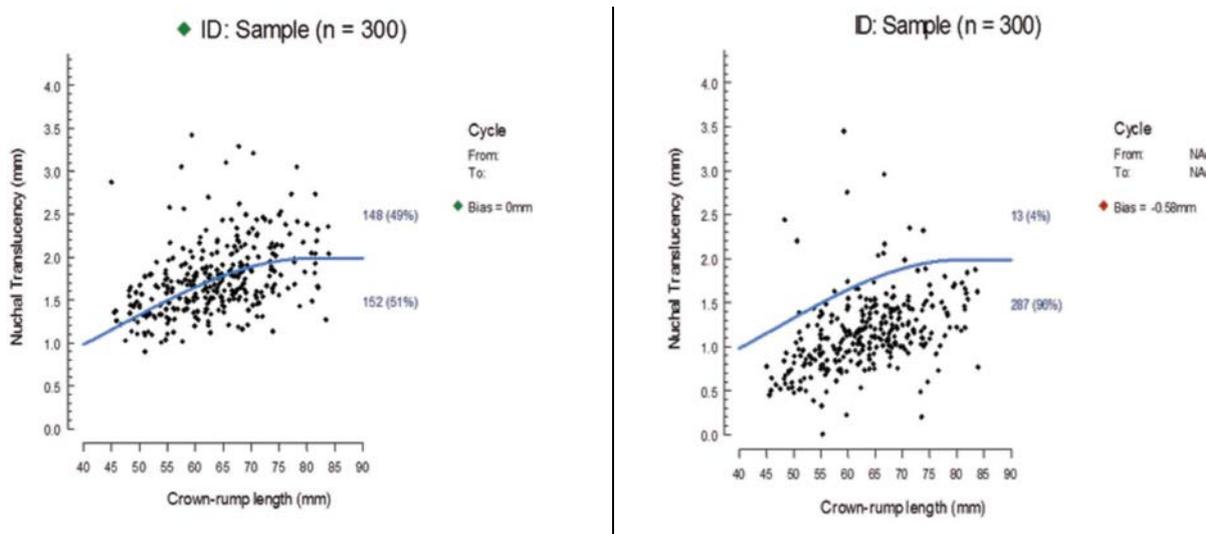
4.3.1 Bias

The bias is the difference between the NT and CRL measurements in relation to the FMF reference curve. The bias as presented, is the average bias over all the measurements which is assigned a flag.

The figures shown in the graphical distribution plot are the number and percentage of measurements above and below the FMF curve.

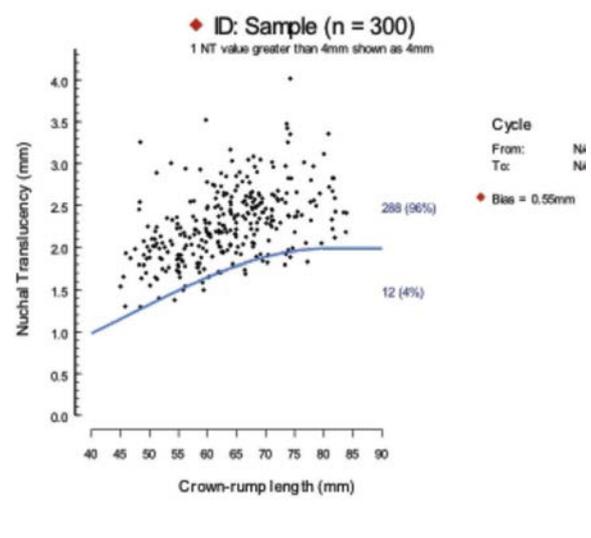
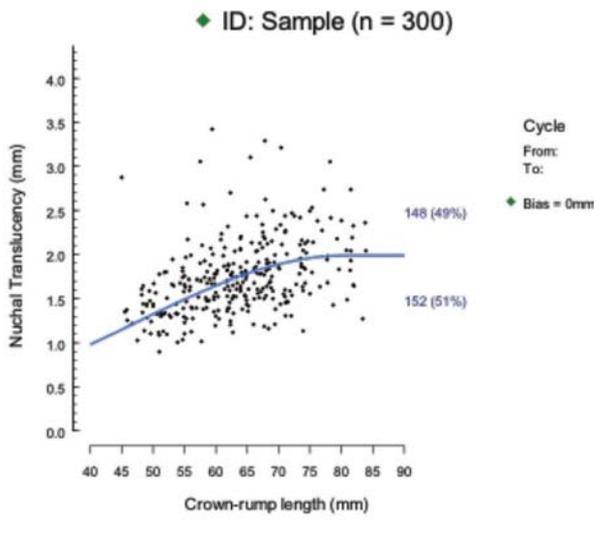
The expectation is that there are an equal number of points above the curve as below.

Bias



The ideal graph with a green flag bias is on the left. The graph on the right with a red flag shows a large negative bias, which could be due to under measuring NT and can lead to lower calculated risk results.

Bias

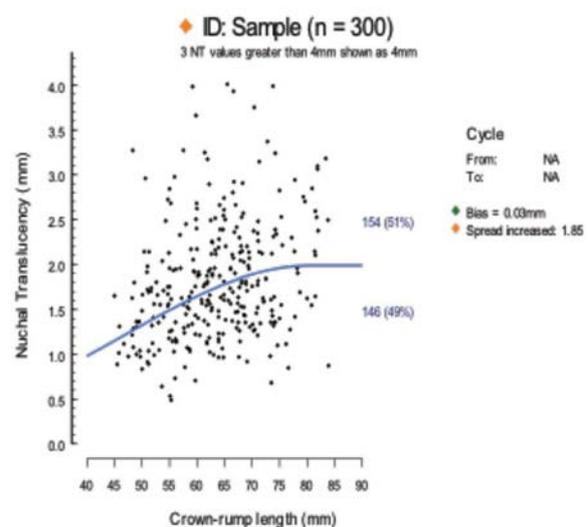
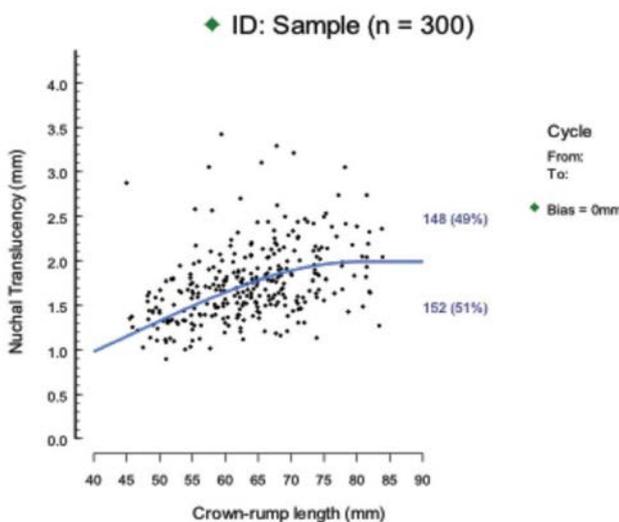


The ideal graph with a green flag is on the left. The graph on the right with a red flag shows a large positive bias which could be due to over measuring NT and can lead to higher calculated risk results.

4.3.1 Spread

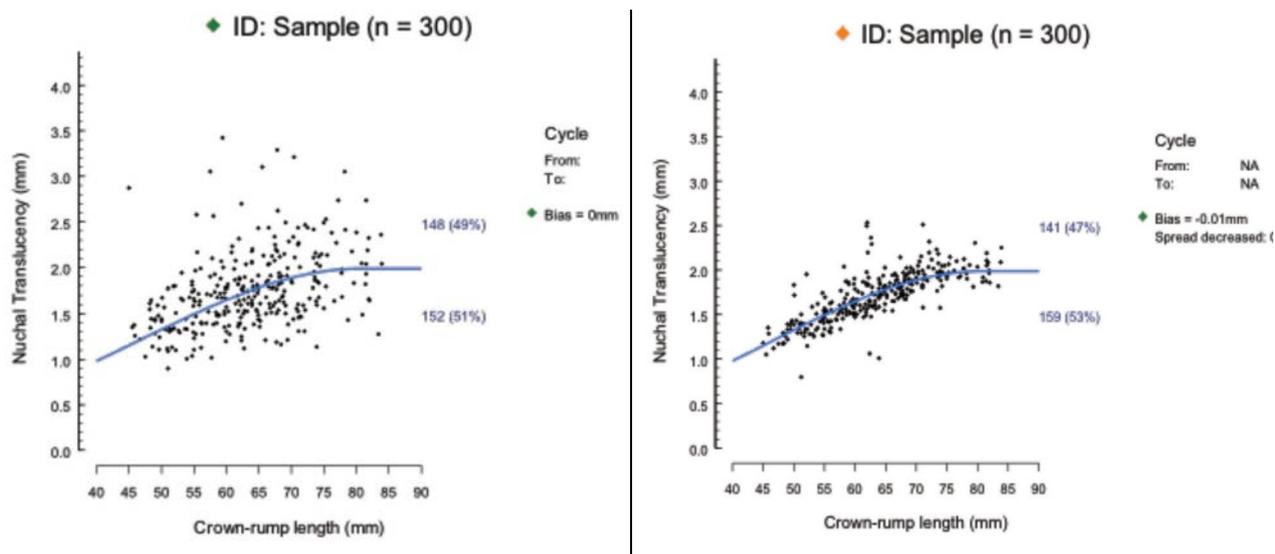
The spread of NT measurements is the way most measurements cluster along the FMF reference curve. The number shown is the factor by which the spread is increased (a greater spread means the measurements vary more greatly than would be expected given the CRL) or decreased (a lesser spread means the measurements cluster very tightly around the curve, without the expected normal variance).

Spread



The ideal graph with a green flag is on the left. The graph on the right with an amber flag shows much more spread which suggests less high quality NT and CRL measurements.

Spread

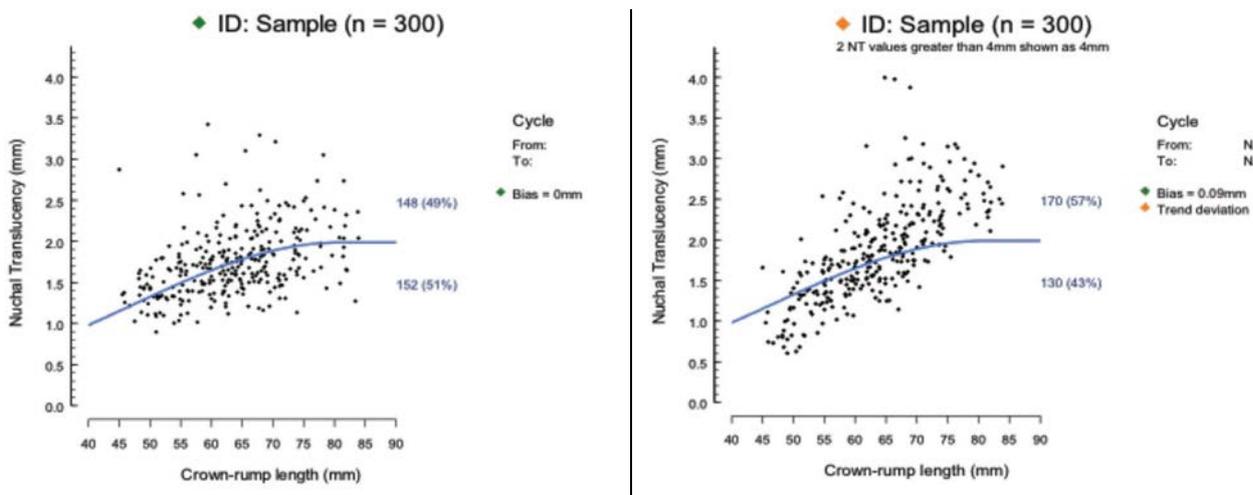


The ideal graph with a green flag is on the left. The graph on the right with an amber flag shows much less spread and does not show the expected degree of biological variation which suggests less high quality NT and CRL measurements.

4.3.3 Trend

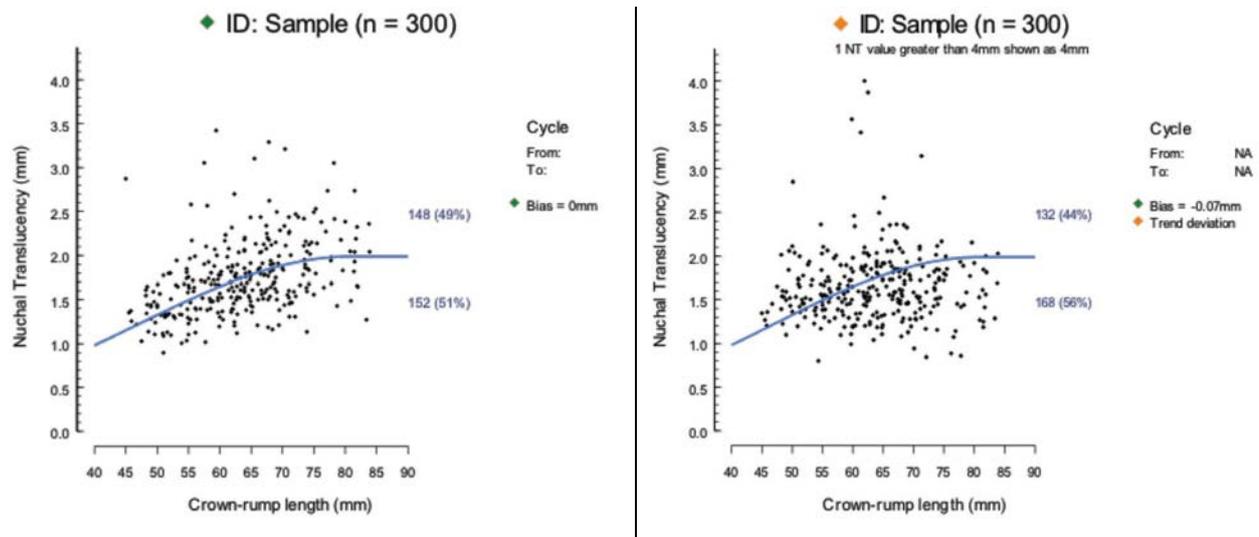
The curve of observed NT /CRL values should mimic the FMF curve in shape and direction. The value displayed shows the degree of discrepancy between the expected trend as compared to the observed measurements.

Trend



The ideal graph with a green flag is on the left. The graph on the right with an amber flag shows different biases at different CRLs and does not follow the FMF curve which would suggest less high quality NT and CRL measurements and can lead to issues with the quality of risk results for antenatal screening for Down syndrome and other conditions.

Trend



The ideal graph with a green flag is on the left. The graph on the right with an amber flag shows another variation of different biases at different CRLs which suggests less high quality NT and CRL measurements and can lead to issues with the quality of risk results for antenatal screening for Down syndrome and other conditions.

4.3.4 Relevance of bias, spread and trend

Deviations in any of these measures (bias, spread or trend) can have an impact on the risk estimate provided to the women for antenatal screening for Down syndrome and other conditions. The effect on the risk estimate is summarised below. (Note that this is a simplified interpretation.)

Table 4: Relevance of bias, spread and trend

Measure	Description	Effect on risk result
Bias		
Negative	Points tend to lie below the FMF curve.	Risks are decreased.
Positive	Points tend to lie above the FMF curve.	Risks are increased.
Spread		
Decreased	Points tend to lie closer to the FMF curve.	Risks tend to decrease with NT so that points that are lower than they should be because of decreased spread will be given lower risks that they should have.
Increased	Points tend to lie further from the FMF curve.	Risks tend to increase with NT so that points that are higher than they should be because of increased spread will be given higher risks that they should have.
Trend		
Negative	For lower CRL values, points tend to lie above the curve whereas for higher CRL values, points tend to lie below the curve.	Risk results are increased with a low CRL and decreased with a high CRL.
Positive	For lower CRL values, points tend to lie below the curve whereas for higher CRL values, points tend to lie above the curve.	Risks are decreased with a low CRL and increased with a high CRL.

4.4 The flag system

4.4.1 Bias

The most frequently occurring departure from the FMF reference curve is a general tendency to under or over measure the NT. This effect of this practice shows on the feedback graph as a shift of NT measurements downwards or upwards relative to the FMF reference curve. This is the most significant factor of the feedback graph in most cases.

An estimate of the overall bias relative to the FMF reference curve is given in each report. This is accompanied by a flag categorising the bias as red, amber or green.

Table 5: Flag status definitions for bias

Flag type	Flag	Bias
Green		Assigned when NT bias relative to FMF reference curve is 0.10mm or less
Amber		Assigned when NT bias relative to FMF reference curve is between 0.11 and 0.30mm
Red		Assigned when NT bias relative to FMF reference curve is 0.31mm or greater

Each graph will also be accompanied by some written commentary to assist with understanding.

In reports where there is an amber flag for bias, the commentary will mention the overall bias and specify its direction.

In reports with red flags, the report will mention that there is substantive overall bias and specify its direction.

4.4.2 Spread

Occasionally, there will be a departure from the FMF reference curve where the points are substantially more or less spread out than expected.

A flag for spread is given on the reports to indicate whether, after taking account of CRL, the spread of NT measurement is greater or less than expected from the FMF reference curve. Only green and amber flags are given for spread.

Table 6: Flag status definitions for spread

Flag type	Flag	Spread
Green		Assigned when there is no evidence of substantive difference from the FMF reference curve.
Amber		Assigned where there is substantive difference from the FMF reference. If more spread than expected, the factor will be greater than 1. If less spread than expected, the factor will be less than 1.

In reports with amber flags for spread, the commentary will mention the spread deviation and specify whether the NT measurements are more or less spread out than the FMF reference curve.

4.4.3 Trend

Occasionally, there will be a departure from the FMF reference curve where, after allowing for any overall bias, the underlying relationship between NT and CRL in the data difference substantially from the FMF reference curve. This is described as a trend deviation.

A flag for trend is given on the reports to indicate whether there is a trend deviation from the FMF reference. A trend deviation describes the situation where, after allowing for any overall bias, the relationship between NT and CRL in the data difference substantially from the FMF reference curve. Only green and amber flags are given for trend.

Table 7: Flag status definitions for trend

Flag type	Flag	Spread
Green		Assigned when there is no evidence of substantive trend deviation.
Amber		Assigned where, after allowing for any overall bias, the NT measurements show a trend deviation.

In reports with amber flags for trend, the commentary will mention the direction of the trend deviation.

4.4.4 Number of scans required for reliable statistical analysis

Twenty-five measurements in a six-month period are usually required for statistical validation. All ultrasound practitioners who perform fewer than 25 NT and CRL measurements will receive a plotted graph and will be assigned a White flag. Where the bias is evident despite small scan numbers a green, amber or red flag will also be assigned to the white flag report. Practitioners who have a white flag will not be assessed for spread or trend.

Reports will be provided cumulatively over a two-year period and report on the last 25 measurements.

Table 8: Flag status for less than 25 scans

Flag type	Flag	Spread
White		Assigned when fewer than 25 paired NT/CRL measurements in an assessment period.

4.5 Recommended actions

Ultrasound practitioners assigned a green flag in all three areas (bias, spread and trend) are performing overall to a high standard and are deemed competent to support other practitioners. They should continue to be involved in quality assurance activities.

The practice of individual practitioners assigned an amber flag is regarded as sub-optimal. It is recommended that practitioners discuss this with an appropriate person within the radiology practice (who may be a radiologist or green flagged operator) and make quality improvements as required.

The practice of individual practitioners assigned a red flag are regarded as unsatisfactory. Further training, support, advice and supervision are recommended until measurements improve to the green range.

The aim of the feedback to radiology quality improvement initiative is that all women ultimately receive a risk report generated by a practitioner with green flag status.

The quality of NT and CRL measurements can usually be improved by developing a thorough understanding of the factors that affect it.

Table 9: Factors that may affect quality

Factors that may affect quality	Detail
Machine factors	Level of sophistication, recent upgrades, servicing, local quality control arrangements
Environment	Ambient light levels within the examination room exceeding Lux level 15 Department workload and the time allocated to perform the scan
Practitioner	Practitioner under or over measuring the CRL Practitioner under or over measuring the NT to maintain a bias to the FMF reference curve Practitioner's improvements in measurement technique Ultrasound practitioner's eyesight
Process	Ultrasound practitioners sharing the same FMF identity codes Very low numbers (less than 25) of NT measurements performed in a six-month period High-risk caseloads Demographic factors (eg, increased prevalence of women with a raised BMI) Automated measurements

5 Internal quality assurance activities

Radiology practices/departments, reporting radiologists and the individuals performing ultrasound scans have a pivotal role in supporting quality assurance processes that ensure best quality NT and CRL measurements are performed.

The responsibilities of practitioners performing NT ultrasound scans include:

- meeting the requirements of the Royal Australian and New Zealand College of Radiologists (RANZCR) and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) within the Section 88 Primary Maternity Services Notice 2007 www.health.govt.nz/publications/section-88-primary-maternity-services-notice-2007
- holding the Fetal Medicine Foundation (FMF) Certificate of Competence and submitting three images annually for external review
- participating in internal image review against the NT and CRL criteria in Sections 2 and 3 and considering changes in practice where required
- where red or amber flag status has been assigned:
 - reviewing the FMF information and certification course
 - ensuring peer review of images and practice by a green flag practitioner

Radiology practices can support quality improvements through:

- supporting and monitoring FMF training requirements
- providing a process for internal quality reviews to lead to key learnings and improvements in practice
- supporting radiologists and ultrasound practitioners to review images
- supporting companion or peer scanning
- supporting sharing of images and measurements both informally and formally.

5.1 Role of radiology practices – best practice guidance

Table 10: Quality assurance activities for radiology practices

Practice responsibility	QA activity
Ensuring identifiable reports	Ensure that all NT scan reports submitted for antenatal screening for Down syndrome and other conditions include the name of the person who performed the ultrasound and their unique FMF number as well as the name of the reporting radiologist.
Receive data from the NSU and distribute to radiologists and NT practitioners	Ensure that all radiologists who report NT scans and practitioners who perform NT scans are provided with feedback on their results.
Ensure that all practitioners who are assigned red or amber flag reports are supported to make improvements	<p>Ensure all practitioners assigned red or amber flags are provided with the support required to improve practice including review of images within the practice.</p> <p>Practitioners assigned a red or amber flags are supported to identify quality improvements to improve image quality (Section 3).</p> <p>This may include an action plan that identifies training and upskilling activities.</p>
Review image quality of all practitioners performing NT scans)	Ensure that the quality of images performed by ultrasound practitioners are reviewed within the practice and all practitioners supported to identify quality improvements to improve image quality.
Education and training	<p>Ensure all ultrasound practitioners performing NT and CRL measurements comply with FMF requirements Section 4.1.</p> <p>Ensure regular peer review occurs within practices to support continuous professional development.</p> <p>The following image guidance tool and FMF training can support education and training: www.youtube.com/watch?v=yJs1OxjtPu8</p>
Support and mentoring	<p>Maintain records of performance, training and completion of action plans to support internal and external quality assurance.</p> <p>Ensure all ultrasound practitioners are given ongoing support and mentoring to maintain improvement in practice.</p>

5.2 Role of reporting radiologists – best practice guidance

Radiologists have an important role in supporting quality assurance processes that ensure best quality NT and CRL measurement are performed.

The key focus for radiologists is reporting the ultrasound image and assessing its technical appropriateness. Radiologists also play a role in the review of images and supporting ultrasound practitioners to ensure high quality NT and CRL measurements.

Table 11: Quality assurance activities for radiologists

Radiologist responsibility	QA activity
Reporting	Ensures that all NT and CRL scan images are reviewed and assessed for technical appropriateness. If the image is not technically appropriate the reporting radiologist should consider not reporting the NT and CRL measurements for the examination. Ensures the written report is accurate eg, 12mm is not 1.2mm.
Support and mentoring	Radiologists should be engaged in review and audit of images and support practices/ultrasound practitioners to produce high quality images.

5.3 Role of ultrasound practitioners – best practice guidance

The provision of high quality NT and CRL measurements leads to high quality risk results for antenatal screening for Down syndrome and other conditions. The feedback provided will assist practitioners to review their practice and take steps to upskill and improve the quality of measurements where this is required.

Table 12: Quality assurance activities for ultrasound practitioners

Ultrasound practitioner responsibility	QA activity
Identifiable reports	Ensure the name and unique FMF number of the person who performed the NT scan is on every report.
Seeking feedback	All practitioners performing NT scans participate in regular internal review of NT scan image quality. If NSU feedback has assigned a red or amber flag practitioners should review their previous NT scan images and seek practice review and support to make quality improvements of images and measurements.
Action plans	Where practitioners have been assigned amber or red flag status they should develop and implement action plans for improvement. It is recommended that action plans include supervision and review of images to lead to high quality NT and CRL measurements.
Education and training	All ultrasound practitioners performing NT scans should comply with FMF requirements Section 4.1. Regular practice internal review of images from ultrasound practitioners may include the following: <ul style="list-style-type: none"> Peer reviewed scoring of each image against the 12 criteria of a good NT or CRL image shown in Tables 1 and 2 (Section 2) Rating each image should be as 'good', 'acceptable' or 'poor' depending on the score obtained (Section 3). If scan performance is identified as being poor, ultrasound practitioners should complete or revise the FMF online training and submit 3 images for external accreditation and participate in practice review and supervision.

Supplementary activities for ultrasound practitioners to support and encourage best practice

- Share and discuss a selection of anonymised, scored images from the practice with team members as a group.
- Share and discuss NT and CRL measurements on retrospective images.
- Consider companion or peer scanning (two sonographers or a sonographer plus a radiologist) which is good for image optimisation, communication skills and time management.
- Share the overall practice or departmental radiology feedback with individual practitioners and the wider team.

Appendix 1

NT image score sheet

NT image score sheet for image review

Ultrasound practitioner			
Assessor			
Date of review			
Patient ID			
Date of scan			
Horizontal mid sagittal section			
Head in line with body, visible skin line			
Echogenic tip of the nose			
Rectangular shape of the palate			
Translucent diencephalon			
Frontal process of maxilla not visible			
Pocket of fluid under chin visible			
Palate angle 30–60 degrees			
Nasal tip level or above chest wall			
Fills over 60% of screen			
Calipers on upper and lower skin line			
Measure widest part of NT			

Outcome

Comments

CRL image score sheet

CRL image score sheet for image review

Ultrasound practitioner			
Assessor			
Date of review			
Patient ID			
Date of scan			
Mid sagittal section, head in line with body			
Echogenic tip of the nose			
Rectangular shape of the palate			
Translucent diencephalon			
CRL axis between 0 and 30 degrees to horizontal			
Clearly defined crown and rump			
Pocket of fluid under chin visible			
Palate angle 30–60 degrees			
Nasal tip level or above abdominal wall			
Fills over 60% of screen			
Calipers on outer borders of crown and rump			
Longest measurement of fetus			

Outcome

Comments

Appendix 2

Action plan template

Ultrasound operator name	
Radiology practice name	
Date	
Feedback cycle #	
Bias assigned Red/Amber/White	

Action	Date completed	Comments
Practitioner received feedback		
Action plan developed		
Review equipment and environment Name:		
Review technique (may include supervision) Name:		
FMF training completed or reviewed		
Image review (number of images reviewed) Name of reviewer:		
Other training or courses		
Outcome		