



The NT Examiner

Sponsored by the Nuchal Translucency Quality Review Program



Winter 2008-2009

" Welcome to the Winter 2008-2009 edition of the *NT Examiner*. It has now been two years since the **ACOG Technical Bulletin #77** brought increased awareness of first trimester risk assessment for Down Syndrome in the United States. This edition will provide tips to avoid overmeasuring NTs, will raise important questions about gaps in existing NT monitoring programs, will review the literature on the use of first trimester risk assessment in cases of vanishing twins, and will review upcoming changes in the NTQR image review process. In this 6th edition of the *NT Examiner* we hope to be a continuing resource of consensus information for our over 4000 NTQR participants."

Steven L. Warsof, MD

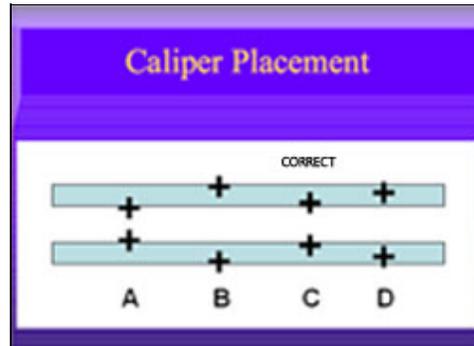
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Top Tip: Maximizing the Information Received in NTQR Reports

NTQR epidemiologic reports are based on nuchal translucency and crown rump length data sets that we receive from participating laboratories and from individuals. To maximize the information provided place two NTQR credential numbers on every laboratory requisition. The sonographer who measures the NT should place their NTQR credential number in the slot for sonographer. The reading / interpreting MD should place their NTQR credential number in the slot designated for supervisor or reading MD. If a physician obtains the measurements himself, he should place his NTQR credential number in both locations on the requisition. If NTQR is not receiving all of your data, Individual participants may choose to send NT / CRL data sets directly to NTQR in MS Excel spreadsheets. Most laboratories will provide complete data sets to the individual upon request and these may be forwarded to NTQR as well. NTQR "cleans" the data that we receive to eliminate duplicates. E-mail ntqrsupport@ntqr.org.

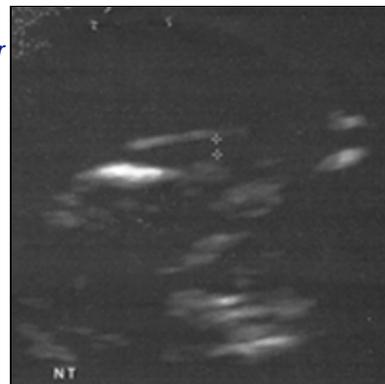
Caution: Over Measurement of Nuchal Translucency



In our last issue of the *NT Examiner* we provided common reasons why the nuchal translucency is undermeasured. In this issue we want to provide tips and suggestions for participants who are over measuring the NT. If your epidemiologic report indicates that your median NT MoM is greater than 1.0 you will want to pay particular attention to the information below.

The NTQR recommends that participants report the largest single measurement of three acceptable NT measurements. It is important that the three measurements considered for report are acceptable and demonstrate the required NT criteria. The NT measurements considered must be done uniformly, correctly, and precisely. If an NT shows evidence of over measurement the NT value needs to be discarded. Here are the most common reasons why the NT is over measured.

- 1) The calipers must be placed at the inner edges of the nuchal borders (see "C" in the image above). If one or both calipers are placed in the mid portion or the outer portion of the nuchal membranes ("B" or "D" in the image above) the NT will be overmeasured.
- 2) The amnion needs to be visualized separate from the nuchal membrane. If the amnion is not visualized, the measurement may be made between the proximal NT border and the amnion. This would lead to an inaccurately large NT measurement.
- 3) If the fetal head is hyperextended the NT may be over measured. The fetal position is hyperextended if its head is thrown back and there is greater than a 90 degree angle between the fetal lower chin and the upper neck.



Gaps in Existing NT Screening and Monitoring Programs

by Joseph R. Wax, MD
and Michael G. Pinette, MD
Maine Medical Center

Figure 1: Image of an NT measurement of 1.2mm (1.15 multiples of the median [MoM]) submitted for a fetus with a CRL of 45mm showing only appropriate magnification and caliper selection. The image was obtained by a noncredentialed sonographer and interpreted by a noncredentialed sonologist. The combined screening results were positive for trisomies 18 and 21. The fetus had triploidy. Images are used with permission from the American Institute of Ultrasound in Medicine as published in the *Journal of Ultrasound in Medicine*.
(article continued inside newsletter)



Aneuploidy screening in multiple gestations: What to do in the setting of a "vanishing twin"

By Karin Fuchs, MD and Mary D'Alton, MD
Columbia University

A significant proportion of twin gestations will experience a demise of one fetus before first trimester screening is performed. What impact does an early fetal demise have on the concentration of first trimester analytes used in aneuploidy screening and what is the best way to offer aneuploidy screening in cases complicated by a "vanishing twin"??

Although there is a modest amount of literature on the effect of multifetal reduction and fetal demise on the concentrations of second trimester analytes such as AFP (Lynch, 1993), there are only two papers formally addressing the impact of spontaneous fetal loss on concentrations of first-trimester serum analytes. In 2006, Chasen et al published a study looking at the impact of spontaneous fetal loss in multifetal pregnancy on first-trimester maternal serum biochemistry. Although Chasen et al demonstrated an effect of spontaneous reduction on concentrations of first-trimester analytes, the impact of these changes on Down syndrome (DS) risk assessment was not reported.

More recently, Gjerris et al published a report on the effect of a "vanishing twin" on first-trimester biochemical markers in pregnancies conceived by assisted reproductive technology (ART). These authors further analyzed their data according to those patients with an early "vanishing twin" (defined as those occurring prior to 9 weeks) and those with a late "vanishing twin" (defined as fetal loss occurring between 9 weeks and when NT measurement was performed). Although both papers noted trends toward increased mean MoM concentrations of PAPP-A and free beta hCG among patients with a "vanishing twin" especially within the first four weeks of the loss, there was no significant difference detected between serum markers concentrations in patients with early losses and those with singleton pregnancies. Also, there was insufficient power to make any final conclusions.

Although an elevation in free beta hCG may theoretically increase the estimated risk of DS, simultaneous elevations of PAPP-A would be expected to reciprocally reduce the estimated risk of DS. Though DS risk assessment may not be substantially affected while both PAPP-A and free beta hCG are elevated in the 4 weeks following spontaneous reduction, the persistent elevation of PAPP-A may lead to underestimation of DS risk even if first trimester serum screening is performed more than 4 weeks after a spontaneous reduction. The authors concluded that although first trimester serum screening can be performed in women with an early "vanishing twin", combined first trimester screening was unlikely to provide a precise estimate of DS risk especially when the loss was within four weeks of the screening.

Given the potential impact of altered analyte concentrations on DS risk assessment, the data of both Chasen and Gjerris suggest that it may be reasonable to still offer first trimester serum screening in cases of a "vanishing twin" if at least 4 weeks has elapsed since the demise. If first-trimester serum screening is then performed, the laboratory should be informed of the finding of a "vanishing twin" given their varying policies regarding the processing of specimens with this clinical scenario. Alternatively, because the persistent elevations in PAPP-A reported by Chasen may continue to impact DS risk assessment, it may also be reasonable to forego first trimester serum screening altogether in such cases. As an alternative, these patients should be offered nuchal translucency measurement in the first trimester, followed by maternal serum screening in the second trimester. Further research should be aimed at determining the impact altered serum analyte concentrations have on first-trimester DS risk assessment in cases of a "vanishing twin".

REFERENCES

Chasen St et al. Does a "vanishing twin" affect first-trimester biochemistry in Down syndrome risk assessment? Am J Obstet Gynecol 2006; 195: 236-9.

Gjerris AC, et al. The effect of a 'vanishing twin' on biochemical and ultrasound first trimester screening markers for Down's syndrome in pregnancies conceived by assisted reproductive technology. Hum Reprod. E-published 2008 Oct 3.

Lynch L, et al. Maternal serum alpha-fetoprotein and coagulation profiles after multifetal pregnancy reduction. Am J Obstet Gynecol

NTQR Image Review Report



By Beryl Benacerraf, MD
Radiologist and Member
Nuchal Translucency Oversight Committee
NTQR Senior Reviewer

As part of the reorganization of NTQR and MFMF, I am very pleased to have been appointed chair of the Image Review committee. My task is to re-evaluate the image review process after it has been in place for more than 2+ years, and to consider changes to better address the uniformity of the NT measurement and the review process itself.

The quality review statistics indicate that NTQR site has evaluated 2167 total batches of images, which include 19,006 images from February 9, 2005 to December 12, 2008. The initial pass rate at first review is 65%. Eight days is the average number of days needed to perform the image review of each batch.

Currently, a score of $\geq 80\%$ on a 9 criterion scoring system is necessary to meet the credentialing criteria. In addition, even if the overall score is 80%, the batch will fail if the same criterion is not demonstrated in any of the 10 images or one image scores less than 6 of the 9 criteria.

The review process is also considered educational, since feedback is provided to each practitioner about each image and the practitioner may resubmit up to 2 more batches of 3-5 images if the first set of 10 images fails. Ultimately, a total of 78% of practitioners who first submit images have become credentialed by NTQR to date. Every batch that is failed by the initial review is sent to one of 2 senior reviewers who must agree with the initial review before the practitioner can be notified of failure.

As the chair of the Image review committee, I plan to reevaluate the review process and resultant reports. Currently 10 images of 10 different fetuses must be submitted to the review committee. We realize that this may be difficult and time consuming for some to gather this many images; therefore we plan to reduce the initial number to 5. Additionally, there are currently 4 criteria among the 9 that pertain specifically to placement of the calipers on the image, and that are considered crucial to the accuracy of the measurement. Because of the importance of these criteria, we will consider a change in the way an image is scored. All 4 of the criteria that pertain to the caliper placement must be satisfied for an image to pass (and therefore for the batch to pass). This will address more specifically the occasional image that may pass many of the 9 criteria but should fail due to a major flaw in caliper placement. We will also intensify the feedback to those failing regarding exactly where the calipers should have been before they resubmit. This will be done by the reviewers and summarized by the senior reviewer on the result page that goes to the practitioner.

We also intend to make it easier for practitioners to contact the senior reviewer with questions, and even be able send an image as a .JPEG for comments before submitting again. This way, practitioners can cut down on failed batches and get needed assistance before resubmitting another set of images. We will also invite practitioners to submit 3 images each year if they want continued feedback and help from our reviewers. This is to be voluntary and used as an aid and is not part of the mandatory remediation process that would start if the practitioner remains off the standard curve repeatedly. Specific pointers can also be given to the practitioner (as a help rather than a warning) before the practitioner embarks into the remediation process.

These changes in the image review process will occur in the first half of 2009.

Gaps in Existing NT Screening and Monitoring Programs (cont. from front page)

by Joseph R. Wax, MD and Michael G. Pinette, MD
Maine Medical Center

Since January 2007, the American College of Obstetricians and Gynecologists recommends universally offering trisomy 21 screening and to include first trimester components when possible.¹ The nuchal translucency measurement is an important part of many of these screening protocols. Integrity of NT-based algorithms relies on standardized measurement criteria, sonographer and sonologist credentialing, and ongoing quality monitoring. We recently described gaps in existing NT screening and monitoring programs that are unlikely to detect poor quality NT ultrasound, and proposed additional quality safeguards (Figures 1-3).² In this article, we summarize our earlier discussion for the NT Examiner.

The first problem was NT imaging failing multiple quality criteria when performed or interpreted by noncredentialed individuals. We recommend that laboratories require documentation of sonographer and sonologist credentialing before accepting and analyzing specimens. Rejected requests should encourage providers to seek NT credentialing and direct them to appropriate resources. Likewise, credentialed clinicians

should consider using only laboratories adhering to this approach, since poor quality NT ultrasound will negatively affect population-based aneuploidy detection and screen-positive rates.

Unfortunately, credentialing does not guarantee NT quality excellence. Thus, continuous quality assessment is an integral part of screening programs. We observed technically poor NT and CRL measurements. These inadequate measurements are unlikely to be detected by current epidemiologic monitoring. They are unlikely to be retrospectively identified since, by their nature, they will be associated with screen-negative results in women carrying normal fetuses. However, one should not underestimate the medicolegal risk if a screen-negative woman with a poor quality NT subsequently delivers a child with Down syndrome. Therefore, we recommend that only centers demonstrating excellence in NT-based screening, evidenced by site-specific detection and screen-positive rates, perform NT measurements.

The final issue applies to referral centers asked to provide genetic counseling and prenatal diagnosis to NT-based screen-positive patients when the NT was measured at outside facilities. We opt to provide counseling and, if desired, prenatal diagnosis without reviewing the NT images, but only if obtained and interpreted by credentialed individuals. A disclaimer is included with each report noting that a) counseling and prenatal diagnosis were provided based on results including an outside NT, b) NT measurement requires specialized training, expertise, and ongoing quality monitoring, and c) the NT measurement was not reviewed for quality by our practice.

Alternatively, NT images could be reviewed before counseling. If quality criteria are not met, options include a) obtaining a quality NT for reinterpretation with previous serum values or b) not using the NT, and obtaining a second trimester blood sample for a serum integrated test. Regardless, anxiety following a positive screen, even if associated with a poor quality NT, may lead to a patient requesting invasive prenatal diagnosis, a request we will honor following informed consent.

Our practice proactively started two programs within our referral base attempting to avoid the above issues. The first initiative was to encourage an on-site aneuploidy screening educational program and on-site NT measurement rather than using the off site measurements. The second project permits us to remotely "double read" NT images via a secure internet-based archiving system for community based credentialed sonographers and sonologists. Quality feedback and on-site education round out this pilot program.

Our experiences with NT-based aneuploidy screening identified several shortcomings in current quality monitoring programs. Suggested logical remedies should be easily incorporated into existing quality programs, hopefully preventing or detecting compromised NT quality.

REFERENCES

American College of Obstetricians and Gynecologists, Practice Bulletin No. 77. Screening for fetal chromosomal abnormalities. *Obstet Gynecol* 2007;109:217-228

Wax, JR, Pinette MG. Nuchal translucency quality monitoring --- holes in the safety net. *J Ultrasound Med* 2008;27:1539-1542.



Figure 2: Image of an NT measurement of 1.6 mm (0.99MoM) submitted for a fetus with a CRL of 73 mm showing only appropriate magnification and caliper selection. The image was obtained by a credentialed sonographer and interpreted by a noncredentialed physician. Although the combined screening results were negative, the fetus had trisomy 21. (Used with permission from the American Institute of Ultrasound in Medicine as published in the *Journal of Ultrasound in Medicine*)

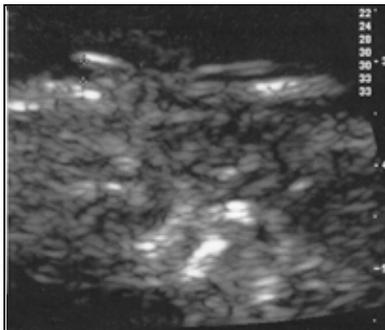


Figure 3: Image of an NT measurement of 2 mm (1.34 MoM) submitted for a fetus with a CRL of 64 mm showing only appropriate magnification and caliper selection. The image was obtained by a credentialed sonographer and interpreted by a noncredentialed physician. The combined screening results were negative, and the fetus had a normal karyotype. (Used with permission from the American Institute of Ultrasound in Medicine as published in the *Journal of Ultrasound in Medicine*)

Participation Fee Discount Available

The Maternal Fetal Medicine Foundation Board of Directors is pleased to announce a discount plan available for participation fees. Discounts are available for practices with 4 or more NTQR credentialed physicians and a low volume of NT examinations. Low volume is defined as less than 1000 NT exams within the practice the first year and less than 600 NT exams in subsequent years. The sole purpose of the

participation fee is to cover data analysis and program expenses and these are tightly managed. NTQR does not want the annual fee to be an obstacle to credentialing. Please email ntqrsupport@ntqr.org for additional information and to apply for the discount.

Join NTQR and Get Credentialed

The Nuchal Translucency Quality Review Program (NTQR) is a United States based effort seeking to establish a NT quality control system and help formalize set standards. NTQR offers a unique opportunity to learn about the proper techniques and theories involved in obtaining accurate and reproducible NT measurements from the 11-14 week ultrasound scan and first trimester risk assessment for Down Syndrome, while also offering a method to evaluate and track provider proficiency through ongoing NT quality monitoring reports.

Two ways to join NTQR and get credentialed!

1. On Line
 1. Go to www.ntqr.org
 2. Register
 3. On your computer, watch the same lectures given at NTQR's land-based courses. (This doesn't have to be done in one sitting)
 4. Take the same on-line test as land-based course participants
 5. Submit 10 slides for quality review
 6. Get credentialed
2. Plan to attend one of these upcoming NTQR land-based courses:
 1. Register and attend a 2009 Planned Land-Based Courses (see below)
 2. Take the on line exam
 3. Submit 10 slides for quality review
 4. Get credentialed

Society of Maternal Fetal Medicine 29th Annual Meeting

The Pregnancy Meeting

Manchester Grand Hyatt
San Diego, California
January 26-31, 2009
<http://www.smfm.org>

The Leading Edge in Diagnostic Ultrasound

Nuchal Translucency Education and Quality Monitoring Program
Borgata Hotel Casino and Spa
Atlantic City, New Jersey
May 19-22, 2009
<http://www.jefferson.edu/jurei>

32nd Annual Advanced Ultrasound Seminar

Walt Disney's World Contemporary Resort
Orlando, Florida
Feb 18 -21, 2009
<http://www.wfubmc.edu/ultrasound>

American College of Obstetricians and Gynecologists

ACOG Annual Clinical Meeting

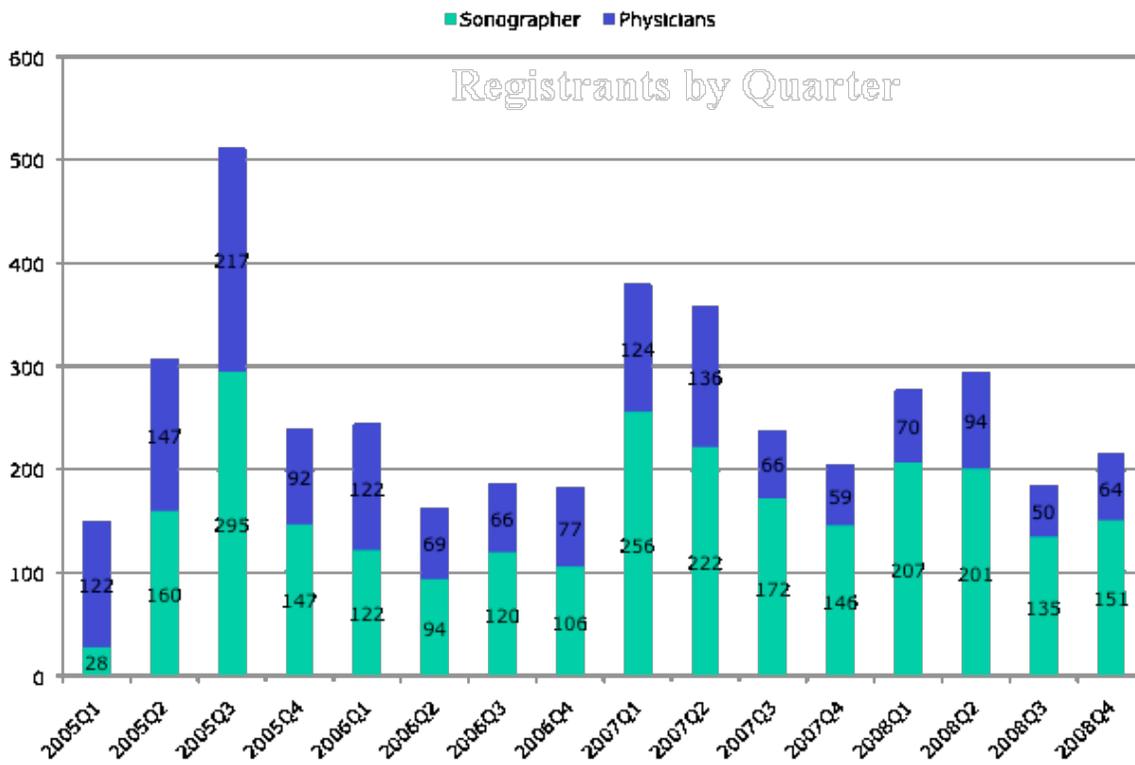
Nuchal Translucency Credentialing Course
Chicago, Illinois
May 2-6, 2009
<http://www.acog.org/acm>

18th Annual Advanced Ultrasound Techniques in Obstetrics and Gynecology

FireSky Resort and Spa
Scottsdale, Arizona
November 5-7, 2009
contact_barbara_shaw@pediatrix.com

NTQR Program Fast Facts

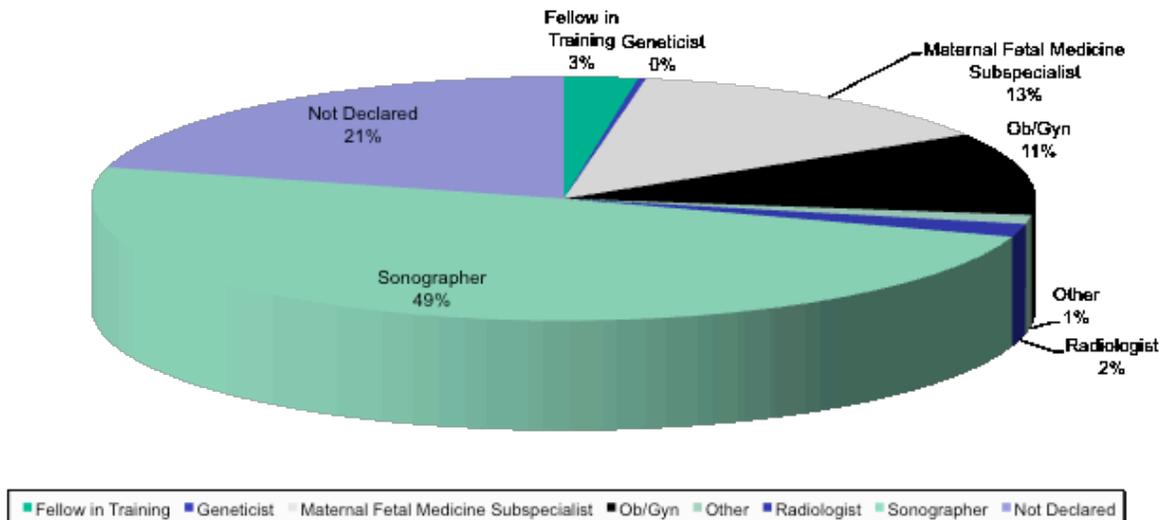
Registrants by Quarter (February 9, 2005 - December 12, 2008)



Program Statistics

- 4,166 providers of NT measurements have registered with the Nuchal Translucency Quality Review Program
- 2,861 providers have been credentialed through NTQR
- Over 19,000 NT images have been reviewed by NTQR's Expert Reviewers
- Over 250,000 data sets have been provided by participants or by twelve laboratories who currently participate with the NTQR Program. These data sets were analyzed to produce three sets of epidemiologic reports in 2008. In November 08 personalized reports were sent to over 1950 participants.
- To see a list of our partner laboratories, go to www.NTQR.org

Primary Clinical Role





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LETTERS AND OTHER INQUIRIES

Send letters to the editor and all other inquiries to the NT Examiner newsletter,
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