

The NT Examiner

Sponsored by the Nuchal Translucency Quality Review Program (2)



Summer 2008

CAUTION: Under Measurement of Nuchal Translucency

"Welcome to the Summer 2008 edition of the NT Examiner. It has now been over one and half 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 highlight important questions on NT measurements, cystic hygromas, and nasal bone education. In this 5th edition of the NT

Examiner we hope to be a continuing resource of concensus information for our over 3000 NTQR credentialed NT measurement providers."



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

resource of concensus information for our over There is a natural tendency to under measure the NT and credentialed NT providers have to be 3000 NTQR credentialed NT measurement providers." there is a natural tendency to under measure the NT and credentialed NT providers have to be constantly vigilant about under measurement pitfalls to keep their measurements from sliding down.

Here are the most common reasons why the NT is under measured:

Steven L. Warsof, MD

- 1. Practitioners often choose the clearest part of the NT to measure rather than the widest part. If it looks like there is a wider section, you need to try to make the edges clear enough to measure the widest part. Measuring a smaller portion just because there are clear edges can result in an underestimate of the measurement.
- 2. It is easy to underestimate the NT by placing the caliper too far into the NT space. It is important to remember that the caliper actually should be placed ON the line (at the edge) and not in the space.
- 3. First trimester fetuses spend a lot of time in a curled up or chin-tucked position. This will render the NT space thinner than it really is. It is important to try to get the fetus to jump up and stretch out so as to obtain the widest NT measurement possible.

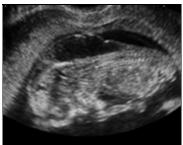
In general, keep in mind that in order to be accurate and conservative in our ability to detect fetuses with an increased risk for Down syndrome, we need to measure the NT as large as it can be on any given fetus. The largest single measurement (not the average) is appropriate.

INSIDE THIS ISSUE

- » CAUTION: Under Measurement of Nuchal Translucency
- » Cystic Hygroma vs. Enlarged NT: Does It Matter?
- » NTQR Remediation Policy
- » NTQR Nasal Bone Education
- » Patient Education Resources for Providers
- » MFM Foundation Guidelines NTQR Credentialing for Sonographers
- » Participation Fee Discount Available
- » Upcoming Courses
- » NTQR Program Fast Facts

Top Tip: Changing the e-mail address listed in your NTQR profile.

NTQR communications and quality monitoring reports are sent through e-mail to the address listed in your NTQR profile. It is very important that you keep your e-mail up to date. To change profile information log into the NTQR website. If you have forgotten your username or password you may click on Forgot your username or Forgot your password and your username or a new



Cystic Hygroma vs. Enlarged NT: Does It Matter?

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

Differentiation between septated cystic hygroma and increased nuchal translucency is a frequently asked question in the field of first trimester screening. Both conditions are known to be associated with an increased risk of aneuploidy, fetal structural malformations, and adverse pregnancy outcomes, but there has been debate as to whether counseling and management should be altered when a septated cystic hygroma is detected on first trimester ultrasound. Review of the literature suggests that differentiation between septated cystic hygroma and enlarged NT greater than 99th percentile may be unnecessary as the outcomes and prognosis associated with these findings are in



password will be sent to the e-mail address in your profile. If your e-mail has changed you will need to contact

NTQRsupport@ntqr.org or call 405-753-6534 for help logging in. Once you have logged in place your cursor (hover) over hover over **HOME** you will see a submenu. Click on **PROFILE** to change your name, username, or e-mail address. On the same submenu you can click on PRACTICE LOCATIONS to change, add, or delete sites where you practice. The same submenu will allow you to change your password. If you need additional information or assistance please E-mail ntgrsupport@ntgr.org.

fact similar.

The FaSTER group used a standardized definition of septated cystic hygroma (CH) which required visualization of an "enlarged hypoechoic space at the back of the fetal neck" that "extended along the length of the fetal back" and "in which septations were clearly visible". 1 Using this definition, HOME on the upper left menu bar. When you 132 cases of CH were identified in the study population of 38,167 pregnancies yielding an overall incidence of 1/285. Among the 132 CH identified, abnormal fetal karyotype was present in 51% of fetuses (67/132) and fetal structural malformation was identified in 34% of chromosomally normal fetuses (22/65). Fetal demise occurred in 20 (15%) cases, including 12 pregnancies with fetal chromosomal abnormalities, 3 with fetal structural malformations, and 5 with apparently normal fetuses. Among 23 ongoing pregnancies with normal karyotype and no evidence of structural malformation, 22 (95%) had a normal outcome. Overall, 17% (22/132) of fetuses with septated cystic hygroma had normal chromosomes, normal structure, and normal pediatric outcomes.

In a review article presenting the data of the Fetal Medicine Foundation, Souka et al suggested that the presence or absence of septations in an enlarged nuchal translucency does not change prognosis and that outcomes are determined primarily by the thickness of the nuchal translucency. 2 Among pregnancies with nuchal translucencies above the 99th percentile - corresponding to a measurement of 3.5 mm or greater – Souka et al noted an increasing risk of major chromosomal abnormalities. The frequency of chromosomal abnormalities was approximately 21% with a nuchal translucency measuring 3.5 - 4.4 mm, 33% for NT of 4.5 - 5.4 mm, 50% for NT of 5.5 - 6.4 mm, and 65% for NT of more than 6.5 mm. Similarly, the risk of fetal structural anomalies increased among chromosomally normal fetuses with NTs above the 99th percentile. The risk of major fetal malformation was 10% with nuchal translucencies from 3.5 - 4.4 mm, 19% for NTs from 4.5 - 5.4 mm, 24% for NTs of 5.5 - 6.4 mm, and 46% for NT greater than 6.5 mm. Overall 15% of fetuses with NT greater than 6.5 mm went on to have normal pediatric outcomes whereas 95% of those with normal karyotype and normal anatomy went on to have normal outcomes.

Table 1: Fetal outcomes based on presence of septated cystic hygroma or enlarged NT:

	Abnormal Karyotype	Structural Malformation	Fetal Demise	Normal Outcome
Septated cystic hygroma FaSTER, 2005	50.8%	33.8%	15.2%	16.7%
Nuchal translucency 5.5 - 6.4 mm FMF, 2005	50.5%	24.2%	10.1%	30%
Nuchal Translucency greater than 6.5mm FMF, 2005	64.5%	46.2%	19.0%	15%

The frequency of adverse pregnancy outcomes among those fetuses with septated cystic hygroma in FaSTER and those with nuchal translucency greater than 5.5 mm in Souka's cohort are compared in Table 1. Given that the mean nuchal translucency measurement in cases of cystic hygroma in the FaSTER study was 6.5 mm and the cystic hygromas were not excluded from the cohort used by Souka, it is not surprising that the frequencies of abnormal karyotype, fetal structural malformations, and fetal demise are in fact quite similar between the groups. 1,2

In a subsequent analysis of the FaSTER data, it was shown that with an NT measurement of 4.0 mm or greater, there is no benefit in waiting for serum screening results. 3 In this group of patients with NT greater than 4.0 mm, consideration of first trimester serum markers PAPP-A and free beta hCG did not significantly decrease the risk of trisomy 21. 3 Even among 128 patients with NT greater than 3.0 mm, serum screening reduced the risk of trisomy 21 to less than 1:200 in only 10 (8%) patients and over 90% of patients remained at high risk for fetal aneuploidy after consideration of serum screening results. 3

Based on these data and the similar outcomes noted in the FaSTER cystic hygroma cohort and the FMF cohort, differentiation between septated cystic hygroma and nuchal translucency above the 99th percentile may not be clinically important. We recommend that women with septated cystic hygroma or with nuchal translucency greater than 4.0 mm be offered chorionic villus sampling without waiting for results of first trimester serum screening. Counseling regarding the associated risk of aneuploidy, fetal structural malformations, and fetal demise should not

be delayed until serum screening results are available. Many centers – including ours – are offering diagnostic testing with NT measurements greater than 3.0 mm given the low likelihood that serum screening results would significantly reduce the risk of fetal aneuploidy. Although serum screening is not necessary to further quantify the risk of aneuploidy in these cases, low concentrations of PAPP-A and beta hCG have been associated with adverse pregnancy outcomes. 4 It is not known whether measurement of first trimester serum analytes may have a role in quantifying the risks of fetal loss, preeclampsia, preterm birth, abruption, and poor fetal growth in cases of enlarged nuchal translucency or septated cystic hygroma.

References

- 1. Malone FD, Ball RH, Nyberg DA, et al. First-Trimester Septated Cystic Hygroma: Prevalence, Natural History, and Pediatric Outcome. Obstet Gynecol 2005;106:288–94.
- 2. Souka AP, von Kaisenberg CS, Hyett JA, et al. Increased nuchal translucency with normal karyotype. AJOG 2005;192:1005–21.
- 3. Comstock CH, Malone FD, Ball RH, et al. Is there a nuchal translucency millimeter measurement above which there is no added benefit from first trimester serum screening? AJOG 2006;195:843–7
- 4. Dugoff L, Hobbins JC, Malone FD, et al. First-trimester maternal serum PAPP-A and free-beta subunit human chorionic gonadotropin concentrations and nuchal translucency are associated with obstetric complications: A population-based screening study. AJOG 2004;191:1446-51.

Nuchal Translucency Quality Review Remediation Policy

Criteria for Continued Participation in the NTQR Program:

In order for a participating provider to remain in good standing, (s)he must:

- a. Submit at least 30 NT measurements annually.
- b. Participate in and complete remediation if required.
- c. Pay all required fees to NTQR in a timely manner.

Data Collection:

Participants' NT data may be received electronically from participating laboratories or can be directly submitted from participating sonologists and sonographers. Data for an individual can only be collected from participating laboratories if the NTQR number is appropriately entered. If both a sonologist and sonographer want their measurements used for monitoring then the NTQR number for each must be entered on the laboratory requisition form that accompanies the patients' serum sample. NTQR strongly recommends nuchal translucency credentialing for all physician sonologists and sonographers involved in first trimester risk assessment.

Epidemiologic Analysis:

NTQR quality monitoring is based on epidemiologic analysis of individual participants' NT case data. Epidemiologic analysis commences when an individual submits at least 30 NT measurements to the NTQR program.

NT review is based on a comparison of the practitioners' measurements to those of a standard referent curve. For review purposes, NT measurements are converted to multiples of the gestational age specific referent median (MOMs). The ideal practitioner's median NT should be 1.0 MOM with an expected 90th percentile range from 0.9 to 1.1 MoMs. Practitioners with values that are statistically outside the expected range will be considered for remediation.

In evaluating a practitioners' performance both long-term cumulative results as well as those from the most recent interval are evaluated.

Examples of monitoring reports may be found within " NT Quality Review - Operations and Guidelines " on the http://www.ntgr.org website.

Report Generation and Distribution:

Even if the requisite 30 NT measurements are not submitted, a report may be generated, but the results of statistical testing will be stated as invalid due to low numbers.

The results of epidemiologic monitoring will be reported directly to:

- a. The individual participant,
- b. The individual's reading physician if indicated by a NTQR credential number recorded on the requisition slips (effective July 2008) and
- c. The designated practice administrator (effective October 2008).

Participating laboratories have access to reports of participants who submit NT data to their laboratory.

Remediation:

If an individual sonographer's / sonologist's measurements are determined to be significantly outside of the expected range for a reporting period encompassing a minimum of 30 NT measurements, the individual sonographer / sonologist will be flagged for remediation. When a provider is flagged for the first time, they should seek out the supervision of participants within their practice whose values fall within the expected range. Supervisors should observe NT image acquisition and measurement and offer constructive critiques to the "flagged" participant. It will be the responsibility of the NT credentialed medical director of the practice to monitor progress of the "flagged" individual.

If multiple participants within the same practice are flagged, the practice must service and calibrate the relevant equipment.

Second Sequential Flag:

If a provider is flagged in a sequential reporting period, the provider will be required to participate in formal remediation. The first stage requires the individual to:

- a. Document completion of review of the technical image lectures,
- b. Retake the NTQR credentialing exam, and
- c. Submit three images for review to the NTQR review committee.

If the submitted images do not pass the image review process, additional images will be required until the standard criteria for NT image acquisition and measurement have been fulfilled. Image remediation associated with the second sequential flag must be completed within 6 weeks of the date of notification. If remediation is not completed within 6 weeks, the relevant laboratories will be notified that the NTQR credential number is invalid until remediation is completed.

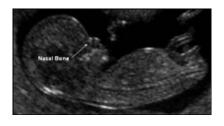
The NTQR will monitor participants who have participated in remediation. Additional remediation activities may be required of individuals to maintain their credential if statistical analysis demonstrates that measurements continue to fall outside of the expected range.

Laboratory Notification of Required Remediation:

Participating laboratories have ongoing access to quality monitoring reports of participants who submit data to their laboratory. A laboratory may request regular notification of "flagged participants." All laboratories receiving NT data from participants will be notified if remediation activities required of individuals are unsuccessful. The credential status of such individuals will be reported to laboratories on a regular basis.

Appeal Process:

A participant who is flagged may write a letter to NTQR offering objective information to explain why their patient load may justify a median NT significantly outside of the expected range. Appeals are reviewed by the MFMF Board of Directors and if sustained may substitute for required remediation.



Nuchal Translucency Quality Review Nasal Bone Education

The Maternal Fetal Medicine Foundation Nuchal Translucency Quality Review Program is pleased to offer an educational program in nasal bone imaging to participants credentialed by NTQR in nuchal translucency. The educational program provides didactic education in nasal bone and requires submission and review of five images. Successful completion of this education is adequate to submit nasal bone images as part of a risk assessment program.

You may log in to your account to begin the Nasal Bone process. To begin the nasal bone credentialing process click on red lettering related to nasal bone on your summary page (available on login or through the upper menu bar under "home"). Similar to NT credentialing NTQR honors

FMF nasal bone certification. A didactic lecture on nasal bone is provided under "education" on the upper menu bar. There is no examination required.

The image review process requires participants to submit 5 images from 5 individual fetuses. The fetus should have a crown rump length between 38 and 84 mm. Participants may submit images by mail after completing data sheets online. Alternatively nasal bone images in jpeg format may be uploaded directly through the website.

Nasal bone completion requires that participants have an active NTQR NT credential, and submit 5 images. Each submitted image must demonstrate 4 of the 5 criteria listed below. None of the 5 criteria listed below can be missed on all images.

Nasal Bone criteria used by NTQR are as follows:

- NB Criterion 1: The ultrasound image must be clear with the fetal facial profile well defined.
- **NB Criterion 2:** The fetus occupies the majority of the image.
- **NB Criterion 3:** The fetal face is in the mid-sagittal plane with the tip of the nose seen in fetal profile and the third and fourth ventricle seen in the fetal central nervous system.
- **NB Criterion 4:** There is a 45-degree angle of insonation with the fetal profile.
- NB Criterion 5: The brightness of the nasal bone is greater or equal to that of the overlying skin.

Participants will fail the nasal bone education module if any image does not demonstrate 4 out of 5 criteria or if any of the 5 criteria are missed on all images. If a participant fails with a score between 70% - 79% resubmission of 3 images is required. If one image does not demonstrate 4 out of 5 criteria or if one criterion is missed on all images resubmission of 3 images is required. If the image review score is less than 70% then resubmission of 5 images is required.

If participants pass the nasal bone education they will be able to print a nasal bone certificate on their summary page and submit the nasal bone certificate to participating laboratories. E-mail ntgrsupport@ntgr.org with any questions that you may have.

Patient Education Resources for Providers



By Renee Chard
Certified Genetic Counselor
Maine Medical Center
Member, Nuchal Translucency Oversight Committee

NTQR is committed to providing high quality, evidence based resources for patients and providers.

NTQR participants can now request a downloadable file containing educational materials for their patients. The easy to read file contains patient friendly information about first trimester screening in a question and answer format. It may be printed on your own practice letterhead. The document was developed by a team of genetic counselors from Maine, Ohio, and New York. The document is in a MS Word format and avaiable upon request from ntgr.org.

This spring NTQR communicated with Mark Leach of the National Down Syndrome Society (NDSS) and Anne Downey of the National Association for Down Syndrome (NADS) regarding the importance of providing up to date and balanced information when counseling patients and their partners after a prenatal diagnosis of aneuploidy in their fetus. Our shared goals are to inform and support patients in making decisions for themselves and their families.

The American College of Obstetricians and Gynecologists' ACOG Practice Bulletin #88, Invasive Prenatal Testing for Aneuploidy states: "

After the diagnosis of a chromosomal abnormality, the patient should receive detailed information, if known, about the natural history of individuals with the specific chromosomal finding. In many cases, it may be very helpful to refer the patient to a genetic counselor or clinical geneticist and national groups such as The National Down Syndrome Society www.ndss.org or National Down Syndrome Congress www.ndscenter.org to help the patient make an informed decision." NADS offers to prenatal care providers information on how to deliver the news of a positive test result, informational brochures, and contacts for local support groups. Here are a number of organizations that can help you better serve your patients:

- National Society of Genetic Counselors (<u>www.nsqc.orq</u>)
- American College of Medical Genetics (www.acmg.net)
- National Down Syndrome Society (www.ndss.org)
- National Association for Down Syndrome (<u>www.nads.org</u>)
- National Down Syndrome Congress (<u>www.ndsccenter.org</u>)
- Trisomy 18 Foundation (<u>www.trisomy18support.org</u>)
- Chromosome Deletion Outreach (www.chromosomedisorder.org/CDO)

MFM Foundation Guidelines NTQR Credentialing for Sonographers

By the Members of the NT Oversight Committee

Preamble:

The Maternal Fetal Medicine Foundation recommends nuchal translucency (NT) credentialing for all physician sonologists and sonographers involved in first trimester Down Syndrome risk assessment. The Maternal Fetal Medicine Foundation is committed to NT credentialing of both members of the team, not just the person who scans, to establish a team approach and to meet the recommendations of the ACOG Practice Bulletin Number 77 titled Screening for Fetal Chromosomal Anomalies. Ongoing quality monitoring of both sonographers and supervising sonologists helps insure that patients receive the most accurate first trimester risk assessment possible.

Sonographers entering the NTQR program are responsible for maintaining a comprehensive sonography credential with relevant obstetrical content provided by a nationally recognized agency. The NTQR endorses sonographer education and certification as required by the AIUM for obstetrical laboratory accreditation (currently the ARDMS OB/GYN credential).

MFM Foundation Guidelines for Sonographer Credentialing

Credentialing for sonographer participants in the NTQR program requires didactic education, successful completion of a written examination, and evidence of image proficiency.

1. Didactic Evaluation

- a. All sonographer participants must take the prescribed didactic course that has been specifically developed for sonographers and pass a written examination that demonstrates their ability to perform the sonography component of first trimester Down Syndrome risk assessment. The course and examination are different from those required for physician sonologists.
- b. Successful completion of the exam will require didactic knowledge of the principals of first trimester risk assessment as well as confirmation of the ability of the examinee to identify appropriately performed NT images that meet the guidelines for image quality.

2. Image Submission

- a. Images sent in for credentialing review must be acquired by the participating sonographer seeking credentialing.
- b. Submitted images must not have been previously used for credentialing by any one else.
- c. A credentialed sonographer may assist with image acquisition by a supervising sonologist for supervising sonologist credentialing but the supervising sonologist must select the desired images for submission. These images must be different from those images submitted by the sonographer for his/her image proficiency evaluation.

The MFM Foundation is a 501(c)(3) non-profit entity. This practice bulletin was developed by the Nuchal Translucency Oversight Committee of the MFM Foundation. The information is designed to aid practitioners in making decisions about appropriate maternal fetal care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

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 ntgrsupport@ntgr.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 though ongoing NT quality monitoring reports.

Two ways to join NTQR and get credentialed!

- 1. On Line
- 1. Go to www.ntgr.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 2008 Planned Land-Based Courses (see below)
 - 2. Take the on line exam
 - 3. Submit 10 slides for quality review
 - 4. Get credentialed

World Class CME The Best of the Big Apple OB-GYN Ultrasound 2008

The Marriot Marquis
New York, New York
October 10-12, 2008
http://worldclasscme.com

17th Annual OB-GYN Ultrasound Update for Clinical Practice sponsored by the Hohler - Gottesfeld Foundation

Lago Mar Resort and Club Ft. Lauderdale, Florida December 11-14, 2008 http://www.cmebyplaza.com

32nd Annual Advanced Ultrasound Seminar

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

IAME 9th Annual Obstetric Ultrasound in the High Risk Patient

Nuchal Translucency Education and Quality Monitoring Program The Venetian Resort Hotel Las Vegas, Nevada Oct 17-19, 2008

http://www.iame.com/courses/hirisk1008/hirisk.html

IAME National Conference on OB-GYN Ultrasound

Nuchal Translucency Credentialing Course Chicago Marriott Downtown Chicago, Illinois Dec 5-7, 2008

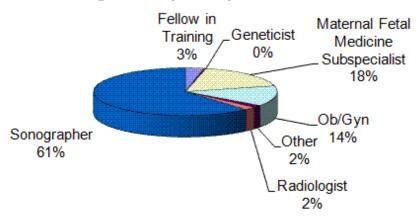
http://www.iame.com/courses/ob1208/ob.html

New Registrants by Quarter (February 9, 2005 - August 20, 2008) 600 *2008 Q3 has not closed 512 500 380 358 400 307 277 296 238 300 239 244 206 186 183 163 150 200 108 * 100 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Time Period

Program Statistics

- 3,847 providers of NT measurements have registered with the Nuchal Translucency Quality Review Program
- 2,562 providers have been credentialed through NTQR
- Over 16,963 NT images have been reviewed by NTQR's Expert Reviewers
- Twelve laboratories currently participate with the NTQR Program. To view the list of our partner laboratories, go to www.NTQR.org

Registrants by Primary Clinical Role





EDITOR-IN-CHIEF Steven L. Warsof, MD warsofsl@evms.edu

LETTERS AND OTHER INQUIRIES

Send letters to the editor and all other inquiries to:

The NT Examiner Nuchal Translucency Quality Review 12316-A North May Ave. #272 Oklahoma City, OK 73120

You may also send e-mail to NTExaminer@ntqr.org.

Powered by DM-STAT, Inc. The NT Examiner is published quarterly by the NuchalTranslucency Quality Review. Copyright © 2008 Nuchal Translucency Quality Review. All rights reserved. Limited copies may be made for internal staff use only. Credit must be given to the publisher. Otherwise, no part of this

publication may be reproduced without prior written permission of the publisher. Review our Privacy Statement.