"Welcome to the third edition of the NT Examiner. Inside you will find what's new as well as some historical perspective of the NTQR. Many thanks to the contributors and to those who have written in questions. We hope that the newsletter will continue to be a source of helpful information on First Trimester Risk Assessment."

Steven L. Warsof, MD

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To gain access to your account when you have forgotten your password, click on the "Forgot your password?" link from our home page and enter your username when prompted. A new password will be sent to you via email after you click "Reset Password". If you do not see an email from NTQR Support with the subject heading "NTQR Password Reset" within a few minutes, you may want to check your Junk Mail folder should you have one.

Milestones of the NTQR

By Mary E. D'Alton
Professor of OB/GYN, Columbia University
Chair, Department of OB/GYN, Columbia University of Physicians and Surgeons

The Nuchal Translucency Quality Review program (NTQR) of the Maternal Fetal Medicine Foundation (MFMF) is dedicated to the education and advancement of safe and reliable first trimester risk assessment Down Syndrome and other chromosomal abnormalities. Our committee believes that establishment of a peer professional society credentialing and quality monitoring program is essential to a successful national implementation of first trimester screening using nuchal translucency. We hope to give you updates on our progress through the NT Examiner. There is much work to be done to achieve our goals and we primarily rely on volunteers to do this work. Let us know how we are doing and how we can better serve you. Listed below are some of the milestones that have been accomplished in a very short period of time.

NUCHAL TRANSLUCENCY QUALITY REVIEW PROGRAM MILESTONES

2004 Maternal Fetal Medicine Foundation (MFMF) established
- MFMF establishes Nuchal Translucency Oversight Committee (NTOC)
- First NT Educational course at Annual SMFM meeting in Reno
- NTOC establishes subcommittees: Website Development; Education Content; Epidemiologic Monitoring; Marketing; and Fund-raising
- NTOC completes first version of educational content for land-based and web-based courses

2005 NTOC completes first revision of course content.
- Image Review process revised
2006 SMFM Coding Committee generates approval for new NT CPT codes
- Seminars in Perinatology issue devoted to NT Education and Quality monitoring
- Agreements with NTD Labs and Genzyme to help support the NTQR program
- Agreement with NTD Labs and Genzyme to transmit NT data to NTQR
- Agreements with University labs and independent labs
- Credentialing Nasal Bone will be an added to the program
- Operational Standards document completed
- First data from NTD Labs.
- Data received from Genzyme, Yale University and other University labs.
- Editor for NT examiner named
- NT Examiner Newsletter - First edition
- NTQC completes second complete revision and expansion of NTQR educational content

- NT Examiner - second edition
- Abstract summarizing NTQR Progress presented at Annual SMFM Meeting (San Francisco)
- NT CPT Codes become activated
- Epidemiologic Monitoring Reports sent to NTQR credentialed participants.
- NT Examiner - third edition

2003 Agreement with SMFM leadership to work with the leaders of FASTER and BUN research groups to create a national consensus program to better assure more reliable national First trimester screening.

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**Is it a Myth or a Fact**

By Larry Platt, OB/GYN
NTOC Member
Prof. Ob-Gyn, Geffen School of Medicine at UCLA,
Director, Center for Fetal Medicine and Women's Ultrasound

**MYTH:** ACOG Practice bulletin mandates integrated testing as the method of choice for prenatal diagnosis.

**FACT:** The ACOG PB provides a variety of ways to achieve the most desirable outcome including combined First Trimester risk assessment with NT and biochemistry alone, second trimester alone or a combination of testing schemes etc. Quality monitoring of NT performance is emphasized as essential.

**MYTH:** The recent change from the $1 per case fee was to increase the costs to participants.

**FACT:** As a result of our physicians and sonographer feedback the decision was made to move to a more manageable system for the physician offices. While on a per practice site basis we will be receiving less money. It is our estimate that with the growing number of NTQR registrants (now over 2500) we will be able to break even by 2008.

**FACT:** The NTQR committee remains a volunteer group of Physicians and sonographers.

**MYTH:** Physician combined first trimester risk assessment obviates the need to counsel patients before performing NT measurements.

**FACT:** All patients should be adequately informed about the benefits and alternatives to First trimester Risk assessment. The NTQR is in the process of preparing helpful patient education materials to be available to NTQR participants.

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**Update on NT Epidemiologic Monitoring Reports**

By Kim Dukes, PhD
President and CEO, DM-STAT, Inc.
In this issue, we describe the second page of the quarterly report (see table below) and describe the statistical methods used to determine whether a provider is within or outside of the expected quality assurance range. The first row of the table below contains summary statistics based on the population referent. Summary statistics are presented for each provider and then for that provider’s center for the current reporting period and then for the cumulative period (over the past year). These are then compared to the population referent. The statistic primarily utilized to determine whether the provider is within the expected quality assurance range is the median NT in multiples of the median (Median NT MoM). The Median NT MoM is computed by taking the ratio of each of the provider’s NT measurements to the expected NT in the referent population at each CRL. This expected value is derived from regression analysis. In the ideal case, the Median NT MoM is 1.0. Recognizing sampling variability, the expected range is 0.9 to 1.1. Formal quality assurance checks are only performed if at least 30 NT measurements are recorded during a specific reporting period. Other metrics utilized are MoM < 5th, MoM > 50th%, MoM > 95th percentile, the standard deviation of the log 10 NT and the slope. Each of these metrics is described in the NTQR Epidemiologic Monitoring Glossary.

The table below summarizes information submitted by a provider who has 250 NT measurements for the quarter and 500 NT measurements for the year. This provider’s center has submitted 2,000 and 4,500 NT measurements, respectively, over the same periods. This provider’s Median NT MoM (0.99 for the current reporting period) is within the expected range of NT MoMs (i.e., between 0.9 to 1.1). The same is true for their cumulative data and also for their center (both in the current period and cumulative). When the Median NT MoM does not fall within the expected range, the provider is flagged and recommended for additional training.

### Table 1: Sample Report: Within Expected Quality Assurance Range

<table>
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<th>Criteria for Nuchal Translucency (NT) Measurements</th>
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<tr>
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<tr>
<td>EDITOR-IN-CHIEF, The NT Examiner</td>
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<td>Prof. OB/GYN, Eastern Virginia Medical School</td>
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<td>Director, Center for Advanced Fetal Therapy</td>
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This will be the second in our series of articles for the NT Examiner to clarify the nine criteria established by the Nuchal Translucency Quality Review (NTQR) Program for NT measurements. It is the goal of the NTQR to standardize the NT measurement. It is critical for First Trimester Risk Assessment that the NT measurement be done uniformly, correctly, and precisely. The NT measurement is unique in diagnostic obstetrical ultrasound as fractions of mm's can make significant differences in individual risk assessment for Down Syndrome, patient's decisions for diagnostic testing, and the overall effectiveness of any Down Syndrome screening program.

Nuchal Translucency measurements must be between 10 3/7 weeks and 13 6/7 weeks gestation. This is equivalent to a CRL measurement between 38-84 mm. In this window of time CRL accuracy for gestational dating is 3-5 days. The CRL measurement must be included with NT measurement as the NT measurement is converted into multiples of the mean (MOM) for the CRL. The measured CRL is not the actual anatomic CRL but rather the longest straight line measurement of the fetus while its head is maintained in the neutral position. Unlike the NT measurement in which the longest of three good measurements is used, the CRL uses the average from 3 good measurements. NT measurements can be obtained either transabdominally or endovaginally. Criteria 1 and 2 were printed in the 2nd edition of the NTQR. We will continue with criteria 3-5.

3. **Fetus occupies the majority of the image.** When scanning for NT measurement, the fetal image should be enlarged to the point that the head, neck and upper thorax should be predominant. The fetus should occupy >50% of both the width and length of the image. A second fetal image of the same length or size, should not fit in the surrounding space. In order to do this it is important to decrease the depth, narrow the sector width, use fetal echo setting if needed, use the magnification box or equivalent, and magnify then freeze rather than freeze then magnify the image.

4. **Fetal Head in neutral Position.** The NT measurement is greatly affected by the fetal head position. The measurement should be done with the head in the neutral position with a pocket of amniotic fluid between the fetal chin and chest. The angle formed should be < 90 degrees. Flexion of the head will lead to underestimation of the NT space, while hyperextension of the fetal head will lead to overestimation.

5. **Fetus observed away from the amnion.** It is critical that the amnion is identified separate from the skin edge. At times this can be very difficult to visualize as frequently the fetus will be lying directly on the amnion. This is the greatest single source for error in NT measurement. Rather than measuring the NT, the measurement is made of the space between the fetus to amnion. If measured in this way the NT will be falsely overestimated. It is important to be patient and allow for fetal movement. We will allow up to 20 minutes in a scanning session to give the fetus an opportunity to come off the membrane. Cineloop will be important to get the correct measurement. Make sure that the transducer is at the proper MHz.
With increasing demand for first trimester risk assessment with nuchal translucency measurements, it has been suggested that individuals can be trained exclusively to perform this measurement with no other credentialing. The NTQR does not agree with this. Sonographers need to demonstrate competency in OB/GYN sonography. It is difficult to sort patients by skills needed before a sonographic examination. If multiple obstetrical patients walk into a room, it's not always clear who needs just a nuchal translucency and who needs more. A sonographer, in the process of performing nuchal translucency examinations, may identify fibroids, multiple gestations of varying chorionicities, ectopic pregnancies, adnexal variants, abnormal pregnancies, and other pathology. Competence requires broad-based knowledge, good judgment, and real-time discretion to analyze and adapt the protocol to image, measure, and obtain essential diagnostic information for interpretation by physicians.

The mission of the MFMF is to improve the quality of Maternal-Fetal Medicine services and to create standards based on data collected from the NTQR program. In keeping with that mission, the NTQR Statement on Governance, Operations, Participation, and Ongoing Monitoring states "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 accreditation which is done by the ARDMS OB/GYN ".

Comprehensive OB/GYN sonography credentialing examinations demonstrate retention of basic knowledge and competencies including the measurement of crown-rump length, essential to a comprehensive NT examination. Credentialing is becoming the standard practice in diagnostic medical sonography and is endorsed by AIUM and SDMS as well as NTQR. To insure quality first trimester risk assessment services, sonographers need to be credentialed in OB/GYN by ARDMS and both physicians and sonographers need to be NT credentialed to respond to increasing demand, new technology, and improved methods.

Where do you go to find information about the "why's and how's" of the NTQR program's operations?

The Maternal Fetal Medicine Foundation (MFMF) sponsors the Nuchal Translucency Quality Review (NTQR) program. The NTQR program is open to physician sonologists regardless of medical specialty and to qualified sonographers (non-physicians). The NTQR has as one of its preeminent roles the charge to identify consensus where it exists and to monitor emerging evidence that may serve as the basis for evolving or new consensus. The NTQR also offers consensus based educational programs, NT credentialing, and on-going standardized epidemiologic monitoring of participant measurements in collaboration with participating laboratories that measure first trimester analytes.

As the NTQR program has developed and matured, our NT Oversight Committee (NTOC) has recognized the importance of increasing the transparency of our operations and providing evidence that the NTQR program will function in a relatively predictable manner within our general guidelines. As a result, the NTOC has recently created an "NTQR Operational Guidelines" that will serve as a reference for both the members of the NTOC and for participating sonologists, sonographers and laboratories. It is our view that the manual will be a "living document" that will be responsive to the needs of our participants, recognizing the importance of evidence-based reports that will influence our activities in the future.

This resource document is accessible on our website at [www.ntqr.org](http://www.ntqr.org). In it you can find information about the origins and mission of the NTQR, the organizations that are represented in NTQR, who represents your interests and needs on the NT Oversight Committee and how we operate. The NTOC and the MFM Foundation Board expects this reference will be useful to those with questions, and will improve understanding of the "why's" and "how's" of the NTQR program's activities. As always we appreciate your comments and suggestions.

Q. My patient has an NT of 4.0 mm. Should she complete serum aspect of her sequential screening?

A. With an NT of 4.0mm or greater, her risk for Down syndrome is approximately 1 in 12. At this point, she should be given the choice of diagnostic testing
based on the NT measurement alone. If she is hesitant to have invasive testing, she could continue with screening and make a final decision on invasive testing based on that number. She should be aware that she will be screen positive on the basis of her NT alone. It is also important to offer any patient with an NT measurement of > 3.4 mm a fetal echocardiogram as there is an increased incidence of a congenital heart defect.

Q. My patient had a negative first trimester screening result and then had second trimester screening with a MSAFP4 at her OB’s office, which resulted in a screen positive result. Which screening result should she base her testing decisions upon?

A. This is referred to as independent sequential screening and should be discouraged due to its high false positive rate. We should attempt to avoid independent sequential screening as much as possible. This will require re-educating referring OB’s and patients. If independent sequential screening does occur, all information should be discussed with the patient because the second trimester screening results cannot be ignored. She will then have to make her decision about further diagnostic testing based on all information available to her.

Q. My low risk patient wanted to have contingency screening, however, her insurance does not cover it. What are her options?

A. Unfortunately, this is a frustrating issue with screening. She could choose to self-pay for the screening or opt for screening that insurance does cover. She should also write a letter to her insurance company about the fact that she is disappointed in what they will not cover.

Q. Does the new ACOG standard really mean that all patients, regardless of age can be offered diagnostic testing?

A. Yes, that is correct. All patients should be offered all options of screening and diagnostic testing based on her individual risk assessment for Down syndrome and chromosomal anomalies rather than her age risk. The arbitrary cut off of 1:270 should not be an absolute in the decision process. Each patient will have their own risk tolerance for Down Syndrome.

Please submit any genetic counseling questions or issues to the editor at NTExaminer@ntqr.org.

Join NTQR and Get Credentialed
By Matthew Joyce
SMFM Liaison

The Nuchal Translucency Quality Review Program (NTQR) is an American 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.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. 2007 Planned Land-Based Courses (see below)
   2. Then take the on line exam at a discounted price
   3. Submit 10 slides for quality review
   4. Get credentialed

IAME National Conference on OB-GYN Ultrasound
The Westin Michigan Avenue
Chicago, IL
September 7-9, 2007
http://www.iame.com/courses/ob0907/ob.html

2nd Annual Patient Safety In Obstetrics 2007: Reducing Risk & Improving Outcomes
The Venetian Resort Hotel Casino
Las Vegas, Nevada
September 27-29, 2007

2007 SDMS Annual Conference
Red Rock Resort, Casino, Spa
Las Vegas, NV
October 11-14, 2007
http://www.sdms.org/meetings/default.asp

IAME 8th Annual Ob Ultrasound in the High Risk Patient
The Venetian Resort Hotel
Las Vegas, NV
October 26-28, 2007
http://www.iame.com/courses/hirisk1007/hirisk.html

10th Annual Mid-Atlantic Ultrasound Symposium for Obstetrics and Gynecology and Nuchal Translucency
The Hilton Hotel at Ocean Front
Virginia Beach, VA
November 9-10, 2007

16th Annual OB/GYN Ultrasound Update for Clinical Practice
Lago Mar Resort & Club
Fort Lauderdale, FL
November 29-December 2, 2007
http://fmfaustrainingpro.info/
Program Statistics
- 2,711 providers of NT measurements have registered with the Nuchal Translucency Quality Review Program
- 1,668 providers have been credentialed through NTQR
- Over 8,800 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

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LETTERS AND OTHER INQUIRIES
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Washington, DC 20024, or send e-mail to NTExaminer@ntqr.org.