NT QUALITY REVIEW – OPERATIONS & GUIDELINES

NTQR STATEMENT – Governance, Operations, Participation, and Ongoing Monitoring

INTRODUCTION

The Maternal Fetal Medicine Foundation (MFMF) offers an educational program, credentialing, and an on-going quality review process for physicians and sonographers (non-physicians) who wish to perform Nuchal Translucency measurements as a "credentialed" provider participating in the MFMF Nuchal Translucency Education and Quality Review program (NTQR).

The NTQR program was initiated by the Society for Maternal Fetal Medicine (SMFM), which provided start-up funding for the formation of the Maternal Fetal Medicine Foundation (MFMF).

The NTQR receives the benefit of ongoing consultation with representatives from other professional societies including the American College of Obstetricians and Gynecologists (ACOG), American College of Osteopathic Obstetricians & Gynecologists (ACOOG), American College of Radiology (ACR), American Institute of Ultrasound in Medicine (AIUM), National Society of Genetic Counselors (NSGC), Society for Maternal Fetal Medicine (SMFM), and the Society of Diagnostic Medical Sonography (SDMS).

The NTQR program is open to physician sonologists regardless of medical specialty and to qualified sonographers, described below. The Quality Review Program consists of on-going standardized epidemiologic monitoring of participant measurements in collaboration with participating laboratories that measure first trimester analytes.

The MISSION STATEMENT of the MFMF is: t*o improve the quality of Maternal-Fetal Medicine medical services by providing state of the art educational programs, and evidence-based, statistically valid monitoring systems to evaluate current practices and facilitate the transition of emerging technologies into clinical care.*

NTQR is the first U.S. based national consensus program where physicians and sonographers volunteer to have one of their professional activities epidemiologically reviewed / monitored by an independent body, the NTQR, that has developed national consensus criteria for educational content, exam content, proficiency evaluation, and epidemiologic monitoring.

GOVERNANCE and OPERATIONS

The Nuchal Translucency Quality Review **(NTQR)** program functions within the Maternal Fetal Medicine Foundation. The MFM Foundation (MFMF) is a 501(c)(3) non-profit foundation established to provide a mechanism to assist in the responsible introduction of new techniques and practices in pregnancy management. The MFMF has in turn created the NT Quality Review program (NTQR) to manage the NT program

The NTQR program is managed by the Nuchal Translucency Oversight Committee **(NTOC)**, which is composed of volunteers with special expertise or interest in first trimester risk scoring. Other professional societies with interest in first trimester risk assessment and sonography also participate in this process. As other interested societies are identified they will also be offered representation.

Members are nominated by existing NTOC members. At present there is no formal rotation of membership, although this will be instituted in the future. The NTOC continues to solicit new members from relevant professional societies.

At the current time there are more than 40 volunteers including MFMs, radiologists, geneticists, OB/GYNs, osteopathic OB/GYNs, genetics counselors, laboratory representatives and sonographers participating as committee members, reviewers, and board members. These volunteers represent a variety of practice settings, geographical locations, and interests.

NTQR Governance Structure

Organizations Represented:

- American College of Obstetricians and Gynecologists (ACOG)
- American College of Osteopathic Obstetricians and Gynecologists (ACOOG)
- American College of Radiology (ACR)
- American Institute of Ultrasound in Medicine (AIUM)
- National Society of Genetic Counselors (NSGC)
- Society for Maternal Fetal Medicine (SMFM)
- Society of Diagnostic Medical Sonography (SDMS)

NTQR Committees:

- **Nuchal Translucency Oversight**
- **Research and Innovation**
- **Quality Assessment**
- **Education**
- **Technology**
- **Membership**
- **Image Review**

Members of the Nuchal Translucency Oversight Committee:

• Alfred Abuhamad, MD	Eastern Virginia Medical School, ***President MFMF***
• Beryl Benacerraf, MD	Harvard Medical School, ***AIUM***
• John Michael Benson, MD	Hancock County Radiology Assoc., ***ACR***
• Richard Berkowitz, MD	Columbia University Medical Center
• Renee Chard, MSc, CGC	Maine Medical Center, ***NSGC***
• Stephen Chasen, MD	Cornell University
• Joshua Copel, MD	Yale University School of Medicine , ***SMFM***
• Howard Cuckle, PhD	School of Medicine, Univ. of Leeds
• Mary D'Alton, MD	Columbia University Medical Center
• Richard Depp, MD	Drexel University
• Greggory DeVore, MD	Fetal Diagnostic Center of Pasadena
• Kim Dukes, PhD	DM-STAT, Inc.
• Mark Evans, MD	Comprehensive Genetics
• James Goldberg, MD	San Francisco Perinatal Associates
• Anthony Johnson, DO	Texas Children's Center, ***ACOOG***
• Thomas J. Musci, MD	San Francisco Perinatal Associates, ***ACOG***
• Daniel O'Keeffe, MD	Phoenix Perinatal Associates
• Anthony Swartz, RDMS	WakeMed Health and Hospital, ***SDMS***
• Roger Newman, MD	Med. Univ. South Carolina
• Larry Platt, MD	Geffen School of Medicine at UCLA
• Ronald Wapner, MD	Columbia Univ Medical Center
• Steve Warsof, MD	Eastern Virginia Medical School
• Gregory Toland, MS	Project Manager, NTQR
• Jean Lea Spitz, MPH	Program Director, NTQR

[1] *Official organizational representatives are shown in* ***bold italics.***

NTOC OPERATIONS – CO-CHAIRS AND SUBCOMMITTEES
(Operationally the NTOC emphasizes delegation of responsibility to subcommittees)

Subcommittees (leaders) and areas addressed

1. **Benefits** (O'Keeffe)
   a. Environmental analysis
   b. Membership Surveys and Benefits
   c. Laboratory Partnerships
   d. Position Statements

2. **Education** (Berkowitz)
   a. Consensus web-course content
   b. Consensus exam for:
      1) Sonographers;
      2) Sonologists
   c. Land-based course polices
   d. Consensus and branded slide sets
   e. Patient Education material
   f. *NT Examiner* Newsletter

3. **Image Review:** (Benacerraf)
   a. Image proficiency evaluation system
   b. Manage image review panel
   c. Consensus format for image review and scoring

4. **Technology** (Goldberg)
   a. Website Appearance
   b. Functionality
      1. **Credentialing** – includes registration through exam and image review / education components
      2. NT Image management for internal review
         a) Consensus image review;
         b) Consensus image review feedback / education
      3. Physician Practice Administrator Account registration
      4. Fee collection
      5. Web interface with analyte laboratories
      6. Participant Information
      7. Patient information

5. **Quality Assessment** (D'Alton and Platt)
   a. Epidemiologic Report format
   b. Statistical analysis of participant data
   c. Communication with laboratories
   d. Performance improvement strategies and requirements

6. **Research and Innovation** (Wapner)
   a. Epidemiologic analysis and publication of results
   b. Database maintenance and use
   c. Research priorities, facilitation, and dissemination

SONOLOGIST AND SONOGRAPHER PARTICIPATION

1) Physician Provider Eligibility

Physicians may enter the NTQR program regardless of their medical specialty, and with either an MD or DO degree. The NTQR encourages physicians to comply with relevant Board and state licensure and hospital credentialing requirements. The NTQR program does not verify physician education, residency or fellowship training, state licensure or hospital privileges.

Physician, or sonologist, credentialing by the NTQR requires completion of the NTQR (or equivalent) background education program for sonologists, including but not limited to: first trimester risk assessment as well as the technical image criteria content required for sonographers; passing the web-based NTQR examination for sonologists; and submission of at least 5 NT images that meet all criteria for proper measurement of the NT, as detailed below.

In many practices sonographers perform the technical acquisition of the NT image. The supervising physician performs the medical management and decision-making including program development, patient counseling, verification of measurement accuracy, and explanation of results and diagnostic options. In recognition of these different roles the NTQR program has developed specific educational and image proficiency requirements for physicians. Details are available in the *MFM Foundation Guidelines: NTQR Credentialing for Physicians.*

2) Sonographers (i.e. non-physician) Eligibility

Non-physician sonographers may become program participants and perform NT examinations. However, because there is no independent practice of sonography in the US, a qualified/credentialed physician must formally interpret all NT examinations in a timely interval.

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. Sonographers must demonstrate ARDMS OB/GYN credentials within 3 years of obtaining their NT credential.

Sonographer credentialing requires completion of the NTQR (or equivalent) background education program for sonographers, passing the web-based NTQR technical examination, and submission of at least 5 NT images that meet all criteria for proper measurement of the NT, as detailed below.

The NTQR will verify sonographer credentials. Sonographers required to complete performance improvement tasks will be required to document supervision by a qualified / credentialed physician who interprets their NT measurements.

Additional information is available in the *MFM Foundation Guidelines: NTQR Credentialing for Sonographers.*

3) Credentialing Process

Educational Course
All participants must view NT training course material (or equivalent), either at traditional land-based courses, on line, or via other media.

Exam
All providers are also required to pass a competency exam. There is a technical examination specifically for sonographers. Physicians must take that examination and an additional theoretic examination to demonstrate appropriate background knowledge beyond the technique of NT measurement. The passing score is 80%. The non-physician exam consists of 25 questions. The physician exam consists of the original 25 questions from the non-physician exam plus ten additional questions. Those who do not pass the exam after three attempts are required to view the course material again before attempting the exam again.

Image Quality Review
After passing the exam, providers (with the exception of those already credentialed by FMF, or through the FaSTER and BUN trials) are required to submit five adequate images for quality review. There is no time limit to when a provider can submit the images after taking the examination. Images may either be uploaded electronically to the NTQR website or submitted via mail. Once a provider submits his/her batch for quality review, it is assigned to a Quality Reviewer. The Quality Reviewer scores each image on nine criteria (see Appendix I). Once all five images are scored and the Quality Reviewer is finished with the review, the system applies a scoring algorithm, which determines whether the provider passed or failed. A provider passes if he/she meets the following criteria:

- Total image batch score of greater than or equal to 80%
- Each individual image must demonstrate 7 of the 9 criteria
- Caliper placement must be correct on every image
- No single image-level criterion may be failed on all ten images

Providers who do not pass on first review are flagged for a second review by one of the reviewer committee chairs, whose score is final, using the same numerical criteria. Those who fail the second review are required to submit 3 or 5 additional images depending on the reason for failure and the provider's total score. Providers who fail image quality review three times are given three additional attempts and to pass and are flagged for individual feedback by one of the two review committee chairs.

Grievance procedure
Providers who disagree with the results of the image scoring may request a review by submitting a letter by registered mail to NTQR. A member of the NTOC, who is blinded to the identity of the candidate and the results of the original scoring, will rescore the images under dispute. No substitution or revision of images is permitted prior to this review. The result of this stage will be reviewed by the full NTOC, preserving the anonymity of the candidate. If the NTOC confirms the image failure the candidate must revert to the process stage outlined above (either resubmission of images or review of the educational materials and retaking the relevant standard test).

4) Participant Standing

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

- Become NTQR credentialed
- Meet on-going monitoring criteria by submitting at least 30 NT measurements annually, or submit 3 additional images for annual review (if less than 30 NT measurements submitted annually)
- Pay all fees to NTQR in a timely fashion.

5) Participant Use of "credentialed" Status

Individuals, centers and laboratories who participate in the NTQR may document their participation in letters and reports, and use the NTQR name and logo on reports, if desired. The only representation that is permissible is the acknowledgement that the sonographer and/or sonologist are NTQR participants. <u>No implication of endorsement of specific patient results is permitted.</u>

EPIDEMIOLOGIC MONITORING

CRL / NT data from participants measurements may be transmitted to NTQR by any of the following methods;

- Participating laboratories may upload data to NTQR
- Participants may insert individual data records by logging into their account
- Participants may send data in a digital format to ntqrsupport@ntqr.org

Once the data is received at NTQR, it is consolidated into one database for monitoring purposes.

The benefits of central monitoring include but are not limited to:

- Providing a standardized approach to QR monitoring in the US,
- Consolidation of each provider's measurements across clinical sites and analyte laboratories

In addition, a centralized, anonymous national database has the potential to have other benefits to increase precision, such as:

- Exploration of different referents
  - population
  - center
  - sonographer
- Exploration of different metrics, such as
  - 5^{th}, 50^{th}, and 90^{th} percentile
  - MoM
  - Std Dev Log_{10} MoM
  - delta NT
  - slope

REPORTING

Once providers are NTQR credentialed, their data will be included in the monitoring process. The results of the epidemiologic monitoring are reported directly to participants as well as the relevant participating biochemistry laboratories.

Statistical testing commences when there are at least 30 NT measurements submitted over a 12 month period. If the requisite 30 NT measurements are not obtained, the reports will be generated, but results of statistical testing will not be provided.

Reports are generated for sonographers and for sonologists.

NT measurement review is based on a comparison of the practitioner's 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 MoM should be 1.0 with an expected 90^{th} percentile range from 0.9 to 1.1 MoM. A median outside this range suggests that NTs are being under- or over- measured. If a median falls just outside the range, particularly when the data numbers are low, there is likely only a moderate discrepancy.

The NTQR epidemiologic monitoring reports provide participants quarterly feedback on their NT measurements. When a participant is first notified that their NT measurements are outside the expected range the targeted performance improvement activities available in their account on the NTQR website are recommended.

NTQR may require targeted quality maintenance tasks of selected participants. Participants will be notified of these requirements and must complete the activities requested to maintain their NTQR credential.

Additional information about the required quality maintenance process is available in the *MFM Foundation: NTQR Guidelines for Performance Improvement*.

PARTICIPATION BY ANALYTE LABORATORIES

Laboratories independently conduct serum assay quality control, which is not reviewed by the NTQR. Laboratories have been incorporating NT measurements into their risk computations using various methods to create medians and methods to ensure on-going quality control.

A number of commercial and non-commercial labs have chosen to participate in the program by transmitting NT / CRL measurements to NTQR for independent epidemiologic monitoring. The data originates from the clinical site and is sent to their respective lab via a requisition form accompanying the blood sample. The information collected on the requisition form is entered into the respective laboratory electronic data capture system. De-identified data is then sent to NTQR on a regular basis (i.e., daily, weekly, monthly) based on volume.

Laboratories are not responsible for and do not participate in the development of educational content, web-based examinations, image proficiency evaluation or ongoing epidemiologic monitoring.

OTHER CONSIDERATIONS

The Maternal Fetal Medicine Foundation (MFMF) does not certify physicians, hospitals or practice sites. Certification of physicians is the prerogative of professional societies such as the American Board of Obstetrics and Gynecology and others.

MFMF does not accredit practice sites. Practice sites offering sonography often submit to voluntary accreditation by either the American Institute of Ultrasound in Medicine or the American College of Radiology.

The MFMF / NTQR does not intend to regulate in any way the manner in which participants practice, or to set minimum requirements for equipment or medical records. In general we encourage participating physicians and sonographers to follow the recommendations of their professional organizations, and where applicable their affiliate hospitals etc. More specifically there are a number of recommendations that are available to guide clinicians:

1) Ultrasound equipment

The NTQR does not establish equipment standards, inspect or otherwise verify that standardized equipment recommendations are met. The recommendations presented below are consistent with ultrasound practice accreditation requirements of the AIUM and ACR and may serve as a useful guide.

The ultrasound equipment should meet all facility, state and federal guidelines.

Studies should be conducted with real-time equipment, and transducers should be available with a frequency range that will optimize beam penetration and resolution, as recommended in the Antepartum Obstetric Ultrasound guidelines jointly issued by the American College of Obstetrics & Gynecology (ACOG), the American Institute of Ultrasound in Medicine (AIUM) and the American College of Radiology (ACR).

While experience has suggested that >90% of NT examinations can be performed using transabdominal transducers, access to transvaginal transducers is important for those patients who cannot be successfully imaged transabdominally.

Instrumentation used for diagnostic testing be maintained in good operating condition and undergo routine calibration and servicing at least annually, according to the manufacturers' specifications or, more frequently, if problems arise. There should also be routine inspection and testing for electrical safety of all existing equipment.

2) Image storage and reporting

The NTQR does not evaluate or inspect ultrasound practices. The following recommendations are excerpted from the AIUM*:

- “There must be provisions for the retrieval and storage of examination records of all studies performed.
- Appropriate documentation of every study must include permanent ultrasound images stored on suitable recording media, as well as a report that indicates the findings obtained by examination.
- Ultrasound images, and a report from the interpreting physician, must be maintained in a readily accessible fashion for comparison and consultation.
- Recording media must have a shelf life compatible with the minimum number of years, required by law, for the maintenance of patient records. In most states this will be for at least 7 years after the patient's last examination was performed; however, these requirements vary from state to state.”

*http://www.aium.org

APPENDIX 1
NTQR Image Review Criteria Scoring Guidelines

Scoring Item*	Details
NT margin of edges clear	• Clear U/S image • Angle of insonation perpendicular to NT space (fetal spine in horizontal position) • Clear NT lines
Mid-sagittal plane	• Mid-sagittal view of fetal spine seen in cervical and thoracic region • Tip of nose seen in face area • Third and forth ventricle seen in fetal CNS
Image area maximized	• Not be able to fit a second (same size) fetus in the ultrasound space surrounding the fetus; this implies that the fetus occupies > 50% of image

Neutral position	• The fetal head must be neutral without hyperflexion or hyperextension.
	  • Hyperflexion: Fetal head is flexed with no free space (amniotic fluid) seen between lower chin and anterior neck.
	  • Hyperextension: Fetal is extended with an angle between lower chin and anterior neck of greater than 90 degrees (subjective assessment by reviewer)

Away from Amnion	• Amnion seen separate from NT line
+ calipers used	• "+" calipers should be used for NT measurement
Horizontal crossbar placed correctly	• Calipers placed on the inner borders of the nuchal space with none of the horizontal crossbar itself protruding into the space; the horizontal crossbar of the calipers on either side should not be in the black space
Calipers perpendicular	• A vertical line connecting the 2 calipers should be perpendicular to the long axis of fetus
Measured at widest space	• Measurement obtained at widest space of NT

***Note:** Each item is scored yes/no directly on the NTQR web portal