Current Commentary

Implementation of a National Nuchal Translucency Education and Quality Monitoring Program

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In 2004, leaders in first-trimester aneuploidy screening and a multidisciplinary group of experts established the Nuchal Translucency Quality Review Program, a national program to standardize education, credentialing, and quality monitoring of nuchal translucency. Since its inception, the program has credentialled more than 6,600 physician and ultrasonographer participants and collected more than 2.4 million nuchal translucency measurements. Ongoing quality monitoring is conducted through statistical analysis comparing the distribution and standard deviation of participants’ nuchal translucency measurements against those obtained from a standard referent curve. Results of these analyses are distributed to participants quarterly and are used to track each participant’s performance and to trigger performance improvement activities or mandatory remediation. This program could serve as a template for future education and credentialing programs that include partnerships with academic leaders, national professional organizations, and industry.

(Obstet Gynecol 2014;123:149–54)
DOI: 10.1097/AOG.0000000000000058

Over the past decade, the measurement of nuchal translucency has become widely used in first-trimester screening for fetal aneuploidy in the United States. The experience in clinical trials by the Fetal Medicine Foundation1 and by the U.S. trials, Biochemistry, Ultrasound, Nuchal Translucency2 and First and Second Trimester Evaluation of Risk,3 demonstrated the importance of precision and need for ongoing quality assurance in nuchal translucency measurements. Small differences in measurement have the potential to significantly alter an individual’s risk estimate for aneuploidy and increase the chance for false-positive or false-negative diagnoses.

A multidisciplinary group of physicians collaborated to develop an education and quality review program that translated nuchal translucency screening from research trials to an effective nationally available clinical application. In 2005, the Nuchal Translucency Quality Review Program was launched as the first nationwide clinical training and ongoing quality review program for nuchal translucency screening in the United States. This article describes the salient features of the program including its infrastructure, educational programs, quality monitoring, and remediation strategies as well as highlighting the lessons learned since its creation.

FROM CLINICAL RESEARCH TO CLINICAL APPLICATION

In 2004, the leaders of the Biochemistry, Ultrasound, Nuchal Translucency2 and First and Second Trimester...
Evaluation of Risk studies collaborated with the Society for Maternal-Fetal Medicine to establish the Maternal Fetal Medicine Foundation, now known as the Perinatal Quality Foundation, an independent non-profit organization with the mission “to improve the quality of Maternal-Fetal Medicine medical services by providing state of the art evidence-based educational programs and statistically valid monitoring systems to evaluate current practices and facilitate the transition of emerging technologies into clinical care.”

The Foundation’s first major project was the establishment of the Nuchal Translucency Quality Review Program to develop standardized education, credentialing, and quality monitoring of nuchal translucency measurements. The Foundation established a multidisciplinary Nuchal Translucency Oversight Committee to create the program’s educational content, determine quality review standards, and foster collaboration among leaders in the field. The committee invited each of the major organizations involved with ultrasound screening of the pregnant patient to send a representative to an organizing meeting. This group ultimately included more than 40 professional experts in first-trimester risk assessment for fetal aneuploidy; among them, radiologists, obstetricians, gynecologists, ultrasonographers and geneticists, and representatives from seven professional societies as well as commercial and private analyte diagnostic laboratories.

Organizational and Administrative Infrastructure

The Nuchal Translucency Oversight Committee formed several subcommittees for more efficient administration of the program including committees for education, image review, quality review, and research and innovation. The initial expenses for the program were funded with a loan from the Society for Maternal-Fetal Medicine. After a widespread search, the Foundation contracted with DM-STAT4 an experienced data management organization, to develop a program in which virtually all activities could be managed electronically. Initial efforts focused on the development of proper software for data acquisition and analysis as well as the creation of a web site (www.ntqr.org) to facilitate transfer of data and information to the health care providers. The program gradually consolidated and centralized all administrative, information technology, and data functions. Administrative staff are salaried; all other personnel involved in the program have been and continue to be volunteers and do not take any stipends. The program’s operating funds derive from several sources including the initial credentialing fees, ongoing participation fees, support from the laboratories performing the serum analyte analysis, and from educational endeavors.

Education and Credentialing

There are three requirements for ultrasonographers and physicians seeking credentialing in nuchal translucency measurements by the Nuchal Translucency Quality Review Program: completing an education course, passing a multiple-choice examination, and receiving a passing grade on the submission of nuchal translucency images. A standardized 4-hour training course was developed for both didactic and web-based training. The training covers such topics as requirements for participation in the program; principles of screening; use of multiple of the medians; likelihood ratios; screening cutoffs; how to obtain optimal nuchal translucency images; quality review procedures; optimal combinations of screening parameters in first and second trimesters; diagnostic testing options; screening in multiple pregnancy; genetic counseling aspects; and other benefits of first-trimester screening. The first course was held in 2005 at the Society for Maternal-Fetal Medicine’s annual meeting. Since then, multiple courses have been provided in conjunction with the annual clinical meetings of the Society for Maternal-Fetal Medicine, the American College of Obstetricians and Gynecologists, and the American Institute of Ultrasound in Medicine and in collaboration with a myriad of postgraduate continuing medical education programs. In addition, a newsletter, the NT Examiner, was created to provide credentialled health care providers with updates on all aspects of the program. Patient education presentations with DVD and iPhone apps have also been developed.

As of February 2013, the Nuchal Translucency Quality Review Program has credentialled more than 6,600 physician and ultrasonographer participants. The programs’ comprehensive web-based course has been completed by more than 4,600 participants, and thousands more have attended land-based seminars sponsored by the Nuchal Translucency Quality Review Program. Approximately two-thirds of the credentialled participants are ultrasonographers and the remaining one-third are physicians. The vast majority of credentialled physicians are evenly divided between general obstetrician-gynecologists and maternal-fetal medicine specialists; the remaining physician participants are radiologists, maternal-fetal medicine fellows, and a small number of geneticists (Fig. 1).

Image review requires five images from five different fetuses. Images are scored based on a standard
protocol to evaluate nine criteria, and each image must satisfy at least seven of those criteria. Once received, the average time from image submission to review and scoring is 9 days. A batch will be rejected if all five images fail to meet a single criterion or if the overall score falls below 80%. The image review process is overseen by the Image Review Committee, which includes two senior reviewers who each supervise a group of primary reviewers.

Quality Monitoring

Although a necessary part of initial credentialing, image review is an impractical tool to ensure ongoing quality monitoring as a result of the millions of nuchal translucency measurements that accumulate over time. Instead, the Nuchal Translucency Quality Review Program applies statistical analysis to compare the distribution and standard deviation (SD) of participants’ nuchal translucency measurements periodically against those obtained from a standard reference curve. Nuchal translucency measurements are converted to multiples of the crown rump length-specific median with the expectation that an individual’s ideal median multiple of medians should be 1.0 and that their 90th percentile range extends from 0.9 to 1.1 multiple of medians. In addition, the variability of each participant’s nuchal translucency measurements is assessed through the SD after log_{10} transformation, which is expected to be between 0.07 and 0.10; a SD greater than 0.11 indicates that nuchal translucency measurements may not be obtained in a consistent manner, whereas a SD less than 0.07 reflects less variability than expected.

The Nuchal Translucency Quality Review Program currently performs these epidemiologic studies of nuchal translucency data quarterly, and results of these analyses are used to generate a detailed individualized epidemiologic report for each participant submitting more than 30 nuchal translucency measurements in a 12-month period (Fig. 2). Epidemiologic reports are sent to the participant, to the supervising physician, and to the designated practice administrator on request. Listings of health care providers in good standing are posted on the Nuchal Translucency Quality Review Program web site, and participating laboratories periodically receive an updated list of credentialed health care providers to help ensure that risk calculations are performed using only measurements obtained by credentialed health care providers.

Performance Improvement and Remediation

The quarterly epidemiologic reports are used to track each participant’s performance and to trigger performance improvement activities or mandatory remediation. When a participant is first identified as having their nuchal translucency median multiple of median and SD minimally outside the expected range, voluntary targeted performance improvement is recommended. For these participants, targeted performance improvement activities, including review of didactic materials, voluntary image submission, self-testing image review, and suggestions related to high and low measurements, are available free of charge on the Nuchal Translucency Quality Review Program web site.

In contrast, health care providers whose nuchal translucency median multiple of median and SD are
the farthest from the expected range are referred for Required Quality Maintenance, a mandatory remediation program. Those assigned to Required Quality Maintenance are required to update practice and supervisor information, review specific suggestions related to high or low measurement, document completion of a technical image review lecture, complete the image review self-test online, and submit five new images for review. Failure to complete remediation within 6 months results in revocation of a participant’s credentialing number; laboratories are notified if participants lose their credentials.

**Lessons Learned**

Since its inception, the Nuchal Translucency Quality Review Program database has grown exponentially and currently includes more than 2.4 million measurements. Although laboratories have contributed the majority of the data collected, individual health care practitioners have uploaded nearly one-fourth of the accumulated data. Analysis of the collected nuchal translucency measurement data demonstrates that the majority of health care providers’ median multiple of medians have been between 0.9 and 1.1 (Fig. 3); of those who are outside this expected range, however, the number of health care providers whose median multiple of median falls below 0.9 is more than 10 times the number whose median multiple of median is above 1.1.8 This “left shift” reflects a tendency to undermeasure and led the Nuchal Translucency Quality Review Program to prioritize image review criteria that assess caliper placement and to require correct placement of calipers on all submitted images. Since these more stringent image review criteria were implemented, pass rates for initial image review dropped significantly from 70% to 50%. Additionally, after completing Required Quality Maintenance, participants demonstrate improved performance, with almost 90% of

![Fig. 2. A. Epidemiologic report. Box graph of nuchal translucency measurements: displays the median nuchal translucency multiple of the median (MoM) along the y-axis and standard deviation along the x-axis. Each dot represents a participant and should fall within the small box. Dots outside the box on the y-axis suggest overmeasuring or undermeasuring; dots outside the box on the x-axis suggest that nuchal translucencies either are not being measured consistently (right) or that there is less variation than expected (left). B. Referent curve graph displays a participant’s observed nuchal translucency measurements as a function of crown–rump length. The solid line in the figure is the referent curve; the individual points are the participant’s nuchal translucency measurements. Approximately half of the measurements should be above the line, and half should be below. If the majority of the data points fall below the curve of expected values, it suggests that nuchal translucencies are being systematically underestimated. In contrast, if the majority of data points fall above the referent line, nuchal translucency measurements are being systematically overmeasured.

remediated participants raising their median multiple of median by 0.05 and more than half having a post-remediation median multiple of median within the acceptable range.8

A clear gap remains in the lack of follow-up data to determine how many aneuploidy cases were accurately diagnosed or missed. Although our colleagues in the United Kingdom have this outcome data more readily available,9 we are at present unable to determine how our efforts compare with detection rates demonstrated in clinical trials. To evaluate this, we have recently completed enrollment of more than 17,000 patients in a prospective evaluation of first-trimester combined screening in which outcomes will be collected; results will be published when outcome information is gathered on all enrolled participants and data analysis is completed.

CONCLUSION
The Nuchal Translucency Quality Review Program’s recognition of and subsequent response to the phenomenon of under measurement demonstrates the imperative for health care providers to submit data for ongoing quality monitoring. This concept is not new. In describing the nuchal translucency measurement in 1998, Herman wrote “the examiner is required to produce a result that resembles laboratory results” and “as in any laboratory study, those implementing the program should take upon themselves the task of an ongoing audit to adhere to the required standards.”10 To optimize first-trimester aneuploidy screening in clinical practice, the Nuchal Translucency Quality Review Program assumed the responsibility of developing a process of education and quality review for the ultrasound analyte (ie, the nuchal translucency measurement). In addition, the Nuchal Translucency Quality Review Program has facilitated a collaborative process between the clinical providers performing the nuchal translucency measurements and the laboratories responsible for serum marker screening. The objective of an effective transition from research to clinical care has been met, and the lessons learned from this endeavor may guide future education and credentialing programs and partnerships among academic leaders, national professional organizations, and industry.

REFERENCES


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