



11-13⁺⁶ Weeks Scan Project Newsletter

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WELCOME to the July 2006 issue of the FMF/USA newsletter. With this issue we are proud to announce the formation of the Fetal Medicine Foundation/USA, a non-profit autonomous organization working alongside the Fetal Medicine Foundation in London. In addition, we are very excited to announce our new FMF/USA online course that covers NT, nasal bone, and tricuspid flow assessments (see box at bottom of page 1). Continuing our series of articles by leading experts, below you will find a fine contribution by Dr. Allan Nadel of Harvard medical School. Finally, the newsletter contains some scanning tips and facts and figures from the Fetal Medicine Foundation's accreditation and audit programs. On the back page is a list of upcoming courses as well as our Q&A section. Thank you for your continuing interest and, as always, we welcome your comments, suggestions, and questions.

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MSAFP After First Trimester Assessment?

Allan Nadel M.D.

Massachusetts General Hospital and Harvard Medical School, Boston MA

The "standard of care" in the United States is to offer second trimester maternal serum alpha fetoprotein (MSAFP) determination to all pregnant women, unless they have an amniocentesis. Indeed, the American College of Medical Genetics recently reaffirmed this, specifically including "women who have elected to have first trimester screening and/or CVS."¹ This recommendation ignores the universally accepted finding that both the sensitivity and specificity of second trimester ultrasound for neural tube defects are better than that of MSAFP (Table 1).²⁻⁴ The diagnosis of anencephaly is always obvious, even in the first trimester.⁵ The presence of spina bifida aperta is highly associated with fetal cranial findings on ultrasound, which were described by Nicolaides et al.⁶ two decades ago. These include Chiari type II malformation ("banana sign") and bilateral anterior skull depressions ("lemon sign"), both of which are easy to see in the second trimester and make the diagnosis of an open spine defect highly reliable as well.

Table 1. Detection Rate

Abnormality	MSAFP > 2.0 MOM	MSAFP > 2.5 MOM	Second Trimester Ultrasound
Spina bifida	90 %	80 %	> 95%
Ventral wall defect	83 %	77 %	> 90 %

There are other structural abnormalities that can be detected on the basis of an elevated MSAFP. The most important of these are ventral wall defects (omphalocele and gastroschisis). Again, both the sensitivity and the specificity of second trimester ultrasound^{2,4} are better than MSAFP⁷ (Table 1). Other abnormalities associated with elevated MSAFP (Table 2) are rare, so detection rates have not been calculated. However, it seems that ultrasound should detect most cases, except for congenital nephrotic syndromes and fetal skin conditions. (continued on page 2)

Want to earn NT / nasal bone/ tricuspid flow certificates?

Don't have time to travel to a course? No problem... check out this site:

http://www.mfmedicine.com/CourseList.aspx

Choose this course title: FMF USA 11-13+6 Week Scan Theory and Practical NT/NB/TF Internet Course (scroll to the bottom of the page)

Everything you need to complete the course and get your certificates

Please come and visit our Exhibit Booth at the SDMS 2006

Annual Convention

Denver, CO

October 12-15, 2006

Booth #120

- NT, Nasal Bone, and Tricuspid Accreditation, Software Information
- Annual audit information
- Free Textbook
- CD with nasal bone and tricuspid flow lectures
- Reprints of recent publications

MSAFP After First Trimester Assessment? (cont.)

Alan Nadel, M.D.

Table 2. Abnormalities Associated with Elevated MSAFP

	Usually detected by ultrasound
Neural tube defects	Yes
Ventral wall defects	Yes
Cloacal or bladder extrophy	Yes
Renal agenesis	Yes
Renal cystic malformations	Yes
Fetal bowel obstruction	Yes
Cystic hygroma	Yes
Teratoma (sacroccygeal, epignathus)	Yes
Congenital nephrosis	No
Skin lesion	No

Women with MSAFP > 2.5 MOM may have a 1% risk of aneuploidy.⁸ However half of these cases are sex chromosome abnormalities, and at least some of the autosomal abnormalities should have sonographic findings.

Some would advocate using second trimester MSAFP to detect a subset of patients that are at increased risk of adverse perinatal outcome such as fetal demise and IUGR. However there is no evidence that using MSAFP in this way leads to appropriate interventions that improve outcome.⁹ Indeed, the median gestational age of fetal demise in one study was 20 weeks,¹⁰ so no intervention could have benefited the majority of these cases. It should be noted that first trimester biochemistries, if they are at a low level (PAPP-A < 5th percentile, free β -hCG < 1st percentile), also identify a subset of patients at increased risk for IUGR.¹¹

At Massachusetts General Hospital, we believe that most patients who have first trimester screening and a properly done second trimester ultrasound that demonstrates normal fetal anatomy do not need MSAFP determination. Since we are cognizant that offering MSAFP remains the “standard of care” we have patients sign an informed consent discussing these issues. The effort, expense, and anxiety associated with MSAFP screening in these women could better be spent elsewhere—for example, fragile X mental retardation carrier screening.¹²

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New FMF/USA—United States Non-Profit Organization

Jiri Sonek, M.D. RDMS

The Fetal Medicine Foundation of the United States of America (FMF/USA) was established on July 11th, 2006. It is a registered not-for-profit charity organization #1635069. Its Board of Governors is, with the exception of Prof. Nicolaides, entirely U.S. based. It is composed of seven physicians, three registered sonographers, one PhD, and one nurse, all of whom have a special interest in fetal medicine. The Board also includes an attorney and a person with a background in administration. We feel that the inclusion of members who are not physicians will provide a more balanced approach to running the Foundation.

The FMF/USA will remain closely allied with the Fetal Medicine Foundation (FMF) in London. The FMF has supported most of the published research in first trimester screening by nuchal translucency and other sonographic and biochemical markers. Over the past decade or more, the FMF has developed a uniform system of training and quality assurance. It has also developed software for calculation of patient-specific risk for trisomies 21, 18, and 13. The algorithm for the nuchal translucency measurements is based on examinations of approximately 100,000 fetuses and the biochemical marker portion (PAPP-A and free beta-hCG) is based on approximately 75,000 studies. The FMF system of training and risk assessment has been adopted by centers in 60 countries and thousands of sonographers around the world.

In the US, FMF-approved courses started taking place in 1998. Since that time, approximately 150 such courses have been held with the total attendance being around 10,000. Approximately 2,200 persons have successfully completed the FMF accreditation process in the US with a fairly steady sonographer to physician ratio of 3:1. These courses have been put on by a variety of entities including universities, hospitals, medical genetic centers and laboratories. In each case, in order for the course to be approved by the FMF, it has to have a standard content, which is included in FMF courses world-wide.

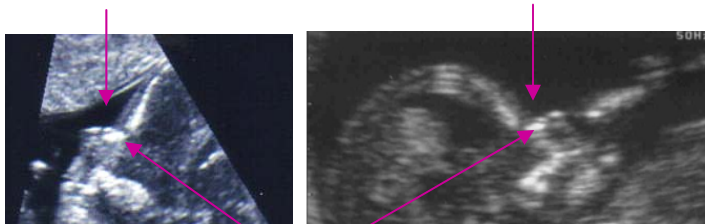
The accreditation and yearly quality assurance evaluations will continue uninterrupted though now completely under the auspices of the FMF/USA. The FMF/USA will continue in the proud tradition of uncompromising quality of the FMF.

Nasal Bone Scanning Tips

Naomi Greene MPH RDMS RDCS

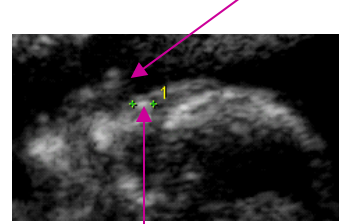
The goal for nasal bone assessment is to produce an image in which the bone is seen as more echogenic and thicker than the overlying skin. In order to accomplish this, the angle of insonation should be perpendicular to the plane of the nasal bone. One of the most common errors I see occurs when the head is tipped back so that the angle of insonation is actually perpendicular to the nasal root and not the nasal bone itself. In this case, one can see an echogenic structure beneath the skin but it is very difficult to be sure this is the nasal bone. As nasal bone presence/absence is such a powerful marker, one must be absolutely certain of the presence or absence before adjusting a woman's risk of Down syndrome using nasal bone.

Here, the sound beam is perpendicular to the plane of the nasal bone:



Nasal Bone

Here the sound beam is not perpendicular:



Nasal Root, **not** the nasal bone

Another important feature is the necessity to see BOTH the nasal bone and the skin overlying it as separate structures, with the nasal bone thicker and more echogenic than the skin. I find that harmonics is often helpful in bringing out the distinction between the two structures although it often makes nuchal translucencies very fuzzy and hard to measure accurately. This is why I recommend turning harmonics OFF for the NT measurement and ON for nasal bone assessment. For the rest of the anatomy, and ultrasound exam, ultrasound machine settings are entirely up to the individual operator to decide.

Upcoming Fetal Medicine Foundation United States Courses

Face-to-Face Courses

**Saturday, August 5th in Seattle, WA (6.75-8 CMEs possible)

**Wednesday, October 11th in Denver, CO at the SDMS 2006 Annual Conference (7.5CMEs possible)

**Saturday, November 4th in San Juan, PR (6.75-8 CMEs possible)

**Contact Melissa Machtolff 1-800-277-4363 (MMachtolff@genecare.com)

or Carrie Spradley 1-800-277-4363 (CSpradley @genecare.com)

Website: www.genecare.com/35/id/Conferences

**Saturday, September 9th in Columbus, OH (7 CMEs possible)

**Saturday November 4 in Long Island NY (7 CMEs possible)

** Contact Ulla Buchner-Howard 1-212-288-9793 (ubuchner@ubhInternational.com)

or Colleen Bobb 1-212-230-1426 (colleen@ubhinternational.com)

Website: www.ubhinternational.com/ultrasound.html

Online course:

***Online FMF/USA Course: http://www.mfmedicine.com/phys_train2.aspx

FMF USA 11-13+6 Week Scan Theory and Practical NT/NB/TF Internet Course

E-mail: naomihg@fetalmedicine.com or John.Lai@mfmedicine.com

Quick Facts and Figures

Since 1998, the Fetal Medicine Foundation has accredited just over 2200 United States sonographers and sonologists in Nuchal Translucency scanning, 483 in nasal bone assessment and 35 already in tricuspid flow assessment. In each of the last 5 years of annual audits, United States FMF-accredited individuals have, as a nation, maintained the USA distribution of NT measurements between 40-60% above the median, conforming with the expected distribution and thereby satisfying the FMF requirements for ongoing quality assurance.

Frequently asked questions:

Question: Is the Fetal Medicine Foundation Nuchal Translucency Certificate accepted by all labs in the USA?

Answer: Yes. To our knowledge, **every** laboratory in the United States (and around the world) doing first trimester combined screening accepts the Fetal Medicine Foundation and FMF/USA Nuchal Translucency Certificate. In addition, for those labs that are able to incorporate nasal bone assessments into the risk calculation, **only** the Fetal Medicine Foundation and FMF/USA have programs of training and accreditation in nasal bone assessment and the certificate earned at the end of this process is accepted by all labs in the USA utilizing nasal bone assessments.

Question: What are the costs for utilizing and maintaining my NT accreditation with the Fetal Medicine Foundation USA?

Answer: There are no costs to you for utilizing the FMF NT accreditation or for maintaining the quality of measurements by participating in the annual audit process. There are no costs to your laboratory for helping you to maintain high quality measurements. All labs in the USA have been very helpful to their clients by sending data for the annual audit directly to Naomi Greene—no patient information is ever requested with this data.