



FETAL MEDICINE FOUNDATION OF THE UNITED STATES OF AMERICA

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11-13⁺⁶ Weeks Scan Project Newsletter

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Exhibit Booth at:

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Sept. 23-25, 2007

SDMS 2007 Annual Convention

Las Vegas, NV
October 11-14, 2007

- **Check your NT status**
- **New research articles**
- **Free Textbook**

WELCOME to the July 2007 issue of the FMF/USA newsletter. The focus of this edition is current controversies and issues pertaining to first trimester screening in the United States. Every week, we receive many calls and e-mails asking for guidance and information on these issues so we hope to resolve confusion and clarify matters regarding these vital topics. Two main topics have emerged as causing the most consternation and confusion, with conflicting answers coming from different organizations. We include in this edition of our newsletter the Fetal Medicine Foundation USA's position on the following two topics: (1) When should screening begin, at 10 weeks or 11 weeks?, and (2) Should credentialing organizations require that a physician who employs NT-credentialed sonographers go through the entire credentialing process himself/herself?

In addition to the above articles, you will find another edition of "What's Wrong with this Picture" and a list of upcoming NT, Nasal Bone, and Tricuspid Flow courses.

We are happy to announce a new feature of the newsletter—Advertisements submitted by organizations looking to recruit credentialed NT providers.

We hope you find this edition useful and interesting. As always, we welcome your comments and questions.

Timing of first trimester fetal evaluation with ultrasound: 11-13⁺⁶ weeks' gestation

Jiri Sonek M.D. RDMS
Kypros Nicolaides M.D.

An argument for using 11 weeks' gestation as the lower limit for nuchal translucency screening:

Optimal gestational age for performing nuchal translucency (NT) measurement has evolved over the years. When we first introduced nuchal translucency screening in the early 1990's, 36mm (10+3 weeks) was chosen as the lower limit in order to provide the patient with information about the risks of fetal abnormalities as early as possible.¹ Indeed this was also the lower gestational age limit used in our publication on 100,000 pregnancies in the Lancet where the normal ranges for nuchal translucency measurements were established and the high efficiency of nuchal translucency screening for fetal aneuploidy was demonstrated.²

However, it soon became apparent that the first trimester scan can provide much more information about the fetus than simply a crown-rump length (CRL) and NT measurement. Waiting until the pregnancy reaches 11 weeks' gestation (CRL of 45 mm), allows for a more complete fetal examination without sacrificing screening efficiency and without causing an unreasonable delay.

The difference between 10 and 11 weeks' gestation may seem trivial. However, the appearance of the fetus in the first trimester changes very rapidly. This relatively small increment in gestational age helps us to avoid some of the confusing ultrasound findings transiently present in the early fetal period and significantly improves our ability to evaluate fetal anatomy overall.

The diagnosis of fetal anencephaly in the first trimester is complicated by the fact that brain tissue is not yet absent as it will be in this condition later in pregnancy.³ This abnormality in the first and early second trimester is best described as exencephaly; upon cursory examination, the fetal head tends to be fairly normal in appearance. Identification of an ossified calvarium is a relatively easy (cont. on page 2)

Timing of first trimester fetal evaluation with ultrasound: 11-13+6 weeks' gestation (cont.)

Jiri Sonek M.D. RDMS, Kypros Nicolaides M.D.

and reliable way to rule out the presence of exencephaly/anencephaly sequence. However, the calvarium does not calcify until approximately 11 weeks' gestation making the diagnosis of anencephaly quite challenging prior to this point.⁴

In the middle part of the first trimester, intestines protrude into the root of the umbilical cord (physiologic exomphalos). This finding mimics a serious fetal anomaly, the omphalocele. However, the intestines retract into the fetal abdomen by 11 weeks' gestation making the diagnosis of this defect much more reliable beyond this point.^{5,6}

The rapid growth of the fetus at this point in gestation is reflected in a very rapid improvement in our ability to evaluate fetal anatomy in more detail. In most cases, the four chamber heart view cannot be obtained prior to 11 weeks' gestation. However, beyond this point in gestation, this can be done fairly reproducibly. With practice, especially if the transabdominal and transvaginal approaches are combined, the fetal four chamber heart can be seen in almost 100% of the cases by 13 weeks' gestation.^{7,8,9}

Prior to 11 weeks' gestation, the fetal urinary bladder can be visualized in only about 50% of the cases. However, it can be seen with increasing frequency over the next two weeks to essentially 100% by thirteen weeks' gestation. Not only is the presence or absence of the fetal urinary bladder informative in itself, but its size, if abnormally large, can also be indicative of fetal problems such as an obstructive disease or chromosomal defects.^{10,11}

Another reason for delaying first trimester screening until after 11 weeks' gestation is the ever increasing list of markers other than NT which have been shown to be useful in first trimester screening. The presence or absence of the nasal bone cannot be reliably determined prior to 11 weeks' gestation since it does not begin to calcify until this gestational age is reached.¹² Evaluation of blood flow across the tricuspid valve cannot be done until a four chamber heart view can be obtained, which as mentioned above, cannot be done until after 11 weeks' gestation.¹³ Doppler imaging of the ductus venosus is limited by the small size of this blood vessel and is essentially impossible to do prior to 11 weeks' gestation.¹⁴ Finally, the newest marker, fronto-maxillary (FMF) angle, requires a reliable way of generating a line along the superior edge of the upper palate.¹⁵ Preliminary experience suggests that this is extremely difficult to do prior to 11 weeks' gestation due to insufficient ossification of the palate.

The last issue revolves around the increasing prevalence of maternal obesity. Fetal evaluation in the latter part of the first trimester and first part of the second trimester can be greatly limited by obesity. This limitation becomes more evident with decreasing gestational age.

An argument for using 13+6 weeks' gestation as the upper limit for nuchal translucency screening:

There are essentially three reasons for using 13+6 weeks' gestation as the upper limit for NT measurement. Firstly, the NT measurement, as a screening test for fetal abnormalities is less efficient at 14 weeks' gestation and beyond.^{1,16}

Secondly, the test loses its advantage of providing the patient with important information early in pregnancy and potentially, a safer method of treatment. Lastly, the NT measurement becomes more technically difficult (90% at 14 weeks vs. 98-100% at 11-13 weeks) due to the tendency of the fetus to assume a position where its longitudinal axis is pointing vertically towards the transducer.^{17,18}

FMF position statement:

Gestational Age Limits for First Trimester Combined Screening.

Gestational age of 11-13+6 weeks presents a unique time period when both the best available screening methods for fetal aneuploidy (nuchal translucency measurement, maternal serum biochemistries [PAPP-A and free β -hCG], presence or absence of the nasal bone, Doppler evaluation of blood flow across the tricuspid valve and through the ductus venosus, and fronto-maxillary facial angle measurement) can be implemented and an informative fetal anatomic evaluation can already be done. Since this is done at an early gestational age, this approach offers the patient maximum privacy and safer reproductive choices.

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(continued on page 3)

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FMF USA Quick Facts

- 2808 persons trained and accredited by the Fetal Medicine Foundation USA in nuchal translucency measurements, through July 4, 2007
- 777 persons trained and accredited by the Fetal Medicine Foundation USA in first trimester nasal bone assessment, through July 4, 2007
- 63 persons trained and accredited by the Fetal Medicine Foundation USA in first trimester tricuspid flow assessment, through July 4, 2007
- 387 new applicants for Fetal Medicine Foundation USA NT accreditation since January 1, 2007 alone.
- 90% of new applicants in 2007 are sonographers (RDMS) and 10% are physicians.
- All laboratories serving FMF-accredited persons send data directly to our Reaccreditation Coordinator to aid their clients in maintaining high-quality NT measurements, at no charge to the lab or to the credentialed provider
- Once the NT certificate has been earned through the FMF, there are no further fees to be paid for earning advanced accreditations, such as the nasal bone and tricuspid flow, and no fees for annual reaccreditation or daily use of the credential in clinical practice.
- 591 persons re-accredited in 2007 alone through July 4th, 2007



Should credentialing organizations require all accredited sonographers be supervised by physicians who are accredited as well?

N. Greene MPH RDMS RDCS, J. Sonek MD RDMS, A. Nadel MD

The Fetal Medicine Foundation and Fetal Medicine Foundation USA concur that each person involved in fetal ultrasound examinations should be appropriately trained to do so. This applies to ultrasound-based diagnosis and screening in all trimesters.

In the case of specialized evaluations such as the nuchal translucency measurement, nasal bone evaluation, tricuspid valve and ductus venosus Doppler, and fronto-maxillary facial angles, standardized views and additional training with ongoing quality assurance are imperative. We are of the opinion that the interpreting physicians should be aware of the requirements for such views. However, it is also our opinion that requiring the interpreting physicians to have the same skills as the sonographers to obtain such views, though highly desirable, is not practicable.

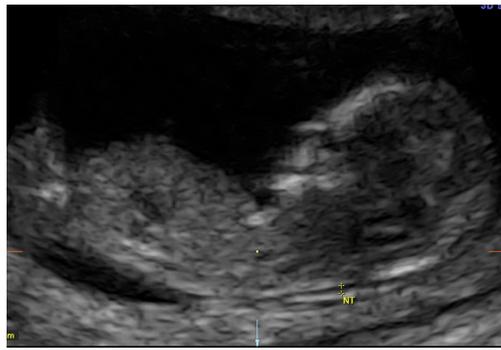
In the United States, physicians commonly depend to a large extent on the skill of the sonographer. This applies to not only general obstetricians/gynecologists but to maternal-fetal subspecialists and radiologists as well. This situation is not likely to change any time soon. Requiring sonologists, in addition to the sonographers, to be accredited in the specific situation of nuchal translucency measurement would lead to significant limitation of access of American women to nuchal translucency screening. At this point in time, the most effective approach is to make sure that the person who is performing the nuchal translucency measurement, (as well as the nasal bone and tricuspid flow assessment) is properly trained and that he or she participates in ongoing quality assurance. It is our belief that it is better to offer standardized screening (accreditation of the sonographer OR the sonologist) to a much larger number of women than it is to insist on restrictive screening strategies (accreditation of the sonographer AND the sonologist) which reach a much smaller number of women.

What's Wrong with this Picture?

Naomi Greene MPH RDMS RDCS



1.



2.



3.



4.

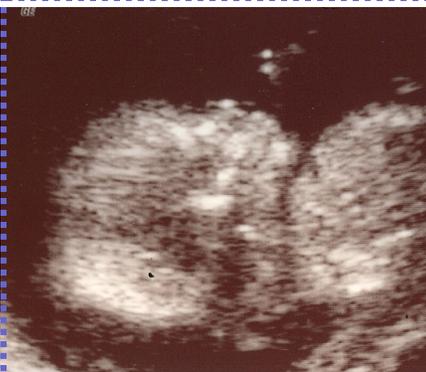


5.

1-5 What's wrong with these NT images?

- A) Nothing is wrong
- B) Inadequate magnification
- C) Flexed/Extended
- D) Whole NT region is not seen
- E) Not midsagittal
- F) Wrong calipers
- G) Thick, fuzzy lines

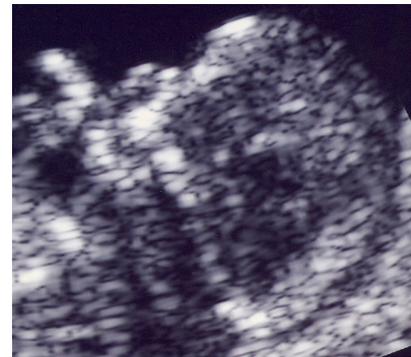
What's Wrong with this Picture? (continued)



6.



7.



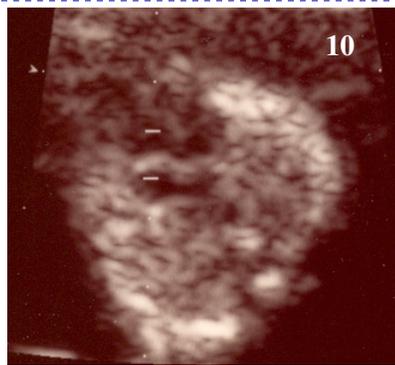
8.

6-8 What's wrong with these nasal bone images?

- A) Nothing is wrong
- B) Inadequate magnification
- C) Angle of insonation not perpendicular to nasal bone
- D) Nasal bone not brighter and thicker than overlying skin

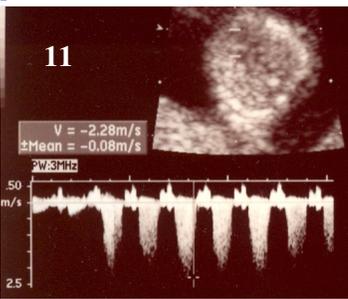


9

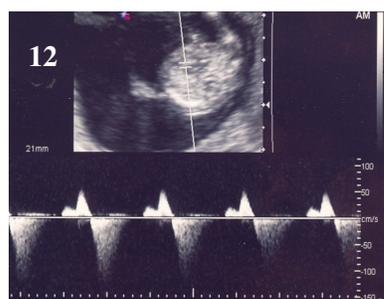


10

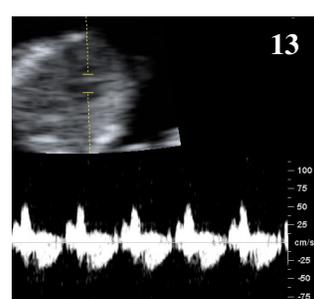
9-10 Which of these images is not appropriate to submit for tricuspid flow accreditation?



11



12



13

11-13 Which of these images shows tricuspid regurgitation, according to the Fetal Medicine Foundation protocol?

What's Wrong with this Picture? (answers)

- 1) C,E,G
- 2) B,C,E,F,G
- 3) D,F,G
- 4) A
- 5) B,C,G
- 6) C
- 7) A
- 8) D

(9) is not appropriate (Doppler gate straddles left-sided [mitral] inflow valve) (11) and (12) meet the criteria for tricuspid regurg



Upcoming Fetal Medicine Foundation United States Courses*

Face-to-Face Courses

Saturday July 28th in Indianapolis, IN (7.5 CMEs possible)

Saturday, August 5th in Seattle, WA (7.5 CMEs possible)

Saturday September 15th in Newark, NJ (7.5 CMEs possible)

Wednesday, October 10th in Las Vegas, NV at the SDMS 2007 Annual Conference (7.5CMEs possible)

Saturday, December 1st in Chicago, IL (7.5 CMEs possible)

Contact Melissa Machtloff or Carrie Spradley 1-800-277-4363 (MMachtloff@genecare.com) (CSpradley @genecare.com)

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

Friday, August 10th in Puerto Rico at Ponce Hilton Hotel & Casino— Contact Germaine Quinones 787-608-1477

Saturday October 20th in San Diego, CA (up to 15 CME's possible)

Contact Lynnette Hayes (Lynnette.Hayes@sharp.com)

Website: <https://www.82sharp.sharp.com/Sections.asp?dblink=1&ServLink=77&ClassLink=1986&Survey>

Online courses:

***Online FMF/USA Course: <http://www.mfmedicine.com/CourseList.aspx>

FMF USA 11-13+6 Week Scan Theory and Practical NT/NB/TF Internet Course (4CMEs for sonographers)

FMF USA Nasal Bone and Tricuspid Flow Theory and Practical Internet Course (4CMEs for sonographers)

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

* The Fetal Medicine Foundation USA accepts NTQR online or face-to-face theory courses when applying to the FMF USA for NT credentialing. You don't need to take the NTQR online exam after taking their course to submit images to the FMF. After their course, simply download our Film Submission form from www.fetalmedicine.com/usa to submit films to the Fetal Medicine Foundation for NT accreditation.

FMF NT credentialed sonographers wanted!

ULTRASOUND OPPORTUNITIES IN GENETICS TESTING
RDMS (OB/GYN) WITH THE NT CERTIFICATION
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OUR CLIENTS ARE THE CORPORATIONS THAT EXHIBIT AT AIUM AND RSNA. WE HAVE SEVERAL OPENINGS THROUGHOUT THE UNITED STATES THAT INCLUDES ALL OF THE TEXAS AREA. WE SEEK POSITIVE, OUTGOING AND HIGHLY SKILLED PROFESSIONALS THAT HAVE AN INTEREST IN BEING ON THE CUTTING EDGE USING THE LATEST EQUIPMENT. ALL POSITIONS HAVE AN OUTSTANDING COMPENSATION PACKAGE. PLEASE EMAIL YOUR RESUME IN A WORD DOCUMENT AND I WILL CALL TO DISCUSS THE OPPORTUNITIES.

CORPORATE OPPORTUNITIES/
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HIGH RISK/NT CERTIFICATION A PLUS

NEW OPENINGS IN THE NORTHEAST REGION AND COLORADO. CANDIDATES MUST LIVE CLOSE TO AN INTERNATIONAL AIRPORT AND ENJOY TRAVEL. ONE DAY A WEEK WILL BE SPENT IN YOUR HOME OFFICE. IF YOU ENJOY TEACHING AND CONSIDER YOURSELF TO BE A HIGHLY SKILLED SONOGRAPHER, THIS MAY BE AN EXCELLENT OPPORTUNITY TO MOVE FORWARD IN YOUR CAREER. EXCELLENT COMPENSATION PACKAGES. PLEASE EMAIL YOUR RESUME AND I WILL CALL TO DISCUSS THE OPENING AND YOUR QUALIFICATIONS.

TO DISCUSS THE ABOVE OPPORTUNITIES, PLEASE CONTACT:
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