

Toronto's Mount Sinai Hospital offers First-Trimester Screening Across Ontario

By Dr. Barry Hoffman and Dr. Jo-Ann Johnson

Mount Sinai Hospital, an internationally renowned 462-bed patient care, teaching and research hospital in Toronto, has implemented a cutting-edge, multidisciplinary prenatal screening program to detect Down Syndrome in the first trimester of pregnancy. Obstetrics, Medical Imaging, Pathology and Laboratory Medicine and Genetics all work collaboratively



Normal nuchal measurement at 12 weeks gestation

at Mount Sinai to provide the initial risk estimate and to follow up positive screens with intensive counselling and definitive testing. Mount Sinai is the first site in Canada to offer first-trimester screening (FTS) as an insured service.

Two aspects of the screening program are particularly noteworthy. Firstly, the Center of Excellence in Obstetric Ultrasound (CEOU) at Mount Sinai Hospital, in conjunction with the Fetal Medicine Foundation (FMF) Canada, has become a national leader in developing a quality infrastructure to ensure accurate ultrasound measurement of the nuchal translucency (NT), an important biomarker of Down Syndrome. Secondly, Mount Sinai's screening laboratory has adopted a novel IT solution, called Waveforms™, to more efficiently obtain and process the complex information required to generate a meaningful screen risk of Down Syndrome.

traditional second trimester prenatal screen carried out from 15 to 20 weeks with higher detection rates (DR) and lower false positive rates (FPR). The test combines ultrasound measurement of fluid in the back of the neck of the fetus, visualized as the nuchal translucency or NT, with biochemical analysis of the maternal blood to determine levels of pregnancy-associated plasma protein-A and free beta-chorionic gonadotropin. These along with the maternal age, weight, race and diabetic status are used to calculate the screen risk of Down Syndrome.

The first trimester screening (FTS) program has grown steadily since it was introduced at Mount Sinai Hospital in January of 2002, and has been associated with a number of important clinical benefits including a 30% reduction in the invasive testing rate (amniocentesis) and increased early detection of other chromosome abnormalities and certain birth defects. Patient satisfaction with the test is high due to the availability of earlier results.

A major challenge in implementing first-trimester screening was to ensure the quality of the NT component of the screen. Measuring the NT is not a trivial exercise and sonographers must learn to do it properly through guided training. Research has clearly shown that sonographers obtain the most accurate and consistent results when trained by a judicious mix of didactic education and expert audit of their submitted images according to accepted international standards. Dr. Jo-Ann Johnson of the Division of Maternal Fetal Medicine at Mount Sinai has been instrumental in setting up the training infrastructure across Canada and developing the evaluation tools to assess measurement quality. Thus far, over 1,400 sonographers have enrolled in the certification program.

NT quality has recently become a hot issue, and various professional and government organizations in Ontario including the College of Physicians and Surgeons of Ontario, the Quality Management Program – Laboratory Services affiliated with the OMA and the Ministry of Health and Long Term Care, are working collaboratively to establish and standardize quality criteria and to apply these to the ongoing monitoring of NT images used in the FTS screen.

The second major challenge to the prenatal program at Mount Sinai has been how to obtain the extensive information needed to generate a meaningful risk estimate of Down Syndrome in a timely manner, and then process the infor-

Detection rate (DR), false positive rate (FPR), OAPR† for Different Screening Combinations			
	DR (%)	FPR (%)	OAPR
MA + >35YRS	33	10	1:150
MSS (15–17 wks)	75	7	1: 80
FTS (11–14 wks)	90	5	1: 20

MSS Maternal serum screen: Maternal age, alpha fetoprotein (AFP), hCG and unconjugated estriol (uE3), FTS : Maternal age + NT + free b-hCG + PAPP-A
†Odds of a true positive screen.

Screening for Down Syndrome in the first trimester is a new advance that improves upon the performance of the

This sponsored report supported is by Aurillion Micro Systems Inc. (www.aurillion.com)

mation with available resources. The amount of required information is substantial, filling a full-page requisition. The requisition typically accompanies the maternal blood sample to the laboratory where the information is entered into a series of computer systems for production of the risk calculation along with results of the biochemical testing. Manual entry of all of this information typically takes 5–7 minutes per requisition. At 20,000 requisitions per year, extensive personnel resources are required. Quality of the incoming information is also a problem. Conservative estimates indicate that 10–20% of maternal



Waveforms™ scanning application in use at Mount Sinai Hospital in Toronto.

screening orders arrive in the lab with missing, illegible and/or faulty information that necessitates time-consuming and labour-intensive phone calls to the care provider to rectify the situation. Multiple calls are often needed and delays of several days

or more in issuing the risk report are frequently encountered. Such delays increase the waiting time and anxiety of the pregnant woman who has opted for prenatal testing.

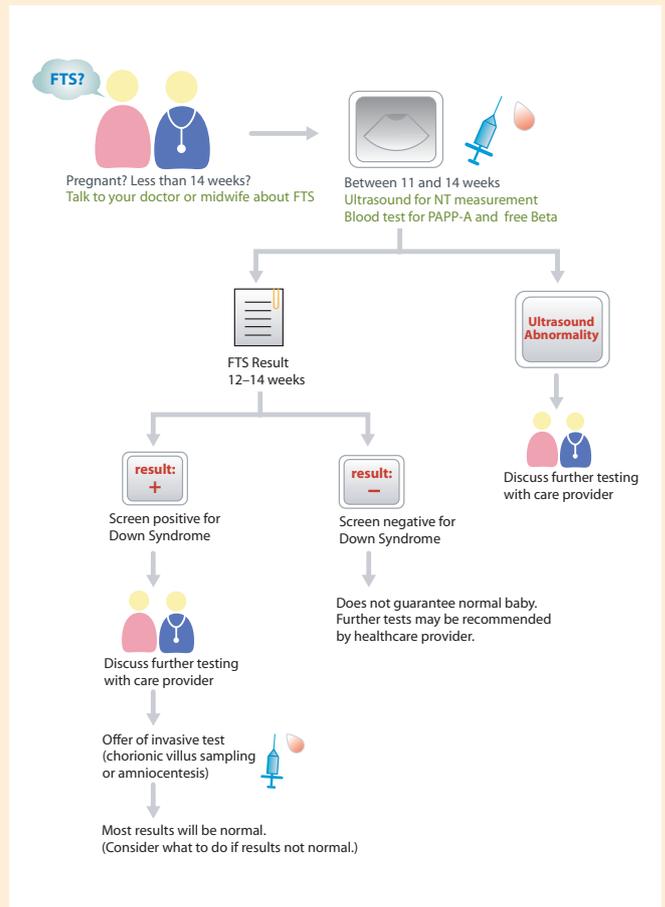
The laboratory has looked to emerging technology from an innovative software company called Aurillion Micro Systems Inc. (www.aurillion.com) to eliminate the above stresses through the use of its Waveforms™ technology. The laboratory employs Waveforms™ to generate intelligent electronic requisition templates that are freely distributed to physicians for use on the ordering provider's office computer at the time the test order is initiated. The electronic requisitions are completed under programmatic control where help/guidance can be provided in conjunction with data quality/error checking to ensure proper completion of each requisition (medical order). In a novel twist, the paper copy also contains a complex 2D bar code encoding all of the patient and pregnancy information for ready scanning when received at the laboratory. In effect, this system provides a complete end-to-end electronic order communication from the physician's office to the destination laboratory computer system using industry-standard communication (i.e., HL7) protocols. Using Waveforms™ has enabled lab staff to process the data entry in just seconds, without concern for transcription error, instead of the seven minutes or so each requisition used to take. In one fell swoop, the Waveforms™ electronic templates have improved information quality while drastically reducing the personnel resources required to process the information upon receipt in the laboratory. Laboratory staff are freed from entering data into the computer and phoning to track down missing information.

The Waveforms™ technology is not restricted to prenatal screening. Once installed, it is a fairly simple matter to customize applications to different requisitions and forms. Potential cost efficiencies are substantial and could total

hundreds of thousands of dollars annually with widespread adoption by the laboratory. Application of Waveforms™ technology is equally applicable throughout the hospital, especially in Ambulatory service areas where important clinical information/requests are provided by outside physicians. Use of the intelligent “chaperoning” Waveforms™ software will ensure the accurate transfer of information. Mount Sinai Hospital is currently considering expanding the use of Waveforms™ for a variety of requisitions and clinical programs.

With the quality of the NT being addressed and the means in place to efficiently accommodate the extensive information required to calculate the risk of Down Syndrome, the prenatal screening group at Mount Sinai Hospital is looking to extend the first trimester screening program more widely across Ontario and even beyond. Increased availability of first-trimester screening will mean that more women will benefit from more accurate testing carried out earlier in the pregnancy.

First-trimester screening program timeline



For further information on First-Trimester Screening

please visit www.fmfcana.com or contact:

The Mount Sinai Hospital FTS Program

3rd Floor OPG Room 3230

700 University Avenue, Toronto, Ontario

Phone: 416-586-4800 ext. 2132 • Fax: 416-586-8405

Web: www.mtsinai.on.ca