2014 Gage Awards

Reference #	7487707
Status	Complete
Name of hospital or health system	Santa Clara Valley Medical Center
Name of project	A new model for providing cell free fetal DNA and risk assessment for chromosome abnormalities in a public hospital setting
CEO name	Paul Lorenz
CEO approval	Check here to confirm that your CEO approves of this project being submitted for a 2014 Gage Award
Submitter name (first and last)	Robert Wallerstein, MD
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Within which of the two categories does your application best align?	Population Health
1. Provide a brief description of the project. (This section should resemble an abstract for a poster presentation or an abstract for a peer reviewed journal. Include an objective, data sources, study design, findings, and conclusions.)	Cell free fetal DNA (cffDNA) is a new highly accurate blood test utilizing a new technology that is changing practice for obstetric patients due the desirability of highly accurate screening for Down syndrome without invasive procedures, such as amniocentesis. However, the utilization of this new technology and the specifics of incorporating this into routine prenatal care are complex. We present our experience with implementing a novel program for cffDNA screening in a public hospital setting with attention to patient education and genetic counseling as well as cost–effective provision of care. The aim of this report is to assess implementation of this program in terms of diagnostic testing elected by participating patients.

2. Describe the methods use in this project. Include where, why, and how the project was accomplished.	In response to the new availability of cffDNA for prenatal Down syndrome risk assessment we created a patient care model entitled “Advanced Maternal Age Options” (AMA Options) utilizing first trimester genetic counseling, cffDNA, first and second trimester serum screening, nuchal translucency (NT) ultrasound, detailed ultrasound, and amniocentesis to provide risk assessment to a public hospital prenatal population. Primary prenatal care providers identified patients at increased risk for chromosome abnormalities: 35 years or greater at delivery or family history of trisomy 13, 18 or 21. These women were referred and scheduled for genetic counseling at approximately 11 to 12 weeks gestation to discuss the panoply of screening and diagnostic modalities available (i.e. first and second trimester serum screening and NT ultrasound, cffDNA, detailed/targeted ultrasound, and amniocentesis). At the time of genetic counseling, women elected one of three options for chromosome risk assessment and diagnosis: 1) cffDNA; or 2) first and second trimester serum with NT ultrasound; or 3) amniocentesis. The novel aspect of this program is that the choice for cffDNA or amniocentesis excluded patients from first trimester serum screening and NT ultrasound. All patients were offered detailed ultrasound at 18-20 weeks, and amniocentesis was available to any patient following initial risk assessment. Patients were seen in the second trimester (near 18 weeks gestation) for follow up genetic counseling to review their first trimester results and finalize testing choices. Second trimester AFP screening was offered to all patients not having amniocentesis performed.
3. Describe the results of the project. What data was used to support improvement results?	In the first 9 months of 2013, 184 patients were seen for first trimester AMA Options counseling. Of those 126 (69%) chose cffDNA, 1 (0.5%) chose integrated screening, 27 (14.8%) chose amniocentesis and 30 (16%) chose no screening. Following the initiation of cffDNA testing in our practice and initiation of the AMA Options counseling in January 2013, several changes in prenatal ultrasound practice patterns were noted. As compared to the first 9 months of 2012, during the first 9 months of 2013 we noted: 1) a decrease in the overall rate of amniocentesis (19.0% vs 13.5%, $p<0.05$); and 2) a shift in NT appointment utilization away from advanced maternal age women (22.4% vs 6.5%, $p<0.05$).
3A. Attachment, if applicable (Only graphically displayed data such as charts will be accepted. Data should include baseline and improvement data)	cffDNAchart.docx (253k)
4. Describe what happened as a result of the project. Was the improvement related to the intervention? Can the project be duplicated by other organizations?	When presented with information about screening options, women often choose cffDNA. Women with low education levels and poor English language skills can assimilate this information and make decisions about their care. Genetic counseling is an essential and cost effective way to stratify women into self-directed paths of care without redundancy in risk assessment. This program is a model for cost effective care delivery of newly available high-level technology in a public health setting.

5. Describe how patients, families, and if appropriate, community was included in the work.	In order to begin bringing this testing to our population, we developed an IRB approved questionnaire as to attitudes around prenatal genetic testing in our patient population. Following administration of this questionnaire, we conducted focus groups with patients to elicit the manner in which they would like to receive information about prenatal testing options. The 2 largest non-English language groups were Spanish-speakers and Vietnamese-speakers They were specifically asked about brochures, videos, and classes. The patients overwhelming indicated that they were not interested in these modalities and wanted a health care provider who spoke their primary language to sit individually with them to educate them about testing options and answer questions. We utilized this response to develop a program for genetic counseling in conjunction with Ambulatory Administration, Maternal Fetal Medicine, and Genetics. The opartnership of these hospital groups together with patient representatives developed the program.
Last Update	2013-12-11 20:13:00
Start Time	2013-12-11 18:56:51
Finish Time	2013-12-11 20:13:00