Cuba's Salgen:
A Provincial Informatics Network for Genetic Services to Pregnant Women and Newborns

Miguel Rodríguez-Vázquez MD, Rubén Pérez, Damicel Valero, Darío G. Santiago PhD

ABSTRACT
The Sancti Spíritus Provincial Medical Genetics Network has been using the Salgen IT platform since 2009 for health care, administrative and research activities concerning pregnant mothers and newborns. The network uses the national Infomed backbone to provide real-time connection between community-based polyclinics in primary health care and the Provincial Medical Genetics Reference Center. The platform has records for 23,025 pregnant women and sequential clinical data on genetic risk assessment in early pregnancy, first trimester ultrasound, sickle cell anemia screening, alpha-fetoprotein levels, cytogenetic antenatal diagnosis, second trimester ultrasound, delivery and newborn characteristics, neonatal metabolic screening, and infant clinical assessment. The system makes health care results immediately available and provides health alerts to enable timely preventive care for pregnant women. It also provides guidelines for processes and practices, and streamlines administrative and monitoring activities through statistical reports. The database generates indicators for assessing fetal growth and applies international standards for antenatal ultrasound quality control. Salgen provides a new source of information for medical research and knowledge management, and its use in this case fulfills Cuba's criteria for an integrated health services network.

KEYWORDS Antenatal diagnosis, prenatal diagnosis, antenatal screening, genetic services, medical genetics, fetal ultrasound, quality control, health care networks, information systems, Cuba

INTRODUCTION

Cuba's National Program for Diagnosis, Management and Prevention of Birth Defects and Hereditary Diseases was mandated in 1982 and fully operational by 1985,[1] when teams were set up in provincial capitals responsible for management of all health care services for pregnant women and newborns. Since 2002, the Psychosocial, Psychopedagogical and Clinical Genetics Study of Persons with Disabilities in Cuba[2] has been instrumental in extending the scope of medical genetics through gradual development of primary health care (PHC) services, by providing genetic counselors and promoting development of provincial and national referral services for patients diagnosed in PHC facilities, as well as those at risk needing assessment or treatment at other levels. The organizational structure and service relationships between the different health care levels constitutes the National Medical Genetics Network.[3]

Sancti Spíritus Province in central Cuba has an area of 6679 km² and a 2012 population of 463,458. It has eight municipalities, with Sancti Spíritus and Trinidad the major towns. Health services are grounded in primary care—consisting of 23 community-based polyclinics and 545 neighborhood family doctor-and-nurse offices—complemented by municipal and provincial hospitals. All polyclinics offer community genetics services, and a provincial facility, the Provincial Medical

Genetics Reference Center (CPGM, the Spanish acronym), is equipped to provide clinical genetics services and antenatal diagnosis using ultrasound and cytogenetic, biochemical and molecular studies.

Since 2006, first- and second-trimester ultrasound screening services have been gradually decentralized from CPGM to municipalities, as training was completed for health professionals to update them on current national programs and the Fetal Medicine Foundation guidelines.[4] Pregnant women thus began to receive the comprehensive services of the provincial genetics program in PHC. Through the program, patients at increased risk were identified and referred to the provincial facility for assessment. Successful implementation of these changes required a high level of coordination and communication provided through an informatics network.

The need to organize and improve multicenter work as a method for assessing utility of ultrasound and laboratory findings in defining genetic risk was set forth in the OSCAR and FASTER projects.[5,6] These reports, which described the benefits of the Perinatal Information System created by the Latin American Perinatology Center, were instrumental in designing specific strategies for the Cuban context.

Although there are Cuban reports on the use of medical intranets and informatics networks in specific programs, such as Sidatrat,[7] no literature is available on use of such networks linking PHC with other levels of care and providing full community coverage.

The System for Genetic Monitoring of Pregnant Women and Neonates (Salgen, the Spanish acronym) is an IT platform with online connections for coordinating and streamlining the genetic monitoring program's services for expectant mothers and newborns. It was developed in 2006 in Sancti Spíritus, taking advantage of the Provincial Medical Genetics Network (RPGM, the Spanish acronym) and building on Infomed's IT and communications infrastructure, to apply a networked approach to clinical practice and knowledge management.[8]

INTERVENTION

Goal Computerize genetic services for expectant mothers and newborns to improve quality and organization of care and research.

Scope Salgen manages data concerning all pregnant women in the provincial health system and covers the range of genetic program services for pregnant women and newborns in PHC, at CPGM, and other referral institutions.

Organizational framework Since 1996, Sancti Spíritus Province has been using the Longitudinal Pregnancy Registry, a print form designed to enable digitalization, to record dates and results of

each medical activity in the genetics program. It has been used throughout Cuba since 2006 and was validated by the Ministry of Public Health (MINSAP, the Spanish acronym), which included it in its Polyclinic Organization Manual.[9] Women are registered after a medical diagnosis of their pregnancy, and since 99.9% of newborns are delivered in hospitals,[10] we may infer that the Longitudinal Registry includes virtually all pregnancies in the province. An individual clinical record contains all clinical data, from medical diagnosis during first visit to family doctor, through clinical genetic assessment of the infant.

Salgen software Salgen is a web-based application designed by the authors with open-source software, using hypertext pre-processor language and a PostgreSQL database manager. The application allows online input and retrieval of data concerning care provided to pregnant women and newborns at any medical facility.

To ensure data privacy, the system has tiered user categories and need-to-know access permissions. Another version of Salgen provides interconnection among all the regions of the country, but this project retains the initial provincial-level version registered with the National Copyright Center (Registration No.1537-2010) and available to any province deciding to use it for its health care services. Program outputs are sorted into 160 reports designed by an expert group to meet users' information needs. Additionally, it provides alerts to make sure that preventive actions are carried out in a timely manner, by reminding health care providers of persons who have missed appointments or procedures indicated for a specific gestational or infant age.

Information on fetal ultrasound The system provides information for assessing ultrasound data for correction of gestational age according to Sahota's formula[11] and current criteria for estimating gestational age.[12,13] Between 14 and 20 weeks of pregnancy, age is automatically corrected according to head circumference, per British Medical Ultrasound Society norms.[13] The system also indicates when fetal biometry measurements lie below the 3rd or above the 97th percentile per Witteman's tables,[12] used in developing Salgen. Additionally, a built-in quality assessment process displays gestational age-specific measurement percentiles referencing cumulative data for all pregnancies at the same gestational age, as well as the median for all records.

Salgen also has the advantage of integrating continuous quantitative assessment of fetal nuchal translucency (NT) measurements for each ultrasonographer. It uses Cuckle's quality criteria (median NT expressed in multiples of the median, or MoM; the SD of the MoM logarithm; and weekly percent increase of median NT),[14] in addition to graphics from the CUSUM test, a statistical technique for sequential data analysis that determines quickly when one measurement deviates from a standard value. It sets the acceptable and unacceptable values of the deviation, and displays the information graphically. Salomon developed this algorithm for ultrasound [15] and it is recommended for quality control of NT assessment by fetal ultrasound.[16,17] Sahota has recently reported an NT quality control model using a method similar to Salgen's.[18] Salgen has incorporated Balsyte's findings on use of CUSUM assessment in fetal biometry in the first and second trimesters,[19] as an additional option for antenatal ultrasound quality assurance.

Salgen's coding system is based on ICD-10 and operates via MINSAP's statistical information system. A U classifier for undefined fetal images was established, adapted to ICD, and is used for ultrasound assessments, as needed.

Ethics and patient privacy The project was approved by Sancti Spíritus CPGM's research ethics committee. Care was taken to ensure that system access codes were limited to accredited users who signed confidentiality oaths and had access only to information needed for their work. Non-nominal identification codes were used to ensure patient privacy.

RESULTS

Reach The system has been in place since 2009 as an online health care IT platform for the RPGM. As of June 2013, the project was used in services provided to 23,025 pregnant women, in daily use by the 23 community genetics services and CPGM, working interconnectedly in data entry, medical assessment and decision-making. Duly accredited guest users, such as heads of medical services, have password-controlled access to data through the Infomed network (averaging over 50 hits per day).

Use of Salgen in health services Salgen provides PHC genetic services and CPGM with immediate bidirectional access to results from patient assessments, which greatly facilitates the work of medical teams at each level of care. For example, under the sickle cell anemia prevention program, counseling was provided to 3371 pregnant women, using data from previous pregnancies stored by Salgen.

Personalized care has improved through the medical alert system: over the study period, only seven pregnant women missed the alpha-fetoprotein test and only three missed antenatal ultrasound. Metabolic tests were performed on all infants who were in the province at the time the test was indicated. The system identified 501 newborn babies whose data had not been entered into the system, either because they were born in other provinces and tests were not done in our province, or because they were transferred to other provinces before the fifth day of life (when the test is done). Tests were not performed for 41 infants who died in the first days of life or on those whose tests were deferred because they were too ill and who did not survive.

The alert system has become a key administrative tool and is now being used in other specialties caring for pregnant women. The system's informatics potential has enabled its extension to use in clinical and administrative processes in provincial perinatal services.

New knowledge The information generated by the system compares fetal biometry findings with growth tables and values in stored data (Figure 1). Data on the number of pregnant women under care and on quality control have been used to create proposed reference tables for use in medical practice (M. Rodríguez, unpublished data).

Quality control of antenatal ultrasound Figure 2 illustrates the use of CUSUM to assess ultrasonographer performance. This technique, along with Cuckle's indicators for NT quality control, also available in Salgen, increase the system's utility, since there is a demonstrated tendency to underestimate NT,[20,21] and because biochemical markers are not used in Cuba to assess genetic risk.

Figure 1: Salgen screenshot showing 2nd trimester ultrasound screening data confirming normal development for gestational age
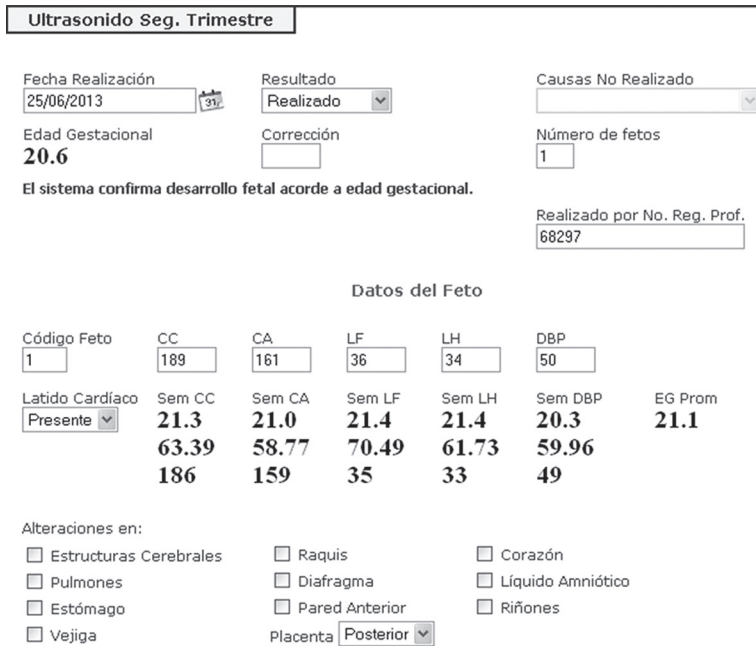
The screenshot shows procedure date, status (whether performed or not, and if not, for what reason) and ultrasonographer's professional registration number. This example is for a single fetus and confirms gestational age of 20.6 weeks. The first row of numbers in boxes shows values for fetal measurements of head circumference, abdominal circumference, humeral length, femoral length and biparietal diameter. Below that row, a box indicates that fetal heartbeat was heard. In line with that box, boldface numbers provide data generated by the software from cumulative records. The first row displays the gestational age corresponding to each measured value, per software growth tables, and mean gestational age of all fetuses with these values;[12] the second row gives the percentile of the current value relative to all stored values for that measurement; and the third row shows the median value for that measurement in all pregnancies of the same gestational age. Tick boxes at bottom are to indicate alterations observed in brain structures, lungs, stomach, bladder spine, diaphragm, anterior abdominal wall, heart, amniotic fluid and kidneys. Finally, a window menu reports placental location, in this case, posterior.

Figure 2: Using CUSUM to evaluate ultrasonographer performance in assessing nuchal translucency

GRAFICO CUSUM PARA EVALUACION DE MEDIDAS DE TRANSLUCENCIA NUCAL
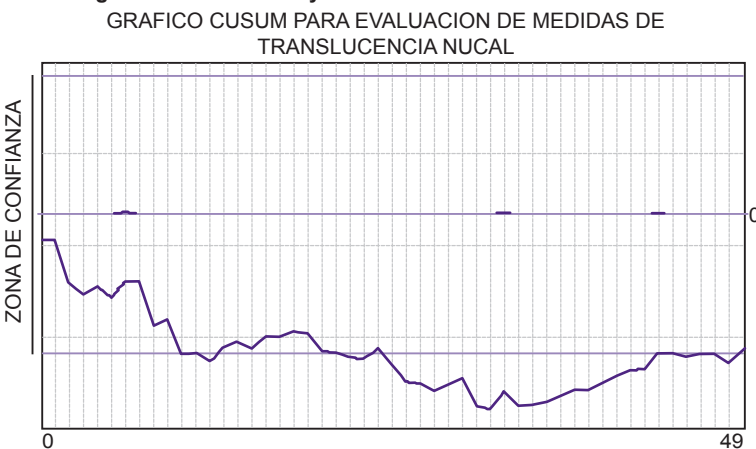
This graphic generated by Salgen shows CUSUM evaluation of nuchal translucency assessment performance by a single ultrasonographer, with data from 50 ultrasound recordings (first and latest labeled 0 and 49 on the X axis). The graphic shows a tendency to underestimation, with most of the later values falling below the lower confidence limit.

Qualitative methods for competency certification based on image analysis have been widely used.[22] Ultrasonographers in our practice undergo an initial certification process and annual recertification with in-person evaluations. A further advantage of Salgen is its capacity to integrate tools for ongoing quantitative assessment of health care activities. Ultrasonographers can access results for continuous self assessment.

Integrated health services network Salgen fulfills Cuban criteria for an integrated health service network[23] by virtue of its ability to dynamically monitor every pregnant woman from the time pregnancy is detected through infant assessment, its interconnection capabilities with other medical specialties serving pregnant women and their infants, and its usefulness in facilitating health promotion and preventive measures, even rehabilitation when needed. Salgen also allows data linkage with vital statistics, through women's and infants' unique identification numbers.

In Denmark, Ekelund reported the advantages of using unique identifiers for linking genetics monitoring services databases.[24] Salgen's capability for data linkage with vital statistics provides an option—previously impractical—for research into antenatal and neonatal conditions and their relationships with individual and population health status.

LESSONS LEARNED

The organizational and service structure of the RPGM and its technological infrastructure have supported genetic monitoring services for pregnant women and their newborns with an IT architecture designed for health service networks.

The IT platform has proven its usefulness in all the institutions included in the RPGM. It facilitates integration of health care services at different levels of medical care, allows for ongoing improvement of administrative and statistical information, introduces updated methods for assessing biometrics in antenatal ultrasound, and generates new knowledge for health care services.

The system is essential for fetal ultrasound quality control. It allows users to dynamically prescribe individual training activities, and its methods facilitate comparison of ultrasound results with international reports.

Salgen provides a novel option for researchers and health care managers by offering them the advantage of using digitalized data to generate new knowledge applicable, in particular, to genetic monitoring of pregnant women and neonates and, in general, to public health in the province.

Salgen's results and the existence of similar organizational conditions and IT infrastructure in other provinces suggest the potential usefulness of informatics networks in medical genetics services for pregnant mothers and newborns throughout Cuba. ⚕

Lessons from the Field

REFERENCES

1. Colectivo de autores. Programa para el diagnóstico y prevención de malformaciones congénitas y enfermedades hereditarias. Havana: Medical Sciences University of Havana (CU); 1986. p. 3–7. Spanish.
2. Colectivo de Autores. Por la Vida. Estudio psicosocial de las personas discapacitadas y estudio psicopedagógico y clínico genético de las personas con retraso mental en Cuba. Havana: Casa Editorial Abril, Cuba; 2003. p. 19–25. Spanish.
3. Marcheco Teruel, B. Cuba's National Medical Genetics Program. MEDICC Rev. 2009 Jan;11(1):11–3.
4. Nicolaides KH, Falcon O. La ecografía de las 11–13+6 semanas. London: Fetal Medicine Foundation (UK) [Internet]. 2004 [cited 2008 May 12]. 119 p. Available from: http://www.fetalmedicine.com/synced/fmf/FMF-spanish.pdf. Spanish.
5. Bindra R, Heath V, Liao A, Spencer K, Nicolaides KH. One-stop clinic for assessment of risk for trisomy 21 at 11–14 weeks: a prospective study of 15 030 pregnancies. Ultrasound Obstet Gynecol. 2002 Sep;20(3):219–25.
6. Malone FD, Canick JA, Ball RH, Nyberg DA, Comstock CH, Bukowski R, et al. First-Trimester or Second-Trimester Screening, or Both, for Down's Syndrome. N Engl J Med. 2005 Nov 10;353(19):2001–11.
7. Aragonés C, Campos JR, Pérez D, Martínez A, Pérez J. SIDATRAT: Informatics to Improve HIV/AIDS Care. MEDICC Rev. 2012 Oct;14;(4):5–8.
8. Delgado A, Gorry C. Cuba's National Health Strategy. MEDICC Rev. 2008 Jan;10(1):6–8.
9. Ministry of Public Health (CU). Manual de Organización del Policlínico. Havana: Ministry of Public Health (CU); 2010. Spanish.
10. National Health Statistics and Medical Records Division (CU). Anuario Estadístico de Salud 2011. Havana: Ministry of Public Health (CU); 2012. p. 19. Spanish.
11. Sahota DS, Leung TY, Leung TN, Chan OK, Lau TK. Fetal crown rump length and estimation of gestational age in an ethnic Chinese population. Ultrasound Obstet Gynecol. 2009 Feb;33(2):157–60.
12. Verburg BO, Steegers EA, De Ridder M, Snijders RJ, Smith E, Hofman A, et al. New charts for ultrasound dating of pregnancy and assessment of fetal growth: longitudinal data from a population-based cohort study. Ultrasound Obstet Gynecol. 2008 Apr;31(4):388–96.
13. Loughna P, Chitty L, Evans T, Chudleigh T. Fetal size and dating: Charts recommended for clinical obstetric practice. Ultrasound [Internet]. 2009 Aug [cited 2008 Apr 7];17(3):161–7. Available from: http://www.bmus.org/policies-guides/23-17-3-161_ultBMUS.pdf
14. Cuckle H. Monitoring quality control of nuchal translucency. Clin Lab Med. 2010 Sep;30(3):593–604.
15. Biau DJ, Porcher R, Salomon LJ. CUSUM: a tool for ongoing assessment of performance. Ultrasound Obstet Gynecol. 2008 Mar;31(3):252–5.
16. Sabrià J, Barceló-Vidal C, Arigita M, Jiménez JM, Puerto B, Borrell A. The CUSUM test applied in prospective nuchal translucency quality review. Ultrasound Obstet Gynecol. 2011;37(5):582–7.
17. Balsyte D, Schäffer L, Burkhardt T, Wisser J, Krafft A, Kurmanavicius J. Continuous independent quality control for fetal nuchal translucency measurements provided by the cumulative summation technique. Ultraschall Med. 2011 Dec;32 Suppl 2: E141–6.
18. Sahota DS, Leung WC, To WK, Chan WP, Lau TK, Leung Ty. Quality assurance of nuchal translucency for prenatal fetal Down syndrome screening. J MaternFetal Neonatal Med. 2012 Jul;25(7):1039–43.
19. Balsyte D, Schäffer L, Burkhardt T, Wisser J, Zimmermann R, Kurmanavicius J. Continuous independent quality control for fetal ultrasound biometry provided by the cumulative summation technique. Ultrasound Obstet Gynecol. 2010 Apr;35(4):449–55.
20. Evans MI, Krantz DA, Hallahan TW, Sherwin JE. Undermeasurement of nuchal translucencies: implications for screening. Obstet Gynecol. 2010 Oct;116(4):815–8.
21. D'Alton ME. Nuchal translucency quality monitoring. The transition from research to clinical care. Obstet Gynecol. 2010 Oct;116(4):806–7.
22. D'Alton ME, Cleary-Goldman J. Education and quality review for nuchal translucency ultrasound. Semin Perinatol. 2005 Dec;29(6):380–5.
23. López P, Morales I, Lara S, Martínez N, Lau S, Soler S. Las Redes Integradas de Servicios de Salud desde la realidad cubana. Rev Cubana Salud Pública. 2009;35(4):34–43. Spanish.
24. Ekelund CK, Skovbo P, Holmskov A, Farlie R, Stornes I, Petersen OB, et al. Development and establishment of a national Danish fetal medicine database for quality surveillance and research. Ultras Obstet Gynecol. 2009;34(S1):218.

THE AUTHORS

Miguel Rodríguez-Vázquez (corresponding author: geness@infomed.sld.cu), clinical geneticist, Sancti Spíritus Provincial Medical Genetics Center, Sancti Spíritus city, Cuba.

Rubén Pérez Rodríguez, informatics engineer, Empresa Desoft, Sancti Spíritus city, Cuba.

Damicel Valero La Rosa, informatics engineer, Empresa Desoft, Sancti Spíritus city, Cuba.

Darío G. Santiago Pérez, physicist, José Martí Pérez Provincial University of Sancti Spíritus, Cuba.