Codman Awards

Reducing Perinatal HIV Transmission Among HIV–Infected Pregnant Women

Rita M. Soza-Vento, Ph.D.
Lakeesha Flowers, M.S.
Alelia E. Munroe, M.P.H.
Kathy Fritz, R.N., A.C.R.N.
Ana Rua-Dobles, R.N., A.C.R.N.
Carmel Munroe, M.A.
Bill Singer, M.S.W., Psy.D., L.C.S.W., C.A.P., C.C.F.C., C.A.R.T.

"I was so scared when I found out I was pregnant because I'm HIV-positive and I didn't want to pass the virus to my baby. I thank God every day for HUG-Me. Because of the special care I received from the doctors, nurses, and nutritionist there—and because I took my medication exactly the way they told me to, my son was born without HIV. Our story is a story of hope." — HUG-Me Client

Orlando Regional Healthcare (ORH) includes the Arnold Palmer Hospital for Children and the recently opened (2006) Winnie Palmer Hospital for Women & Babies. ORH is one of Florida's most comprehensive, not-for-profit organizations. It is a community-supported hospital organization that serves the health care needs of 540,000 residents and more than 4,500 visitors annually in four counties. As the community arm of ORH, the Howard Phillips Center for Children and Families provides a wide array of social services to more than 14,000 clients a year. Help Understand and Guide Me (HUG-Me) is one of the center's seven programs.

HUG-Me has served as the primary care provider for infants, children, youth, women and families infected with or affected by human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) in central Florida since 1994. HUG-Me is the hub for meeting the tertiary medical needs of high-risk patients with HIV/AIDS residing throughout a 5,000-square mile area. The medical, psychosocial, and nutritional care provided

Article-at-a-Glance

Background: In 1995, Help Understand and Guide-Me (HUG-Me) began planning the implementation of Protocol 076, a treatment that aids in the reduction of perinatal transmission of human immunodeficiency virus (HIV). A program coordinator and a social worker worked with a 1,572 bed-hospital system to successfully implement the protocol.

Methods: Program effectiveness was tracked through monitoring of client outcomes. HIV test results of infants born to HIV-infected mothers were tracked for nine years. In addition, chart audits were conducted on all patients to ensure that testing and counseling were documented for every pregnant woman who delivered at the hospital.

Results: From 1996 to 2005, among 434 births to HIV-infected women enrolled in the clinic, only one HIV-infected infant was born. Chart audits revealed that HIV testing and counseling were not being performed and/or documented by all physicians. Therefore, in-service training was initiated for providers on a regular basis. In addition, other factors were addressed to aid patient adherence to treatment.

Discussion: The initiative's success in virtually eliminating perinatal transmission has had a major impact in reducing rates of pediatric HIV/AIDS for the community.

by HUG-Me greatly increases the likelihood that HIV-positive clients of all ages can stay healthy. Furthermore, HIV-positive women can prevent transmission of HIV to their unborn babies through the support that HUG-Me provides. In the perinatal (or vertical) transmission prevention program at HUG-Me, specialists work closely with obstetricians to provide pregnant women with the most current therapy options for preventing HIV transmission to their unborn babies. Within one year of adopting the prevention program, HUG-Me had a zero transmission rate from mother to child, a transmission level that was maintained for eight out of nine consecutive years. This article describes HUG-Me's efforts in greater detail.

Establishing the HUG-ME Program

The HUG-Me program was established in 1994 in response to the growing needs of the pediatric AIDS population in central Florida and advancing knowledge and resources for preventing further transmission. That year, the Centers for Disease Control and Prevention (CDC) estimated that 1,000 to 2,000 children were born HIV-infected per year in the United States.[1] This was specially noteworthy to this hospital, where approximately 6,500 births occurred in 1994 alone and 54 HIV-positive children infected at birth were already being treated. Previous efforts to prevent perinatal transmission focused on preventing HIV infection among women or targeting HIV-positive women to avoid pregnancy and/or refrain from breastfeeding. However, these efforts still resulted in a transmission rate consistently estimated at 25% among untreated women.[2]

In 1994, the first interim analysis of the Pediatric AIDS Clinical Trials Group (PACTG) Protocol 076, a controlled study of the use of zidovudine (ZDV, an antiretroviral therapy) to prevent perinatal transmission of HIV, found a 67.5% reduction in the risk of transmission.[3] The CDC's and Public Health Service System (PHS)'s published recommendations for the widespread implementation of Protocol 076,[4–6] combined with the high incidence of HIV in this community, inspired ORH to respond immediately by implementing the initiative to prevent transmission of the HIV virus from mother to child.

Methods

The goal of this initiative was to reduce perinatal transmission of the HIV virus from infected pregnant women to their newborn child by implementing the CDC and PHS Protocol 076 and providing HIV counseling and testing to pregnant women. This protocol recommends the antenatal oral administration of antiretroviral therapies (ARTs) at 14–34 weeks. During labor and delivery, clients receive intravenous (IV) infusion of AZT. Postnatal medication consists of oral administration of AZT to infants for six weeks after birth.

Implementing the Protocol

In 1995, HUG-Me used Ryan White CARE Act funding to hire a program coordinator/registered nurse [A.R.-D.] and a social worker and began implementing the protocol and started following its first pregnant mother in care. Formal implementation of the protocol, through written policies and procedures and requisite training and education, took place in 1996.* The initiative's time line is provided in Table 1 (page 189).

Medical and Policy Developments. Since the protocol's initial implementation in 1995, several medical and policy developments have played a role in shaping its subsequent implementation. The Health Resources Services Administration (HRSA) and the CDC have issued modifications in guidelines for drug combination therapies to lower viral load and improve testing processes. Other significant medical improvements include the introduction of protease inhibitors and combination therapies, which have allowed greater flexibility in treatment regimens and provided a stronger arsenal for suppressing viral loads. In identifying which combination of drugs to use, the program coordinator continues to gather data, participate in the Antiretroviral Pregnancy Registry, and consider such factors as optimal absorption, minimal side effects, ease of swallowing, taste, and solubility when presenting her recommendations to the medical director. Currently, nelfinavir, retrovir, and epivir are providing excellent results. In addition, Florida state law now requires health care providers serving pregnant women to counsel them about the benefits of testing and to offer a second test at 28–32 weeks.

Rapid Testing. The introduction of rapid HIV testing has affected hospital care for those admitted without prenatal care or a history of HIV testing. On admission to the

* The five-page Procedures and Policies for Management of HIV+ Pregnant Women and Procedures and Policies for Rapid HIV Testing Pregnant Women with Unknown Serostatus can be obtained by e-mail request from the authors.

Table 1. Time Line of the Help Understand and Guide Me (HUG-Me) Initiative.*

Year	Event
1994	First Ryan White CARE Act Title IV planning grant received
1995	HUG-Me program named and staffed; 54 HIV-positive children followed
	Ryan White CARE Act Title I and Title II funding received
1996	Protocol 076 implemented, registered nurse and social worker hired, first client treated
1996	State law mandated health care providers counsel and offer HIV testing to all expectant mothers
1996	Formal policies and procedures written for intrapartum and postpartum management of HIV-positive pregnant women
	Training and education of doctors and nurses at hospital and in community
1997	First positive birth recorded
1998	0% annual transmission rate reported
1999	120 HIV positive children followed in care
	0% annual transmission rate reported
2000	TOPWA program introduced to improve identification of pregnant HIV positive women and engage them into care; implemented policy and procedure for rapid testing of admitted women; 0% annual transmission rate reported
2001–2005	0% annual transmission rate reported

* HIV, human immunodeficiency virus; TOPWA, Targeted Outreach to Pregnant Women Act.

hospital for delivery, all pregnant women (whether clients of HUG-Me or not) are screened for HIV. Persons who have not previously been tested for HIV receive a rapid test on site so that prevention efforts can be enacted if necessary. Current protocols ensure a one-hour turnaround for laboratory test results.

Targeted Outreach to Pregnant Women Act (TOPWA). One of the policy changes that has aided the program was the funding of the (TOPWA) to identify at-risk women, offer pregnancy and HIV testing to women who are unaware of either their pregnancy or HIV status, and link them to care.

Clinical and Psychosocial Issues. The program staff focused treatment not only on preventing transmission to an unborn child but also on meeting the clinical and psychosocial needs of the mother, offering support, answers, information, and guidance 24 hours a day, 7 days a week. The program coordinator R.N., who wrote the policies and procedures for hospital staff, included provisions that would eliminate barriers to adherence, such as ensuring that mothers have their baby's medications in hand, with syringes marked for correct dosing, before being discharged from the hospital. This practice addresses issues of inability to pay, lack of transportation, distance from her provider, language barriers, health restrictions, and any other impediment to mothers' ability to administer preventive medication to their infant. The care to clients has also benefited from the effective and collaborative relationship between the program coordinator and hospital staff, who are all aware and capable of administering the protocol and can contact the program coordinator R.N. with any questions or concerns.

Quality Improvement. The reduction of perinatal transmission of HIV has been a stated goal of the program since its inception, and various actions have enabled the program to realize this objective. HUG-Me has an extensive continuous quality improvement process that reviews overall goals, specific objectives, and clinical benchmarks, as well as other outcome indicators, such as customer satisfaction, and process considerations as recommended by staff, administration, clients, and indicated by any of the above results. A quality improvement (QI) committee meets monthly to address issues, develop correction plans, review correction plans, and continue to monitor all aspects of program activity.

Measures

HIV Test Results. To measure presence of the HIV virus in the baby, the HIV-DNA Polymerase Chain Reaction (PCR) test is performed at birth, at 6 weeks, and at 4–6 months of age. Although the Association of Nurses in AIDS Care (ANAC) Core Curriculum for HIV/AIDS Nursing indicates that HIV can be reasonably excluded with two negative HIV PCR results (the test has a sensitivity of 90% at 3 months and nearly 100% at 6 months of age),[7] the HUG-Me program also performs a confirmatory ELISA and Western blot test at 18 months.

HIV Testing and Counseling. This program also aspired to achieve 90%–95% voluntary HIV testing in the clinic population. To that end, a second mechanism used to

measure the organization's performance was instituted. Between 1995 and 2002, the program coordinator regularly audited all obstetrics records of the hospital to ensure evidence of appropriate HIV counseling during prenatal care. For each of the 13 audits she conducted, she reviewed each chart to determine that documentation of one or more of the following were present:

- HIV results dated within the period of the pregnancy
- Documentation of HIV test counseling
- Signed consent for HIV testing during the pregnancy
- Signed refusal for HIV testing and documentation of follow-up intervention for clients that refused an HIV test
- Recommendation for HIV testing to referring physician for consult clients that did not have documented HIV results

The chart audit was conducted to identify women who may have been appropriate for program services and to determine compliance with recently enacted state laws that mandated HIV test counseling for pregnant women. The accuracy of the chart audit procedure was established through rational assessment by HUG-Me program staff of the appropriate indicators to be included and was routinely evaluated by assessing the relevancy of the items against markers such as state laws and other guidelines.

In the event of missing relevant information, the appropriate avenue for intervention is identified and pursued, depending on the source of the patient (for example, state health department, consult, clinic, private practice). The program coordinator then contacts the provider and informs them of the missing information, and the parties engage in the necessary actions to obtain the missing data.

Although the formal chart audit process has ended (because HUG-Me's goals were achieved), quality assurance and monitoring to guarantee compliance continues.

Analyses

HIV Test Results. The primary data—the results of the HIV-DNA PCR test—were analyzed by considering the number of transmissions and the number of deliveries annually and cumulatively. Because all clients are included in these figures, no statistical extrapolation was employed. The results of these tests are recorded by program staff in each client's chart and an electronic database, which facilitates quantitative data analysis. Before the use of Protocol 076, the transmission rate for women not receiving treatment was 25%. In the first years of the implementation of this protocol at other institutions, the benchmark transmission rate suggested was 8%.[8]

Client Charts and Patient Needs. The program coordinator reviewed every single client chart—more than 4,400—to determine the percentage of clients who were counseled, offered testing, declined testing, and actually tested. She also determined the sources of referrals to the program and if there were patterns between counseling compliance and referral source that may have warranted action. The staff used these results to identify the major sources of referrals to the clinic and to determine if any referral sources were systematically not providing counseling or offering a test.

Although results of the chart audit were collected for aggregate transmission rates and analyzed quarterly and annually, staff also carefully observed the wider system of care and how it addressed patient's needs. They acted quickly to follow guidelines and to anticipate and identify any potential barriers to staff implementation or patient adherence, as discussed in the following section.

Results

HIV Transmission Rate. As of the end of 2005, 434 babies of HIV-positive mothers had been born under the initiative. The first year of program data (1996–1997) included one HIV-positive birth, resulting in a transmission rate of approximately 2%. Subsequent years have registered a 0% transmission rate. Overall, the current rate of transmission at this program since inception stands at 0.23%.

Chart Audit Results. A second source of data, the obstetrics chart audits, supplied ample internal data that were used to compare the program's performance and improvements in performance over time. The chart audits indicated that HIV counseling and testing have become a routine element of the care of pregnant women in this area. The portion of clients tested for HIV more than doubled within a two-year time period. In 2002, when the extensive chart audits were discontinued, compliance rates met or exceeded expectations and were sustained at over 95% (the upper range of the original goal) for the 13 audits (Figure 1, page 191).

The program coordinator determined that the women who were not tested were consistently identified as patients referred for counseling to have HIV testing only. In 2001, when the audit revealed that the percentage of women counseled fell below the program's goal of 95%,

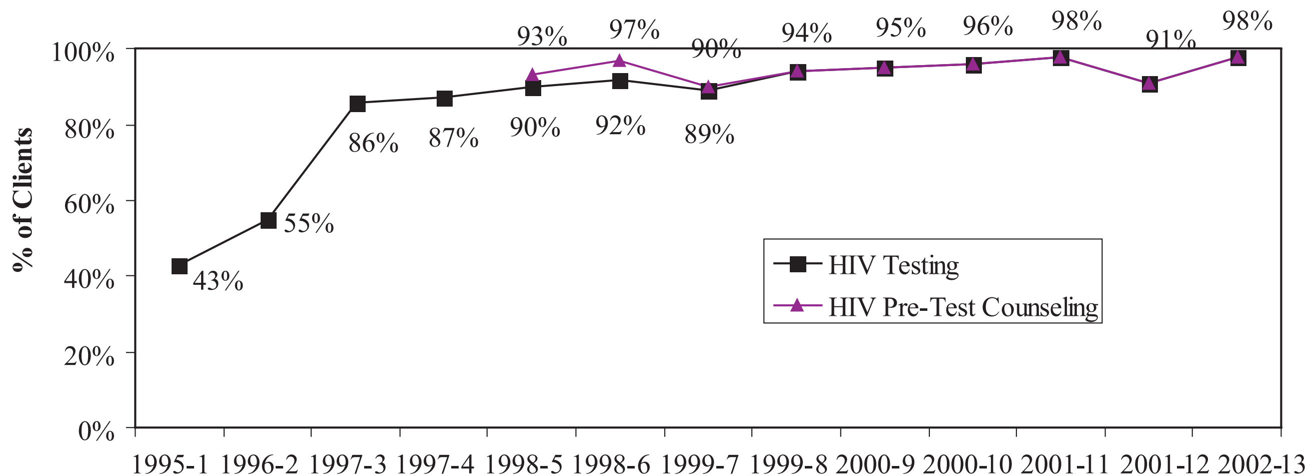

Figure 1. *When auditing began in 1995, fewer than 50% of the pregnant women were receiving human immunodeficiency virus (HIV) testing. By 2002, HIV pretest counseling and HIV testing were being performed on 98% of pregnant women.*

she realized that two new agencies that had recently begun referring women to the program were not supplying the appropriate documentation indicating that the women had received counseling. When situations such as these were identified, appropriate interventions to ensure that these women in fact received HIV counseling were pursued. The results of the chart audits were submitted to parties responsible for formulating policy in clinical obstetrics practice.

Patient Needs. Careful observation of the wider system of care as well as each patient's needs also occurred. For example, a key to successful treatment is knowledge of HIV positive status. The collaboration with the TOPWA program and the program staff's and administration's efforts have resulted in widespread testing and the availability of rapid testing not only at Winnie Palmer Hospital for Women and Babies but at the other hospitals in the community—all critical to improving not just the program's performance but the entire community's response to this issue. Now, all area hospitals require rapid testing if a pregnant woman has not yet been tested. In addition, the hospitals are required to contact HUG-Me's program coordinator in the event of a positive result.

A barrier to the patient's successful adherence to the protocol involved insurance and Medicaid enrollment. When it was determined that pharmacies were only provided with a small supply of AZT liquid to have on hand for new babies, the program's management negotiated with the Orlando Eligible Metropolitan Area (EMA) Ryan White CARE Act Title I Office to ensure that the entire 6-week supply was provided to the mother before she was discharged from the hospital.

Discussion

The aggregated results of HIV tests of newborns from HUG-Me clients, obstetrics chart audits, and testimonials from clients and staff indicate that HUG-Me's perinatal transmission prevention program has been successful in preventing perinatal transmission of HIV from a positive mother to her newborn. Compared with the CDC baseline of 25%[2] and a Protocol 076 benchmark transmission rate of 8%,[4] the cumulative transmission was reduced to 0.23% for a nine-year period, and the HUG-Me program has reached and maintained 0% transmission for eight of those nine years. The results of this initiative indicate that the mother to child transmission rate was successfully reduced.

Measurement and careful examination of service delivery coupled with building strong, collaborative relationships with service providers and clients have aided all parties in achieving the stated goals.

Audits of obstetrics charts revealed gaps in knowledge and services, such as service providers that were not aware of current legislation or policies. As a result, for example, the HUG-Me staff initiated in-service training using the Florida/Caribbean AIDS Education and Training Center (http://www.faetc.org) as a resource.

The greatest obstacle to successful implementation of this initiative and the elimination of perinatal HIV transmission continues to be identification and testing of women and their timely engagement into care. TOPWA outreach programming has helped recruit many women into care who would most likely not have otherwise received any care before delivery and may never have known their status. The continued education, training, and persistent reminders to area providers and private physicians to test all pregnant women is the other greatest tool that the program offers the community in improving overall results.

This initiative's sustainability is evidenced by the consistent results reported for the past eight years. With performance improvement processes in place to continue to monitor the care and treatment of pregnant women in this community, updating of state legislation to align with best practice in treating infected pregnant women, appropriate policies and procedures in place, and dedicated staff, there is every reason to believe that such rates can be sustained. Meanwhile, the policies and procedures developed to ensure appropriate care and treatment of HIV-positive pregnant women have been in practice now for more than nine years, indicating the institutionalization of this standard of care.

The replicability of this initiative has been frequently discussed at the local, state, national, and international levels, with HUG-Me program staff serving as trainers, committee members, and conference presenters. In addition, Florida/Caribbean AIDS Education and Training Center training materials on testing and pregnancy have been translated by staff from English to Spanish for distribution throughout the state. It is believed that through effective social marketing, a single obstetrics nurse dedicated to the initiative, a hospital's involvement and commitment, and availability of the appropriate medications, this initiative is easily replicable. J

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Rita M. Soza-Vento, Ph.D., is Lead Program Evaluator, Howard Phillips Center for Children & Families (HPC), Orlando Regional Healthcare, Orlando, Florida, and **Lakeesha Flowers, M.S.,** is Program Evaluator. **Alelia E. Munroe, M.P.H.,** is Manager, Help Understand and Guide Me (HUG-Me), HPC; **Kathy Fritz, R.N., A.C.R.N.,** is Assistant Manager; and **Ana Rua-Dobles, R.N., A.C.R.N.,** is Program Coordinator. **Carmel Munroe, M.A.,** is Director, HPC, and **Bill Singer, M.S.W., Psy.D., L.C.S.W., C.A.P., C.C.F.C., C.A.R.T.,** is Operations Manager. Please address reprint requests to Carmel Munroe, Carmel.Munroe@orhs.org.

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