

NC-based drug company developing new resources for the war on HIV

by Doug Stokke
Special to Q-Notes

RESEARCH TRIANGLE PARK—Pharmaceutical industry giant Glaxo Wellcome has unveiled plans for two new programs to assist people living with HIV.

They are testing a data collection system in a few sites around the country that should provide the best picture thus far of the health, social and economic impact HIV has on infected individuals.

The other program being evaluated is an all-encompassing 11-part course designed to empower and educate infected individuals and their care-givers in a host of HIV-related areas. Controlled studies on the effectiveness of the course are currently being conducted with a dozen medical agencies across the nation, one of them in Durham.

Just the facts

A computerized database system which will — for the first time — produce important observational information on clinical, economical, humanistic and epidemiological outcomes in patients with HIV or AIDS has been launched. Healthcare professionals at four clinical sites across the US are in the process of entering a variety of information into the database from patients with HIV or AIDS who have volunteered to participate.

The CHORUS (Collaboration in HIV Outcomes Research — US) database program will ultimately enroll approximately 8000 demographically representative patients with HIV or AIDS and is expected to become the premier disease management data source for HIV/AIDS. CHORUS will provide the most comprehensive information of any such HIV database available and will include data on such parameters as clinical outcomes of patients, economic/healthcare utilization, quality of life, epidemiology and patient satisfaction with healthcare.

Housing of data and database management will be provided independently by Research Triangle Institute (RTI) of Research Triangle Park, NC. Data review, analysis, publication

and presentation will be the responsibility of an independent database advisory board which includes national thought leaders in HIV research and treatment, as well as representatives from the HIV community. Study questions addressed to the database, whether clinical, pharmacoeconomic or otherwise, will be determined and prioritized by the database advisory board. The CHORUS database program was conceived and created by the Care Management Division at Glaxo Wellcome. The first analyses of data from CHORUS are expected to be presented at scientific meetings as early as the summer of 1998.

"CHORUS offers the first 'real-time' observational study of HIV that has the capacity and power to study the clinical and nonclinical aspects of HIV disease," said Stephen Becker, MD, co-chair of the CHORUS scientific advisory board. "Many important questions facing clinicians, patients and policy makers can be answered only through this type of longitudinal and multidimensional study. The retrospective and prospective elements of CHORUS are likely to provide a robust and generalizable data source for research of the complex and interactive elements of HIV."

Through the use of the HealthPoints ACS computerized medical record system, CHORUS collects patient data at the point of care and thus enables real-time data collection. At

the end of each day, data which have been made anonymous are captured and transmitted to a central information repository at RTI. In addition, healthcare utilization, quality of life and satisfaction with healthcare will be documented in writing and provided to RTI for data entry. Extensive quality assurance and systems validation programs have been put in place to ensure the accuracy, security and integrity of data entered into the CHORUS database.

"Due to the large demographically diverse population expected to be enrolled, and as more antiretrovirals and other drugs become available, CHORUS has the potential to answer some very important scientific questions that are not appropriately addressed by traditional clinical trials," said Kevin Frost, director of clinical research and information for the American Foundation for AIDS Research (AMFAR).

Patient participation is completely voluntary and individual confidentiality is protected. Patients must sign a consent form before any of their data are collected and they may withdraw from the database at any time. The CHORUS study has been reviewed and approved by institutional review boards.

"CHORUS is a unique collaboration between the HIV treating, research and patient communities and representatives of the pharmaceutical industry, created to provide a centralized, credible source for the most compre-

hensive HIV data available," said Gary Slatko, MD, MBA, vice president of the Care Management Division at Glaxo Wellcome. "It is the only resource that combines clinical, economic and patient-perceived outcomes on a national level with the goal of making possible new efficiencies in clinical trial and research design, and to stimulate improvements in HIV disease management."

The four sites and principal investigators who will be entering data into the CHORUS database program are Pacific Horizon Medical Group, San Francisco, CA (Stephen Becker, MD); Pacific Oaks Medical Group, Beverly Hills, CA (Anthony Scarsella, MD); Comprehensive Care Center, Nashville, TN (Stephen Raffanti, MD); and Liberty Medical, New York, NY (Douglas Dietrich, MD).

The new class

Better equipping and empowering persons living with HIV and AIDS to make informed health decisions at a time of unprecedented advances in the treatment of the disease is the principle behind an innovative new program currently being piloted in several sites throughout the country.

THE (Tools for Health and Empowerment) Course is an 11-week, interactive, educational care management program for persons living
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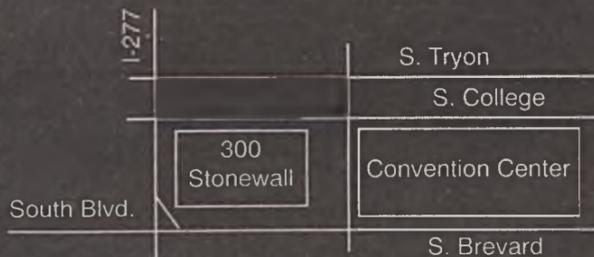
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