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TITLE: Advances in T-Lymphocyte Immunophenotyping and Absolute CD4 T-Cell Count Determinations

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BACKGROUND: Since October 1990, the CDC Model Performance Evaluation Program (MPEP) has evaluated T-cell marker percentage results on whole blood specimens, reported by participant laboratories performing flow cytometric testing. Participant laboratories also complete questionnaire surveys, which collect laboratory demographic and testing information. In April 1997, the MPEP began collecting absolute CD4 and CD8 T-cell count performance results. Participant laboratories use multi-platform methods (flow cytometer in conjunction with a hematology instrument) and/or single-platform methods (single instrument or procedure) to obtain the reported absolute CD4 and CD8 T-cell counts. The primary laboratory classifications for the 327 laboratories currently enrolled in the MPEP for T-lymphocyte immunophenotyping (TLI) are Hospital (62.10%), Independent (18.1%), Other (12.0%), Health Department (6.5%), and Blood Bank (1.3%).

METHODS: Results from Questionnaire surveys from 1991 to 1997 and specimen testing results submitted by participant laboratories from October 1990 to October 1998 were examined to determine the advances in methods of testing used by the laboratories performing TLI by flow cytometry and determinations of absolute CD4 T-cell counts.

RESULTS: Even though whole blood lysis was the generally accepted standard of practice in 1990, some laboratories, 11 (7.6%) of 249, were still using separated lymphocyte preparations. In October 1998, all of the participant laboratories used whole blood lysis for TLI. In 1992, participant laboratories generally used 1-color alone, 2-color alone, or a combination of both 1 and 2-color monoclonal reagents for their TLI testing panels. The number of reagents available to laboratories had increased to the point that by 1997, there was no standard among laboratories for types of monoclonal antibody combinations used in TLI testing panels. Some laboratories used 1-color alone, 2-color alone, 3-color alone, or 4-color alone in their testing panels. Other laboratories used combinations of monoclonal antibody reagents to create multi-color testing panels consisting of 1 and 2-color; 2 and 3-color; 2 and 4-color; 3 and 4-color; 1, 2, and 3-color; 2, 3, and 4-color; 1, 2 and 4-color; and 1, 2, 3, and 4-color. In April 1997, of the participant laboratories submitting absolute CD4 T-cell counts; 83.1% used a traditional multi-platform method, 15.3% used single-platform methods, and 1.6% used both. In October 1998, 81.4% used a multi-platform method for absolute CD4 T-cell enumeration, 17.6% used a single-platform method, and 1.1% used both methods.

CONCLUSIONS: Reliable and accurate CD4 T-cell enumeration is vital for AIDS diagnosis and for the monitoring of antiretroviral therapy in HIV-infected individuals. Since no standard method of enumerating CD4 T-cells exists, an ongoing performance evaluation program is essential to monitor trends in testing practices.

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