the DCC must work both on preparing the final Pilot Phase report and on developing systems for the Full Scale study.

Development of a Data Transmission System for a Multicenter Clinical Trial with Distributed Data Entry

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A distributed data entry system in which data are entered into intelligent data entry software on PCs at each Clinical Center (CC) allows data to be screened prior to its submission to the Data Coordinating Center (DCC). Data may be sent to the DCC by mailing floppy disks or by electronically transmitting data via modem to a DCC computer. Electronic transmission provides the most timely data transfer. However, if electronic transmission is used, communication software using an error checking protocol must be employed and the higher cost must be justified. In the Pilot (feasibility) Phase of the Modification of Diet in Renal Disease (MDRD) Study, CC staff transmitted data to the DCC daily by logging into the DCC computer and typing file transfer commands that sent data over phone lines. This involved CC personnel time, more DCC computer login time, and higher long-distance fees. Experience gained regarding the technical difficulties, the speed and accuracy benefits, and the expense of this, plus the new availability of customizable transmission packages led to development of an automatic nightly data transmission system that was simpler for CC staff and less expensive for the 3tudy.

Adherence Problems and Interventions

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The VA Epilepsy Cooperative Study includes a prospective system to categorize adherence problems and strategies. Adherence issues (six psychological, four planning, and three medical) are reviewed at interim points. Study Assistants indicate which strategy is used to enhance adherence (provide information, increase motivation, collect information from the patient, modify drug schedule, change contingencies, or refer patient for other assistance). Interim data show that at 436 of 674 visits analyzed (65%), patients had no problems. Nevertheless, strategic intervention was provided at half of these visits for behavioral reinforcement. When patients had problems, psychological (39%) and planning (46%) issues were most common; medical issues (8%) were minor. General motivation (38%) and providing information or education (29%) were used to stimulate or maintain good compliance. Adjusting dose schedule, making contingency plans and referrals for other support each were used 9%–10% of the time. These pilot data demonstrate the role of Study Assistants in adherence counseling and patient education.

Using a Simple DBMS for the Generation of Complex Research Databases

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The development and maintenance of database management systems (DBMSs) suitable for large multicenter clinical trials can be very time consuming. Although some popular microcomputer DBMSs are quick to set up, they are often inadequate for large-scale research purposes.

The use of a microcomputer DBMS for the generation and maintenance of large research databases is examined. Data entry screens on the development system are used for collecting the specifications for the large research database, and the report subsystem is used to generate the data dictionary. The development system may be used to create multiple research databases and facilitates the use of common fields and record types across databases. The addition or modification of record types or fields is simplified.

The data descriptors (type, format, missing values, variable, and the value labels) for a statistical system are included in the specifications. The dictionaries for both the main database and the statistical system can be created and maintained together. The transfer of data between systems is facilitated by using the development DBMS to generate the statistical data description for variables extracted from the main database for analysis.

Examples using SIR and UNIFY are described.