

A Model Protocol Management System

by
Margaret A. Riley,
M.N., R.N., C.N.A.A.;
and
Tera Lee Hice,
R.N., OCN®

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The Atlanta Regional Community Clinical Oncology Program (ARCCOP) has grown and matured significantly in its 15 years of operations and continues to evolve in response to changes in technology and health care. The ARCCOP was initially funded in June 1987 after a year of affiliation through the University of Mississippi. The initial tools used for data management included an index care system that kept track of accruals, protocol calendars, and due dates. However, a better system was needed within a brief period of time.

The Protocol Management System, fondly referred to as the PMS program, was developed as the central tool for organizing, tracking, and maintaining all protocol data within the ARCCOP. The PMS program has evolved from a single-user, text-based DOS application in 1987 to a multi-user Windows™-based application today.

The ARCCOP is currently an eight-hospital consortium surrounding the metro Atlanta area and includes three office practice sites for cancer prevention trials at a distance of 100 miles or more from the city. The challenge of maintaining quality data remains the highest pri-

ority, and the PMS system helps us meet that challenge.

Protocol implementation and management are straightforward processes. However, the system becomes increasingly complex as multiple patients, protocols, research bases, physicians, and affiliate institutions are added to the clinical research program.

THE BASIC PROCESS

Once a protocol is approved through the Protocol Selection Committee and Institutional Review Board, a master definition template is developed specific to each protocol. When the first patient is accrued to a specific protocol, the master definition template is entered into the PMS. From that template, a calendar of events is automatically generated. These events become part of a larger "to-do" list arranged in chronological order.

Each protocol's master definition template is written so that as it is activated, it automatically assigns the appropriate dates to all of the events due for the duration of the active and follow-up phases of the protocol. Other specific information entered into the PMS includes patient demographics, the name of the treating physician, the research base, the protocol name, the case number, and the ARCCOP institution. The master definition

templates are activated only upon the first accrual to save computer space. Following the activation of a protocol, an “Events Due” calendar reminds staff and physicians of the clinical data required. Calendars are updated every two weeks, and updates trigger the next two-week cycle of events, which are printed and distributed as a working document for the nurse and physicians.

As amendments, revisions, or other changes occur, the master definition template is changed accordingly. To protect the integrity of the master definition template and patient files, only the coordinator has the administrative user code, although user access codes are given to the research nurses.

Protocol data from affiliate sites are updated every four weeks. The nurse data managers in the ARCCOP central office enter the hard copy of the previous month’s events in PMS. When events are completed, they are taken off the “to do” list for the next calendar generated. Source documentation and data continue to be collected and documented in the patient’s medical record and on research-base forms as standard practice. The PMS summary is submitted to the patient’s medical record as well.

MANAGING, TRACKING, AND REPORTING

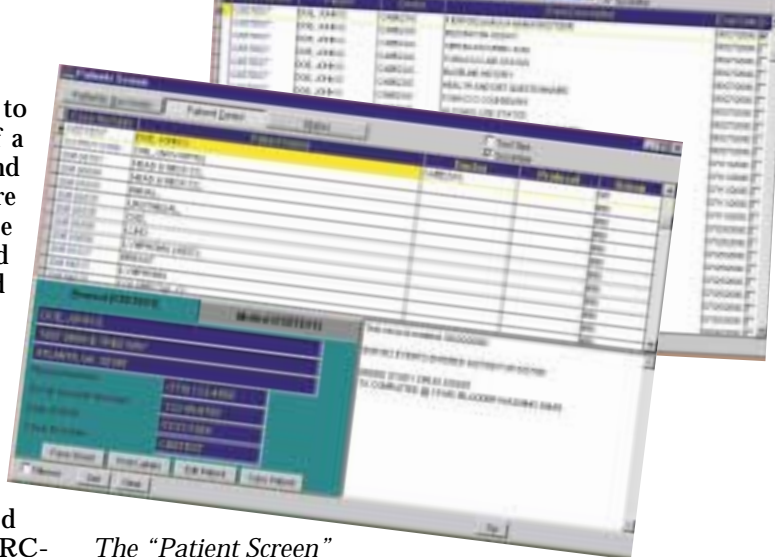
The Protocol Management System program can be subdivided into four modules: events, patients, protocols, and utilities. The four modules interact with each other to enable the program to effectively manage and track events for each patient as well as to provide the reports and tools necessary to administer the clinical trials program for the ARCCOP.

Events. The “Events Screen” is at the heart of the PMS program and contains all of the event records, by patient (case number) for a given ARCCOP hospital (i.e., SJHA Events Screen). Events can be filtered to allow a nurse to “see” only a select group of events (i.e., by patient, physician, description, disease site, completed, or due date). Filters can be saved and/or edited for future use. There are three “pages” or views to the Events Screen: the Events Summary, Events Detail, and Events Status. Both the Summary and Detail pages display the events in table format with columns for case number, patient name, physician, event description, due date, and a check box denoting whether the event has been completed or not. The main difference between the Summary and Detail pages is that the Detail page displays specific patient personal and clinical information. The Events Status Screen provides event filtering information along with other database information.

The Event Screens are the repository for the entire PMS program and can be populated by well over 100,000 events. Various reports are available in the Events Screen.

The Calendar of Events module presents the events due in a calendar format, allowing the user to filter the events for a certain day, week, month, or year.

Patients. The “Patients Screen” contains all the patients that have been added to the PMS program, which to date is more than 2,000. Like the Events Screen, the Patients



The “Patient Screen”

Screen has powerful filtering options. More than 10 different patient criteria in various combinations can be filtered, including patients’ race and disease site, which are useful for preparing grant reports. The Patients Screen also contains three “pages” or views: Patient Detail, Patient Summary, and Patient Status. Another recently added filter was the treatment arm by patient. Individual reports can be viewed and printed for each ARCCOP hospital. These reports can be prompted to print alphabetically, in protocol order, or chronologically by treatment start date.

Protocols. The protocols are the foundation for all of the events added and tracked for all patients. Therefore, the “Protocol File Maintenance” (PFM) is a unique and important module in the PMS. Accessed with supervisory rights only, the protocols must be defined and entered accurately. Any revisions and amendments to the protocol must be changed manually for each patient affected. The PFM module can contain hundreds of protocols, and a protocol definition can contain an unlimited number of events. Events can be defined as periodic (i.e., CBC/DIFF every three weeks) or non-periodic, one-time event (i.e., submitting a consent form).

Utilities. “Supervisor Utilities” allows for administrative management of the PMS program. The Utilities module includes such activities as adding or deleting affiliate groups, user file maintenance, reconstructing index files, PMS file backup, and other functions relevant to maintaining an accurate and efficient data system.

The PMS program has been a powerful tool for managing the research program. PMS has helped ensure compliance with protocols, research bases, and NCI grant requirements. ☐

Margaret A. Riley, M.N., R.N., C.N.A.A., is director of the Specialty Center for Cancer Care and Research at Saint Joseph’s Hospital of Atlanta in Atlanta, Ga., and past president of ACCC. Tera Lee Hice, R.N., OCN®, is oncology research coordinator at Saint Joseph’s Hospital of Atlanta. Special thanks to Carlos E. Emmons, B.S.E.E., an independent consultant specializing in database applications, who has been with the program since its inception.