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A Model Protocol Management System

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A Model Protocol Management System

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The Atlanta Regional Community Clinical Oncology Program (ARCCOP) has grown and matured significantly in more than a decade, and it is still evolving due to constant changes in technology and health care.

ARCCOP was initially funded in June 1987 after a year of affiliation through the University of Mississippi. For a few months, the program used an index care system to keep track of accruals, clinical plans and due dates. However, it became apparent as accruals grew that a computer-based data system was needed. The coordinator, Susan Emmons, B.S.N., R.N., suggested the development of such a program to a computer analyst. Since then, the Protocol Management System (PMS) program has become the central tool for organizing, tracking, and maintaining all protocol data within the ARCCOP.

Since 1987, the ARCCOP has grown from the grantee organization of Saint Joseph's Hospital of Atlanta (SJHA) to an eight-hospital consortium surrounding the metro Atlanta area. Also, ARCCOP has competed and succeeded in renewing the NCI grant four times. The program's current grant extends funding from June 1999

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to May 2004. The Protocol Management System has been critical to our success and has kept pace with the evolving data requirements of the program. The system has evolved from a single-user text-based DOS application in 1987 to a multi-user Windows™ based application today.

The basic process of protocol implementation and management is simple. However, it becomes complex as multiple patients, protocols, research bases, physicians, and affiliate institutions engage in the clinical research program.

BASIC PROCESS

Once a protocol is approved through the Protocol Selection Committee and Institutional Review Board, a master protocol definition template is developed from the protocol. When a patient is accrued to a protocol, the PMS program will automatically generate the events to be tracked based on that master-template definition. These events are created in the Events Screen and become part of a larger "to-do" list.

Each protocol definition is written so that as it is activated, it automatically will assign the appropriate dates to all of the events due for the duration of the active and follow-up phases for the life of the patient. The activated protocol information includes patient demographics, treating physician, research base, protocol name, case number, research base, treating physician, and affiliate institution. The individual-protocol definitions are activated in the PMS only at 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, which

triggers the next two-week cycle of events to be printed and distributed as a working document for the nurses and physicians.

As amendments, revisions or other changes occur, the individual protocol definition is changed as well. User access codes are given to the research nurses and an administrative user code is given only to the coordinator to protect the integrity of the master protocol definitions and patient files.

The PMS affiliate data is updated every two weeks. The hard copy of the previous week's PMS from each affiliate is entered by the staff of the ARCCOP central office at SJHA. A subsequent PMS calendar of events-due is printed and sent back to the appropriate affiliate nurse. 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 record as well.

PROTOCOL MANAGEMENT SYSTEM: OVERVIEW

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 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 affiliated hospital (i.e., SJHA Events Screen). Events can be filtered in order to

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Cancer Research and the Aging Population

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geriatric care by working with geriatricians, especially during the training phase in oncology. Integrating geriatrics into oncology training could help establish guidelines for teaching geriatric assessment and care as part of oncology training and postgraduate education. At the same time, promotion of research efforts could lead to better cancer management for older persons. In addition, primary care physicians must teach cancer prevention, be qualified to diagnose neoplastic disease early, and coordinate cancer management with oncologists.

MORE ASPECTS TO CONSIDER

The cost of cancer care, and medical care in general, will have a major impact on our aging society. Under the current system, Medicare will not be able to pay the bill. Medicare must pay for peer-review clinical trials and cover appropriate screening procedures for early detection of cancer. In the long run, this would be a cost saving.

We can learn a great deal by studying the aging population in other countries as well. Japan, for example, is the nation with the oldest population. In 2010, its demographics will resemble those that we will face in 2030. We have an opportunity to learn how others are handling this issue.

Cure by eradication of cancer is not the only effective goal for older patients with cancer. Control and palliation, as well as quality of life and psychosocial support at the end of life, are important to the older cancer patient. Older Americans should be able to look forward to improved health just as do younger Americans. ☐

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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 page 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.

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 well over 1,500. Like the Events Screen, the Patients Screen has a powerful filtering option. More than 10 different patient criteria in various combinations can be used for filtering. As in the Events Screen, three "pages" or views exist in the Patients Screen: Patient Detail, Patient Summary, and Patient Status pages. Various reports are available in the Patients Screen.

Protocols

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. 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 (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.

IN CONCLUSION

The PMS program has been a powerful tool for managing the research program. It has helped ensure compliance with protocol, research base and NCI requirements. We have been fortunate to have our computer systems consultant, Carlos Emmons, since the inception of the program. He has been responsive to our needs to adapt the PMS program to the ever-changing technology and data requirements. ☐