

Computerized Case History - an Effective Tool for Management of Patients and Clinical Trials

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Abstract

Monitoring diagnostic procedures, treatment protocols and clinical outcome are key issues in maintaining quality medical care and in evaluating clinical trials. For these purposes, a user-friendly computerized method for monitoring all available information about a patient is needed.

Objective: To develop a real-time computerized data collection system for verification, analysis and storage of clinical information on an individual patient.

Methods: Data was integrated on a single time axis with normalized graphics. Laboratory data was set according to standard protocols selected by the user and diagnostic images were integrated as needed. The system automatically detects variables that fall outside established limits and violations of protocols, and generates alarm signals.

Results. The system provided an effective tool for detection of medical errors, identification of discrepancies between therapeutic and diagnostic procedures, and protocol requirements.

Conclusions: The computerized case history system allows collection of medical information from multiple sources and builds an integrated presentation of clinical data for analysis of clinical trials and for patient follow-up.

Keywords:

Diagnosis; Clinical trials; Computerized case history; Standard protocols; Prevention of medical errors; Telemedicine

Introduction

Analysis of disease progression and treatment outcome in Hematology require primary data with reference to their temporary occurrence and causal connections. Therefore, there is a need for readily accessible unified instrument for management of clinical data with simultaneous access to clinical records and diagnostic material without compromising patient's privacy and safety. This instrument should be useful for real-time evaluation of clinical data based on primary evidence. Use of such an instrument will prevent bias in data

interpretation and provide immediate access to new information on an individual patient as well as record storage in a database.

Advances in modern computer technology were helpful in design of various types of electronic patient records. Several studies suggest cost-effectiveness of electronic patient records [1, 2]. These computerized systems for storage of patient data were developed for such diverse fields as pediatric [3], drug rehabilitation [4], surgery [5, 6] diabetes treatment [7], radiology [8], nursing case [9] and others. Most existing systems are designed on a hierarchical basis or similar structured formats [10, 11], utilizing object-oriented (GEHR, Synapses, HL7 RIM) or other document-oriented methodologies (HL7 PRA)[12]. Although many systems are Internet-based, some use hospital-wide computer networks which may incorporate desktop systems [13, 14].

In our effort to create a computerized case history, we implemented the following principles:

- The system should be patient-focused. This led us to a common time-axis design rather than hierarchical structure for data analysis.
- The system should permit easy communications between health providers of different specialties. Thus, it has to accommodate different documents, such as text files, pictures, laboratory results, and others.

Materials and Methods.

We have taken advantage of an existing system used for logical structuring of data known as “temperature sheets” where leading parameters and therapeutic assignments on one sheet of observation have a common time axis. This approach is common in Hematology/Oncology units and, in our hospital, it has helped to develop clinical parameters for treatment of acute radiation (biological dosimetry, in particular), as well as to improve protocols for treatment of hematological malignancies [15, 16]. We used the following steps to generate this instrument:

1. Integration of data stored in different formats (text, tables, roentgenograms, microphotographs, videos etc.);
2. Compression of clinical data by highlighting important and urgent information;
3. Display of information in an integrated fashion on the same screen;
4. Automatic matching of entered data with stored timetables derived from established protocols for diagnostic procedures and treatment.
5. Generation of warning signs (“flags”) wherever the data indicate divergence from specified protocols. Exit from the assigned limits of selected parameters is similarly controlled.

The data was plotted manually on the basis of standard case history (wherein the physician acquires medical or diagnostic information and enters it manually on a Page of Dynamic Observation (PDO)), or based on a computerized case history designed for TOMICH program (which provides a template of diagnostic criteria, current protocols and clinical management).

Manual method of entering data on PDO does not require additional devices or software besides a regular PC computer with Microsoft Office and a PDO template in an Excel format. PDO data entry form is an Excel spreadsheet, in which certain rows are reserved for specific type of information (i.e. clinical data, laboratory results, medications, etc.), and the far left column A contains row headings. The software contains a set of templates for widely used clinical protocols and a system for automatic detection of protocol violations.

PDO description

Therapy: The appropriate medication is selected from a list. Drugs on each line can be selected by cursor for each day followed by pressing a button “therapy” which enters the dose for each specific medication.

Events: Significant events and diagnostic procedures are recorded by selection from a common list or by entering a descriptive term. The user marks the significance of each event by color coding and enters information on the given event. Files representing morphological images, roentgenogram, text documents, etc. can be attached to a specific time period by the indicating of the file’s address. After filling the “event form”, a cursor tags the event to a “window” for a brief description (i.e. CT scan description on Fig. 1). A double click opens a map of all pictures and text files linked to the event. All “windows” can be augmented or reduced for proper viewing.

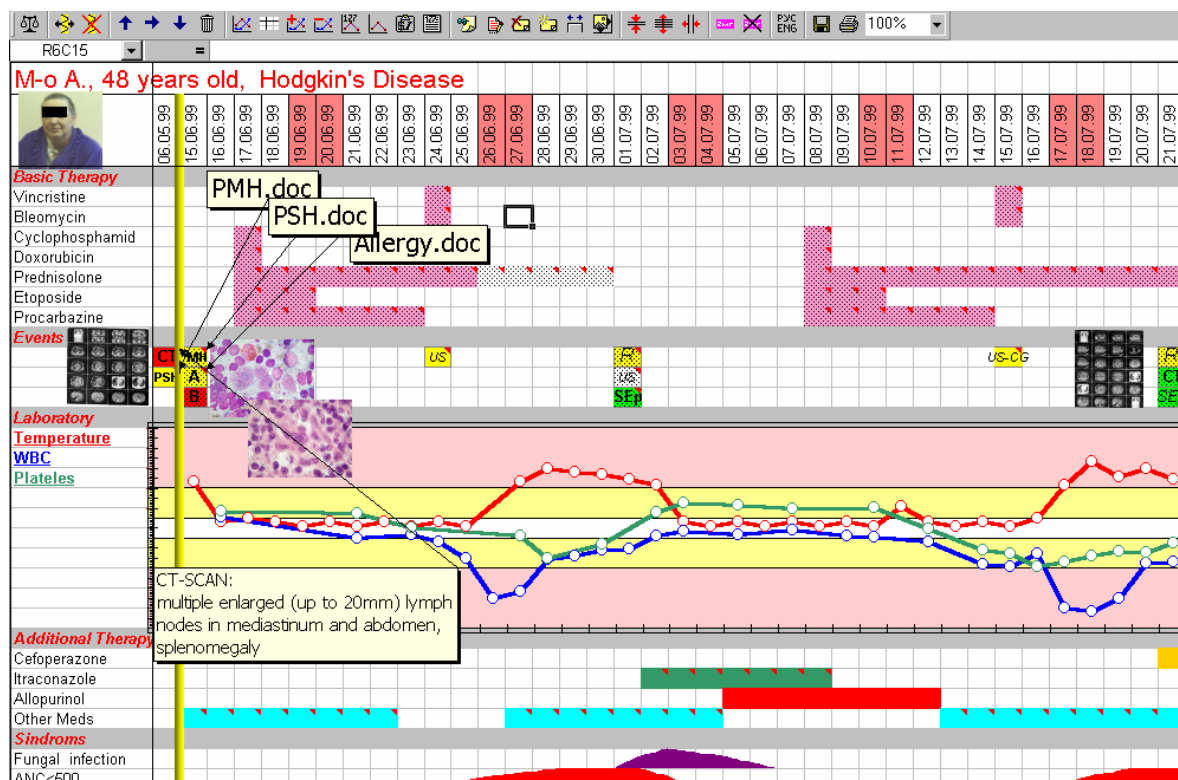


Fig.1. Example of the Page of Dynamic Observation of a patient with Hodgkin’s Disease (HD) who underwent treatment with BEACOPP chemotherapy regimen. Some information presented as marks only, some as small windows. The dynamics of chosen parameters (Temperature, WBC and Platelet counts) are normalized and color-coded as described in Methods.

Laboratory data. All test results for a particular patient for each specific time are entered in this appropriate PDO field.

Normalization. All numeric clinical data is broken into normal, sub-normal and pathological range with values stored in PDO. This provides normalization of all parameters and presentation by using common axes. Division of the measured value by the accepted average value accomplishes the normalization. The calculation is executed separately for normal, sub-normal and pathological values. To define the range of sub-normal values, a team of experts empirically established the scope of “acceptable” (for the given diagnosis and selected method of therapy and, in some cases, for an individual patient) parameters. If a parameter stays within the defined sub-normal or normal range, no special action is required. The pathological range covers all the zone of possible values beyond the sub-normal values. In case of manual input, under the date of the analysis, the

measured value should be entered. The cell on PDO is automatically converted to the color conforming its position on a scale of normal or pathologic range. If the specific value is out of the acceptance limits, the program generates an automatic alarm signal.

Transfusion: Transfusion data is entered into the PDO cell on a relevant line which includes patient's transfusion information, blood component and dosage for a particular date.

Complications: Complications are recorded on a specific line in PDO and serves to visualize the dynamics of patient's symptoms. After a symptom/syndrome is selected from a list, a window appears on the screen with a definition and criteria to assist in the diagnosis and management. Additional functions are available for further user assistance.

Presentation. The information on PDO presented in the spreadsheet can be automatically transformed in to a graph with the screen broken down into the three shaded zones: norm (white background), sub-norm (yellow) and pathological range (red). To the left of the graphics there is a list of parameters. The color of a title corresponds to color of a curve on the graphics. In each case, when the curves hinder perception of an important parameter, some data may be removed manually (Fig. 1).

Results and Discussion

TOMICH has a standard format for presenting key components of patient's medical record (the constant form of a positional relationship of the main (basic) semantic units of a case history), but also has the flexibility for adding new templates, as necessary for a specific diagnosis. These templates accumulate pre-defined lists of medications, required lab tests and syndromes, and define sub-normal and pathological range of values, as well as color palette for drugs and graphs. Also, the template may refer to the standard protocols for specific diseases or clinical trials stored in the database.

Using the steps outlined above, we developed a system of TOMICH the centerpiece of which is PDO. All information on PDO is structured and stored in sections briefly or graphically identified and interrelated in a time sequence. In addition, for every event, the user has an easy access to additional related information. All information on PDO is structured and stored in sections briefly or graphically identified and interrelated in a time sequence.

The beforehand constructed template permits standard recognized images for diagnosis and helps to discriminate general characteristics and specific features for an individual patient. For example, there are accepted criteria for decrease in platelets, leukocyte and hemoglobin in response to chemotherapeutic treatment. We found that these values express similar stability with a dose-dependent drop in leukocyte count after acute total body irradiation in doses between 50 and 600 cGr. Slower drop suggests a decreased dose; slower recovery indicates a poor bone marrow reserve, severe infection or other complications. We found that comparison of shapes of drug-dependent changes in blood counts is a valuable estimation of outcome.

In a real-time mode, TOMICH automatically performed data validation and notified a user when selected parameters were beyond acceptable ranges or when the timetable set by the protocol was not followed. These software features permit health care personnel to monitor and correct, when needed, individual actions taken by medical personnel. TOMICH links the actions of medical staff with requirements set by the protocols. Attention of physicians and staff is prompted by a color indicator and alarm signals and letter to the e-mail address of the individual in charge of the protocol management. Thus, the error is detected in real-

time and the system facilitates collective decisions for corrective action to avoid possible damage.

TOMICH has been successfully used for several years in the National Center for Hematology (NCH) in Moscow, Russia [17]. More recently, the system has been implemented in the Bryansk Diagnostic Center, Russia. The local users electronically transmit TOMICH files to NCH, where experts consult with Bryansk professionals by the means of telemedicine [18].

Conclusions

TOMICH is a convenient and easily automated method for entering all available information about a patient. It may be classified as a decision-support and expert – oriented system, which allows a physician to select a pre-entered template and to modify it for creating the most appropriate template for a particular patient. It provides easy access to primary data and allows generation of a common time-line axis format for multimedia presentation of a patient's record. The system links different medical images (pathology slides, EKG, x-rays, photos of patients, etc.) as well as text files (reports, notes, etc.) forming a recognizable image. This presentation allows real-time evaluation of disease and response to established protocols. Use of TOMICH facilitates the analysis of clinical course and compliance and reduces the probability of medical errors.

TOMICH was developed using a platform of Microsoft Windows with a standard interface and does not require re-training of users familiar with Microsoft Office. Modifications of Microsoft products, such as Word and Excel, will be instrumental for the further modifications of this program.

Acknowledgments:

This work was supported, in part, by a Grant 99-07-90314 of RFBR, Russia, Grant IBA812 of Institute for Open Society, Grant 0074821 from the NSF and by the Grant No 650 of the International Consortium for Research on the Health Effects of Radiation.

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