TREATMENT PROTOCOLS AS HIERARCHICAL STRUCTURES

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ABSTRACT

We view a treatment protocol as a hierarchical structure of therapeutic modules. The lowest level of this structure consists of individual therapeutic actions. Combinations of individual actions define higher level modules, which we call routines. Routines are designed to manage limited clinical problems, such as the routine for fluid loading to correct hypovolemia. Combinations of routines and additional actions, together with comments, questions, or precautions organized in a branching logic, in turn, define the treatment protocol for a given disorder.

Adoption of this modular approach may facilitate the formulation of treatment protocols, since the physician is not required to prepare complex flowcharts. This hierarchical approach also allows protocols to be updated and modified in a flexible manner. By use of such a standard format, individual components may be fitted together to create protocols for multiple disorders. The technique is suited for computer implementation. We believe that this hierarchical approach may facilitate standardization of patient care as well as aid in clinical teaching. A protocol for acute pancreatitis is used to illustrate this technique.

1. INTRODUCTION

During the past 20 years considerable research effort has been devoted to the development of methods to structure and systemize medical knowledge. One of the most popular examples of this work has been the problem oriented approach developed by Weed [1] for diagnosis and management. The incentive for these efforts came, in part, from the rapid development of computer technology and the recognition of potential computer applications to aid clinical practice. However, even without computer implementation structuring and systemizing medical knowledge has its own merit in that diagnostic and therapeutic possibilities, alternatives and interactions may be viewed in a more organized manner. Such structuring of information may also facilitate instruction of physicians, nurses and paramedical personnel. This potential for teaching was identified by Entwish and Entwish as early as 1963 [2].

The most common approach to structure both diagnosis and treatment has utilized algorithms. An algorithm is a network of step by step instructions organized by a branching logic which serves as a road map in the performance of a decision making process. Algorithms have been developed for a wide variety of medical tasks, including history taking [3]-[6] laboratory screening [7], and the work-up of endocrine and fluid and electrolyte disturbances [8]. Several algorithms have been proposed for emergency and critical care medicine, including the American Heart Association’s guidelines for cardiopulmonary resuscitation, the management of injured patients [9,10], and for the treatment of pulmonary complications of burns [11].

Algorithms serve three main purposes:

1. Teaching: A flow chart or outline may be easier to learn than a narrative in a textbook. As Shoemaker has observed, "The traditional educational approach, which involved the rote memorization of a list of conditions and their treatment is less palatable by some contemporary students who find the algorithmic approach easier to learn and apply [12]."

2. Delegating: Some clinical responsibilities may be delegated to para-medical professionals such as physician-assistants and nurse practitioners by use of a "rule" approach in the form of an algorithm. By following predesigned algorithms, many of the routine and repetitive tasks that are usually done by physicians may be competently performed by paraprofessionals [4-6,11,13-17].

3. Error Reduction: Algorithms may prompt the physician to attend to medical details that are often forgotten, particularly at time of intense pressure. The conditions of a busy medical practice substantially decrease the ability of a physician to function optimally because "the amount of data presented to the physician per unit time is more than he can process without error", McDonald [18]. Although the well-trained physician is likely to perform with low incidence of error, some errors cannot be prevented because "there are limits to man’s capabilities as an information processor that assure the occurrence of random errors in his activities" [18]. Indeed, experimental observations by McDonald have demonstrated that many of these errors of omission or commission can be avoided by using predesigned protocols. Many algorithms are presently used in classrooms and clinics. In the clinic algorithms for diagnosis and/or treatment are often posted on a bulletin board or filed in a reference loose-leaf among standard procedures and medical orders. Even this rather primitive use of the algorithmic
presentation of clinical protocols may improve training and the quality of care [6]. However, when protocols are implemented with the aid of a computer, the efficiency of implementation may be greatly enhance. The system developed by Bleich and his associates for management of patients with electrolyte and acid base disorders has had wide acceptance [8]. For practical purposes, computer implementation becomes almost mandatory when algorithms are complex.

The purpose of this paper is to present our concept of a modular-hierarchical technique for the formulation and representation of treatment protocols. This technique overcomes some of the limitations and disadvantages of the single block flow-chart approach presently used (see section 2) and is particularly suited for use with a computer system.

2. CURRENT PRACTICE

Formulation of treatment protocols is difficult. Current methodology incorporates the use of detailed decision networks similar to flow charts that are used in computer programming. Using current methodology the clinician must consider all possible effects of each therapeutic step before proceeding to the next step. In turn, alternatives for each secondary effect must then be considered; and these may be linked to the effects of earlier steps. The end result of this process is typically a very complex flow chart with a highly rigid structure. Furthermore, it is usually necessary to add multiple control paths that direct the user back and forth all over the chart. This classic methodology represents an attempt to capture the complexity of a protocol on a single conglomerated flow chart. The chart cannot usually be segmented into components that can stand alone. The exponential growth of the decision network and the complex interconnections between the various portions impose a severe burden for the clinician who prepares the protocol, and for the clinician who exercises the protocol in clinical practice.

In the classic flow chart approach, there is no facile way to develop treatment protocols that can cope with the simultaneous existence of multiple disorders. This is an important limitation in emergency and critical care medicine since multiple disorders are commonly encountered. Although the flow chart approach provides a treatment plan that may be appropriate for a classic textbook situation, the flow chart fails to provide the flexibility that is in fact desirable in actual clinical practice.

Another disadvantage of the flow chart approach to protocol development is the need to repetitively describe or insert elements that may appear more than once in a set of protocols. The rigid structure of a flow chart and the lack of flexibility that stems therefrom, also makes it difficult to update the protocol as medical knowledge is expanded and/or refined. Points where the algorithm fails to consider important alternatives or situations that may be cited from an actual case can easily be identified by the experienced clinician. Accordingly, some physicians view these flow chart algorithms as only crude guides, representing a scheme for the general approach to a therapeutic problem, and therefore of only limited usefulness.

3. EXPERIENCE OF OUR GROUP

Over the past three years we have been working on the development of a set of treatment protocols as a component of a computer-based system (MEDAS—Medical Emergency Decisions and Assistance System) to aid in the diagnosis and management of common life threatening conditions in emergency and critical care medicine. At the outset of the project, we sought to formulate comprehensive treatment protocols using the conventional flow-chart approach. For each disorder, the result of this effort was a large sheet of paper filled with many boxes each of which contained instructions or comments. The development of even one protocol was both a time-consuming and laborious process. Even small changes of medical intelligence or therapeutic options triggered numerous changes in sequence. Inevitably, the "final" protocol was still incomplete and to update the protocol required a substantial effort by our team of clinicians.

After working on these protocols for more than one year, we found that many portions of treatment protocols for separate disorders were essentially identical. We also found that we could often combine the component tasks of treatment into simple separate actions, or into identifiable groups of related actions that could be performed as a unit. These methods provided the basis for our present concept in which protocols are viewed as modular hierarchical structures in which each module represents a single therapeutic task. (The subtasks of a given task are represented by the modules at the successive levels of this task).

The branching logic of a treatment plan is represented by a series of control points. These may consist of a question, to answer which an alternative branch is taken. The selection of an item of medical knowledge (e.g., is arterial blood pressure less than 90 mmHg?); a precaution e.g., Note: calcium should be given with caution in the presence of digitalis); or a comment that interrelates one medical problem with another (e.g., Respiratory support, that may include supplemental oxygen, endotracheal intubation and mechanical ventilation, must receive priority attention for patients in circulatory shock).

4. THE HIERARCHICAL APPROACH

We view a treatment protocol as a hierarchical structure of therapeutic modules that are sequentially related by temporal and life-saving priorities. The low level units for defining therapy are actions. The term ACTION refers to a single act or maneuver that provides a basic monitoring or therapeutic function for patient care. For instance, "Give lidocaine 100 mg intravenously"; "Start intravenous with 5% Dextrose-water"; "Obtain blood for glucose determination"; or, "Request emergency thoracic surgery consultation".

An intermediate therapeutic unit, composed a set of actions that constitutes a more elaborate process for life support, or disorder correction, is termed a ROUTINE. Accordingly, one routine in critical care medicine is the fluid challenge. This is a technique for correction of hypovolemia by volume loading in which large volumes of fluid are given rapidly while observing the cardiac filling pressures. This routine consists of several
actions, including establishing a large bore intravenous catheter, giving aliquots of fluid, and measuring the response of the central venous or pulmonary artery pressure. Another routine is peritoneal lavage. This is used to detect intraabdominal bleeding or inflammation. This routine also incorporates several actions, such as insertion of a trochar, infusion of fluid, and recording the volume and appearance of the lavage fluid.

Several routines may join together to create a higher level routine, which, in turn, may join other routines or single actions to further create a higher level routine. Such a hierarchical structure of routines and actions constitute the skeleton of a treatment protocol that is designed to manage the problems associated with a given disorder. Figure 1 depicts a portion of the skeleton of a protocol for acute pancreatitis.

The skeleton of a treatment protocol for a given disorder contains the actions and routines that may be required for the treatment of a patient with this disorder. However, it does not include the branching logic or modifiers which guide the selection of actions and routines under certain conditions. We utilize the concepts of questions and comments to address this problem. A QUESTION refers the user to particular finding(s) whenever a given action or routine is considered, such as: "Are cardiac arrhythmias present?"; or "Is systolic blood pressure less than 90 mmHg?". The questions serve to qualify or quantify the physiological defects for a given patient to determine if the measures are appropriate for the conditions of that patient.

In addition to questions, a series of comments may appear before or in conjunction with actions and routines. A COMMENT may describe precautions or contraindications; provide a short summary of assumed patient findings prior to implementation of an action; give guidelines for administration of drugs; or provide additional information about an action or routine. For instance, for the pancreatitis protocol, the physician is cautioned, "Moderate hypoxia, atelectasis, and pleural effusions are common, but these can usually be treated with supplemental oxygen delivered by mask. If severe respiratory failure and pulmonary congestion are present, intubation and mechanical ventilation may be required," prior to the display of the recommendation that supplemental oxygen be given, or that endotracheal intubation and mechanical ventilation be initiated. Table 1 summarizes the basic concept of our approach.

### 5. FORMULATION OF PROTOCOLS

The preparation of protocols involves three tasks:

1. To identify and list the potential pathophysiological defects by priority.
2. To design the therapeutic plan for each physiological defect.
3. To formulate the complete integrated protocol.

1. In preparing a protocol for a given disease or problem a group of physicians works as a task force. They first list by priority the most serious pathophysiological defects that are likely to be associated with the disorder. For example, in the disorder Acute Pancreatitis, these defects include respiratory failure, hypovolemia, electrolyte disturbances such as hypokalemia and hypocalcemia, and coagulation defects that may lead to bleeding and further volume loss.

2. Once the list of pathophysiological defects is prepared, measures that may be used to correct these defects are identified. A technique that we have found useful is to categorize the physiological defects into successive levels of more general defects (higher level). Thus in pancreatitis, we identify nausea, vomiting, the collection of inflammatory fluid in the abdomen, coagulation defects, gastrointestinal bleeding, an increase in vascular permeability, and the loss of fluids by nasogastric suction as low level defects. These conditions or processes may be classified as components of a more general or higher-level defect, hypovolemia. Measures that will restore and maintain vascular volume are therefore addressed early in the protocol for pancreatitis. The clinicians who prepare

<table>
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<th>Table 1</th>
<th>Basic Concepts of Treatment Protocols</th>
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<tr>
<td>Mode</td>
<td>Concept</td>
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<td>Active</td>
<td>Routine</td>
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<td>Protocol</td>
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<td>Passive</td>
<td>Question</td>
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<td>Comment</td>
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the protocol may then consider separate mechanisms that lead to hypovolemia and identify the actions and routines that may correct or monitor these mechanisms.

3. Once the actions, routines, questions, and comments associated with each of the defects have been identified, the protocol is ready for an integrated formulation. The protocol begins with a comment that describes precautions, contraindications, or other useful information that may be appropriate for that action. The remainder of the protocol consists of questions and/or comments followed by actions and/or routines that match the list of potential pathophysiological defects for this disorder. The protocol concludes with summary comments (sequelae) that describe complications or the need for subsequent monitoring and/or treatment. The detailed descriptions of routines included in the protocol appear separately after the protocol. This format streamlines the display of the protocol, but still provides the physician with the option to review the details of a routine if he wishes to refresh his memory.

As development of a set of treatment protocols proceeds, a resource of actions, questions, comments, routines, and protocols is created. When one of these components, e.g., an action or routine, is defined for the first time it is assigned an identification number and added to a bank that contains the components that have already been developed. Whenever a given component(s) from this bank is subsequently required, it may be called upon and utilized. In this way a collection of modules is created that eliminates the repetitive development of modules that already exist. For instance, once we identify the precautions and contraindications that should be considered whenever a certain action (Aj) is recommended, we may use this list again whenever Aj is considered. Similarly, a routine developed for the protocol of a disorder Dg, e.g., the fluid challenge routine for pulmonary thromboembolism, may simply be called upon whenever it is required for a treatment protocol of another disorder Dg, e.g., acute pancreatitis. A portion of a protocol for acute pancreatitis is shown in Table 2.

6. COMPUTER IMPLEMENTATION

The modular-hierarchical construction of a treatment protocol conforms very well to the modern philosophy of software design that is reflected in concepts such as structured programming, top-down analysis, program design language (PDL) and metacode programs. In fact, our approach was inspired in large measure by these concepts. Specifically, we approach the programming of a set of treatment protocols in the following manner:

All actions, questions and comments, routines and treatment protocols are stored in three files:

1. Action File
2. Question and Comment File
3. Routine and Protocol File

Comments, such as precautions, that should

| Table 2 | Extracts From A Treatment Protocol
|---|---|
| **I. General COMMENTS** | Pancreatitis may stimulate any abdominal catastrophe. Elevation of serum and urine amylase is NOT specific for pancreatitis...

Overall mortality is approximately 12%, but more than 50% of patients with acute hemorrhagic pancreatitis die...

Management of acute pancreatitis includes correction of hypovolemia, nasogastric suction, and relief of pain. Exploratory laparotomy may be considered if the diagnosis is not secure or if the patient deteriorates despite medical treatment...

**II. Immediate ACTIONS**

1. Start IV 14-16 ga with 0.9% Saline or Ringer's Lactate.
2. Insert nasogastric tube-empty stomach.
3. Ensure airway/adequate ventilation.

**III. QUESTION** Is systolic blood pressure < 90 mmHg? YES: See below NO: Proceed to #IV.

**COMMENT** Shock is due to hypovolemia. Crystalloid infusion with replacement of electrolytes is indicated. With severe pancreatitis plasma volume and plasma proteins escape into the inflamed retroperitoneum and lead to hemoconcentration and/or hypoproteinemia. Replacement with albumin or plasma protein fluids and blood may be required.

**ROUTINE**

1. Begin fluid challenge* with 0.9% Ringer's Lactate (≥ 50 ml/10 min.

**XI. Concluding COMMENTS (SEQUELAE)**

**COMMENT**

1. Pseudocyst: Follow up in 4-6 weeks; if unresolved consider surgery.
2. Pancreatic abscess: Immediate surgery is required for this uncommon complication

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*aAt this stage if the clinician wishes to have more information regarding fluid challenge, central venous catheterization and/or pulmonary artery catheterization, he may refer to the appropriate routine or action in the central bank.
always be considered when a specific action is
recommended are linked to this action by pointers
that connect the action file to the question and
comment file. For instance, certain actions that
are related to calcium administration should be
avoided or undertaken with caution in patients
who are receiving digitalis. Using this link the
computer is instructed to display this comment
whenever calcium administration is recommended.
Thus, the physician's attention is called to poten-
tial complications that might override the sug-
gestion for the administration of calcium.

A data clerk uses the three files to code the
text submitted by the physicians into a format
which is later used for computer programming.
A typical code (actually a metacode) is illustrated
in Figure 2 for the acute pancreatitis protocol.
In this figure, C1 represents the overview com-
ment given at the beginning of the protocol.
This comment is not displayed unless requested.
The immediate actions to be taken (part II of the
protocol) have code numbers A12, A17, and A15
where, for instance A15 is the action. "Ensure
airway/adequate ventilation". Subsequently,
(part III) Q26 represents the question: "Is systolic
blood pressure < 90 mmHg?" The comment that
follows this question ("Shock is due to...") is coded
C62, R6 is the fluid challenge routine and A23,
C63 are the subsequent action and comment. This
code is then used by a programmer for writing
the computer program that implements the proto-
col.

The hierarchical-modular approach is partic-
ularly useful when many treatment protocols are
being developed, since the same files for actions,
routines, questions and comments may be shared
by all of the protocols. Whenever a new treat-
ment protocol is developed, the actions, routines,
questions and comments are checked for existence
in the lists contained in the central bank. If any
components are not included, they are simply
added. Also, protocols and actions may be refined
periodically by replacing, editing or modifying
an action, comment or question. For instance,
to update an action all that is needed is to give
the new or revised action the same identification
number as the one in file; then the old one is eli-
minated from the list. No other changes are required
in the computer programs which drive the proto-
cols.

The software that drives the protocols provides
the user with an immediate access to any compo-
nent of the central bank. A single command leads
the user to a display of the main menu from which
the user may branch to any portion of the bank.
For instance, if the user wishes further informa-
tion on a routine such as peritoneal lavage, he
can branch to the main menu from which he may
select the peritoneal lavage routine.

SUMMARY

The following practical considerations prompt-
ed the development of the hierarchical modular
approach:

1. Complexity is controlled. Each protocol
module describes a well defined circumscribed
process. This facilitates the formulation stage

Figure 2: A Typical Protocol Code

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<tr>
<td>10</td>
<td>Optional display C21</td>
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<tr>
<td>20</td>
<td>Display A42, A47, A45</td>
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<tr>
<td>30</td>
<td>If Q26 display C62, R6, A23, C63</td>
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<tr>
<td>40</td>
<td>Display A30, A31, A32...A39, C31, A40</td>
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<tr>
<td>50</td>
<td>If Q27 positive display C63</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60</td>
<td>If Q27 negative display C64</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>70</td>
<td>If Q28 positive display C65, A41, A42, A43, A44</td>
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of the protocol and may enhance the quality of the
protocol by sharing the load between several ex-
erts.

2. Ease of update. To modify a routine, action
or comment only the portion to be modified is
affected. Accordingly, if a routine is modified,
all of the treatment protocols that include this
routine are automatically updated. Henceforth
only the modified or edited routine will appear
in the system. This advantage is particularly
useful when a large number of treatment protocols
with common components are contained within the
system.

3. Treatment protocols that include multiple
disorders may be created. Since all treatment
protocols in the system retrieve their components
from the same files, it would be possible to create
combinations of protocols if multiple disorders
are presented to the system. In this manner
duplicate actions could be avoided and actions
could be organized by the priority of life-saving
care. Also, actions that contradict one another
could be easily identified. However, a series of
priority linked ranking lists would be required,
so that the system would display a reasonable
sequence of actions.

4. Physicians are not required to evolve
complex flow charts. The physicians who prepare
the protocols express their ideas in a natural
language which best communicates the essence of
the treatment process. It is the data clerk's task
to translate the protocol to a language which can
be understood by a programmer.

To conclude let us note that we are not
against flow chart representation. We do object,
however, to physician preparation of conglomer-
ate non-modular flow charts. We believe that
flow charts may provide a very effective pictorial
presentation of a decision process. However, the
clarity of presentation is dependent on the com-
plexity of the flow chart itself. To be useful, a
flow chart must be compact and simple. A hier-
archical-modular formulation of a protocol pro-
vides a manageable description. It may also
suggest a high level flow chart that corresponds
to the top level of the protocol.

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**Fig. 1**

**ACUTE PANCREATITIS**

T1

R3

Fluid Challenge

R6

Peritoneal Lavage

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Insert CVP Cath

Measure CVP

Give 50 ml NS/10 min.

...... Insert NG tube Start IV ...... Insert Foley Cath

Insert PD can-asp

Infuse 1000 ml Fluid

Collect Fluid

Measure Amylase WBC

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