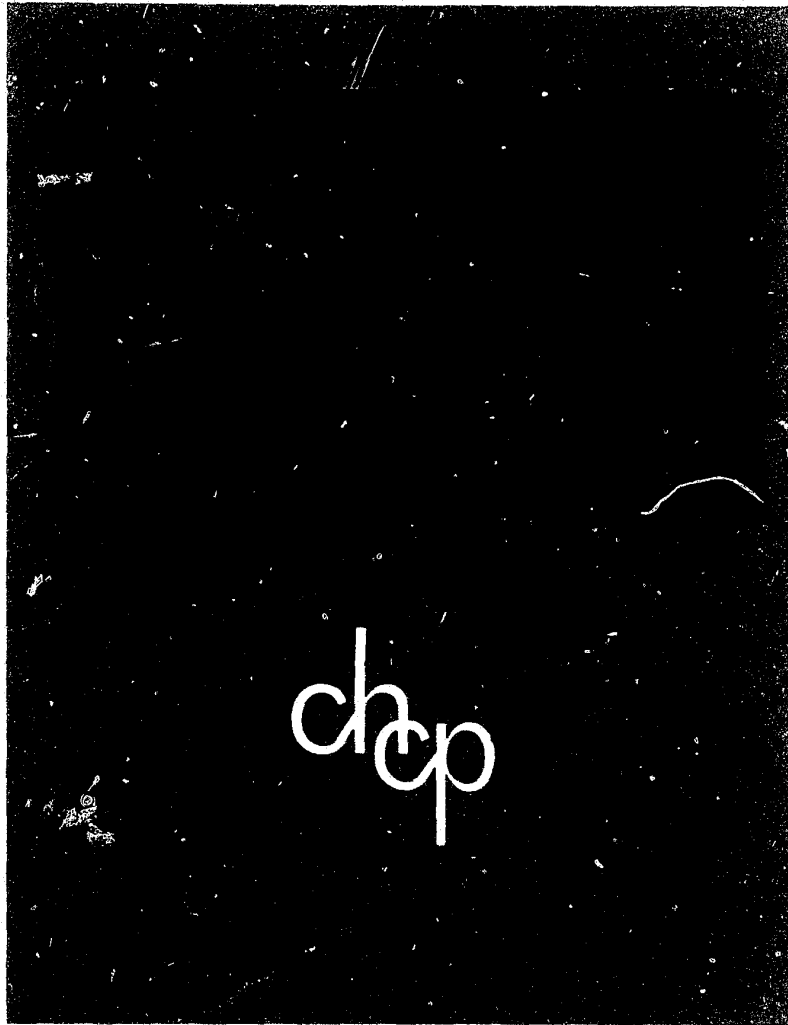


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CORRECTIONAL HEALTH CARE PROGRAM

Correctional Health Care Program

ESTABLISHING PROTOCOL-DIRECTED
HEALTH CARE

NCJRS

JUN 25 1980

ACQUISITIONS

MICHIGAN DEPARTMENT OF CORRECTIONS
OFFICE OF HEALTH CARE

LAW ENFORCEMENT ASSISTANCE ADMINISTRATION
UNITED STATES DEPARTMENT OF JUSTICE

ESTABLISHING PROTOCOL-DIRECTED
HEALTH CARE

Prepared by:

Carol Charney, R.N.
Charles L. Maynard, M.A.

Department of Community Health Science
Colleges of Human Medicine and Osteopathic Medicine
Michigan State University

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Michigan Department of Corrections
Office of Health Care
3222 South Logan - Logan Center
Lansing, Michigan 48913

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Sample Policy Manual for Correctional Health Care

A C K N O W L E D G E M E N T S

We wish to extend warmest appreciation to several person who have contributed much to making the Manual possible: to Lt. Col. Barry W. Wolcott, M.D., Department of Medicine, Brooke Army Medical Center, Fort Sam Houston, Texas for the invaluable information he shared about his research experiences with mid-level care providers and clinical protocols; and to Richard Huff, D.O., Medical Director, Muskegon Correctional Facility, Muskegon, Michigan for sharing the successes and failures of implementing clinical protocols in a correctional setting. Special thanks is also owed to the project secretary, Barbara McWilliams, for her patience and professional assistance in organizing, typing, and editing this Manual. Without the expertise and generous sharing of time and information from these persons, this Manual would not have been possible.

C H C P P R O J E C T S T A F F

Michigan Department of Corrections
Office of Health Care

Michigan State University
Colleges of Human and Osteopathic Medicine
Department of Community Health Science

University of Michigan
School of Public Health
Department of Medical Care Organization

American Medical Association
Division of Medical Practice
Program to Improve Health Care in Correctional Institutions

University Research Corporation

F O R E W O R D

The issues of adequacy, accessibility, and quality of health care service delivery in correctional institutions are increasingly receiving well-merited attention. Long plagued by neglect and paucity of resources, most correctional agencies throughout the country have recognized the need for clear direction in addressing these issues. The unique characteristics of prison populations and facilities pose a problem in applying directly the standards and policies which prevail in community health care settings. Once the basic ingredients common to good health care practice have been identified, the challenge remains of their adaptation without essential compromise to the correctional environment. Implementation of a system which meets statutory and professional standards is the responsibility of correctional health care administrators in the 1980's.

Through a grant from the Law Enforcement Assistance Administration, the Michigan Department of Corrections has provided technical assistance to ten states with a view to improving their health care system for residents of correctional institutions. This manual is one of a series published under auspices of the grant. Together, the manuals will support and extend the training sessions and technical assistance efforts of the past two years. Their purpose is to define concisely the major elements which must constitute a comprehensive health care program for a correctional agency.

There is no substitute for proper planning, adequate resources, and good management. These manuals can assist in the planning effort to identify the kind of resources which will comprise an adequate program. In addition, they address the alternatives which must be considered, the integration of various components, and establish a foundation for the decisions which must be made by each agency.

The manuals have been compiled by persons who are experts in their professional field and by persons active in the delivery of health services to correctional residents. There are too many divergencies among correc-

tional agencies to permit a single approach to be universally applicable. For this reason, the manuals are intentionally broad in scope and will require careful analysis and specification by each user.

A health care system does not stand alone and isolated from its environment. It can succeed only through a cooperative and carefully planned effort which involves health care personnel, staff of the correctional system, community health resources, and residents as interested consumers of the services. Where multiple institutions exist within a state correctional agency, appropriate central direction and coordination are essential for coherent and consistent form and quality of the services provided. It is at this level, in particular, that the overall planning, resource development, and management of policy should occur.

These manuals are written in a simple "how-to" format and are intended to be self-explanatory. Local regulatory agencies and other community and professional health resources can be helpful in their interpretation and application.

The goal which has prompted development and issuance of this manual and of others in the series has been attainment of professional quality health care for residents of correctional institutions comparable to that available in the community. The sponsors will consider their efforts well rewarded if, as a result, changes are implemented which improve access and cost-efficient delivery of needed health services.

Jay K. Harness, M.D.
Director
Correctional Health Care Program

P R E F A C E

This resource manual represents one of a series of manuals resulting from the planning and implementation of an intensive workshop and technical assistance program conducted at Michigan State University. These and other educational and professional development materials have been produced to assist correctional health care providers in developing and implementing more effective programs for the populations they serve. The manual has been designed as a practical guide for program development based on current state of the art, advice from prominent experts in the field, and information drawn from direct experience with health care providers in the Correctional Health Care Program Project. As such, the concepts, methods, and practices presented will contribute to the need for advanced knowledge in this highly specialized area of health care delivery.

Through the Department of Community Health Science, the Colleges of Human Medicine and Osteopathic Medicine at Michigan State University have been privileged to work with the Michigan Department of Corrections' Office of Health Care and the Law Enforcement Assistance Administration as part of the Correctional Health Care Program. Participation in this challenging and worthwhile endeavor has allowed us to further our commitment to improved health care services and to extend knowledge and experience in this recognized area of need.

Joseph Papsidero, M.P.H., Ph.D.
Director
Correctional Health Care Project
Michigan State University

Thomas Gunnings, Ph.D.
Director
Correctional Health Care Project
Michigan State University

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CHAPTER 1

INTRODUCTION

The problems associated with the delivery of adequate health care in correctional institutions has justifiably given rise to increasing concern for the improvement of services in what has been called "the last frontier of modern medicine." The United States General Accounting Office recently reported that, "health care delivery systems of most prisons and jails are inadequate and many correctional agencies are under increasing pressure particularly from courts to provide more adequate levels of care."

In every sector rising costs, budgetary constraints, recruitment of qualified personnel, and other difficulties cause grave concern to those responsible for providing care and to the recipients of that care. In nearly every major prison riot in recent years, inmates have included health care issues in their grievances, thus demonstrating their concern for availability and quality of care. Without question, prison health care personnel face problems different from and in addition to those experienced on the outside. Methods must be sought, and efforts made, to facilitate the dissemination of current medical knowledge to correctional health care personnel and to assist in applying such information to the establishment of effective and efficient health care programs within the prisons.

The design and development of effective health care programs, or the initiation of significant programmatic changes with regard to existing procedures, requires several important ingredients. Sound and workable ideas, the support and commitment of key staff members, and the employment of systematic methods for establishing and managing the proposed endeavor, are each significant factors which must be considered. This program development manual is designed to serve as a general guide for program development in the correctional setting. As such, it proposes specific program recommendations and decision-making guidelines to aid those responsible for carrying out the various program development functions.

While references are made throughout the manual to hypothetical "program planners" and formalized "planning committees", this work is, in fact, intended to accommodate a wide range of program needs and circumstances. It is recognized that the purposes and scope of particular programs will differ and these differences will influence the process of its development. Thus, the information presented here should be considered in light of the unique qualities, constraints, and interests of the individual setting in question.

The development of successful programs is seldom a simple and easy task. This manual has been written on a practical level, based on actual experiences in the field of corrections. It is meant to aid in determining both a viable course of action and appropriate methods for achieving the anticipated program goals.

It should be emphasized that the primary aim of this manual is to assist program planners and managers in the promotion of systematic program strategies. In this regard, Chapter 2 describes in detail the overall features of the program, while subsequent chapters are devoted to key aspects of the development process: planning, development, implementation, and evaluation. Guidelines within each of the chapters devoted to the program development process (Chapters 3, 4, 5, and 6) are objective-based and task-specific with concrete examples and worksheets.

Following the initial description and rationale for establishing a clinical protocol program outlined in Chapter 2, Chapter 3 defines practical considerations and actions to be taken during the planning phase of the program development process. This includes the immediate steps of clarifying the problem, appraising alternative solutions, setting programmatic goals and objectives, and establishing program management procedures.

Chapter 4 is concerned with the program development phase. Activities related to the preparation of a "plan of action", and decisions as to program methods and materials are reviewed.

Guidelines for implementing the program are delineated in Chapter 5. In general, this involves establishing systematic procedures for managing and monitoring the progress of the project and the use of evaluative information in arriving at particular management decisions.

The final chapter, Chapter 6, presents an overview of the program evaluation process. Basic guidelines are provided with respect to drafting an appropriate evaluation plan, designing evaluation instruments, and utilizing evaluation findings. The appendices display supplementary materials keyed to sections of the manual and list available resources.

It is hoped that the program development process described in this manual will begin to provide some of the answers to questions that arise during the establishment of a clinical protocol program in your particular setting. An attempt has been made to present, in a straight-forward and logical manner, basic principles and procedures to meet the needs of planning groups with a variety of expertise, experience, and resources. This manual is organized to help define the action you want to take, convey that message to those participating in the process, and subsequently to carry out the successful accomplishment of the proposed program.

CHAPTER 2

PROTOCOL-DIRECTED HEALTH CARE IN CORRECTIONS

Objective: To define clinical protocols and to provide a rationale for establishing protocol-directed health care in the prison setting.

A. What is a Protocol? The terms protocol and algorithm are often confused and sometimes used interchangeably. Before considering the use of protocols in the correctional setting, it is important to clarify these concepts:

A clinical protocol is a set of specifically defined and delineated steps to be taken for the management of a health condition. Further, a clinical protocol is a data collection and decision-making tool to be used by non-physician care providers in the process of providing medical care.

The word algorithm, as used in relation to health care, is simply a very refined clinical protocol. Algorithms are refined to the point that data items are obtainable by answering "yes" or "no" to a series of questions. They are also generally designed so that data can be processed by computer. Throughout this Manual, the more generic term "protocol" will be used.

If the use of clinical protocols in health care delivery is a new concept to the reader, it is strongly suggested that some time be spent in background reading. While this Manual provides some discussion of the rationale for development and use of protocols, reviewing other resources will give a broader understanding of the concepts discussed. Reviewing how protocols have been used in other health care settings, as well as the difficulties encountered and the benefits derived, will enhance the reader's ability to make informed decisions later. A list of suggested readings can be found in the Reference section of this Manual.

Clinical protocols are designed to reflect the specific needs and purposes of the particular setting in which they are employed. Consequently, the content and format will likely vary significantly.

Clinical protocols are generally condition-specific. That is, any particular protocol can be expected to be useful in managing only one health condition such as the Headache protocol in Figure 1. Most are not so specific as to manage only one diagnostic entity (e.g. migraine headaches). A protocol that is too specific will be useful in managing only a very small percentage of complaints. For use in delivery of primary care, protocols have been developed for the triage (U.S. Army Health Services Command, 1978) and treatment (Komaroff and Winickoff, 1977) of a majority of common conditions including minor and chronic illness, health maintenance, and emergencies.

In some settings, protocols are used by non-physicians primarily as tools for collection of data prior to the patient being seen by a physician. The Dysmenorrhea protocol in Figure 2 is an example of this type of protocol.

Flow sheets are another type of data collection protocol. Familiar to most health care providers, flow sheets are invaluable in the long-term management of chronic diseases such as hypertension and diabetes. Their utility stems from the amount of data displayed on a single sheet. Deviations from previous patterns and current therapy can be seen immediately. Any data items that are omitted are also readily apparent. Figure 3 is a flow sheet for the management of hypertension.

In settings where non-physicians are responsible for making decisions about diagnoses and treatment, protocols have played an important role. Physicians are generally the only persons recognized as legally sanctioned to make medical diagnoses. Protocols such as the URI protocol in Figure 4, represent the mechanisms whereby persons designated by a physician may invoke physician-generated rules for making medical decisions. If those rules are followed precisely (and this fact can be demonstrated), then non-physicians are enabled to provide medical care that is accountable and acceptable.

HEADACHE PROTOCOL[©] (11/75)

Chief complaint(s) and headache location:

ID #:

Date:

Name:

Birthdate:

Phone:

Protocol User:

PRELIMINARY OBSERVATIONS

yes no

STAT	<input type="checkbox"/>
STAT	<input type="checkbox"/>
STAT	<input type="checkbox"/>
STAT	<input type="checkbox"/>
STAT	<input type="checkbox"/>

- Pt disoriented
- Appears very sleepy
- Appears to be in great pain
- Has trouble talking
- Has trouble walking

HISTORY

STOP	<input type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

- Head injury in last 48 hours
- Headache at this moment
- Worst headache pt ever had
- Became severe in first 5 min.
- Followed by:
 - Numbness of hand/arm/leg
 - Weakness of hand/arm/leg
 - Difficulty speaking
 - Difficulty walking
 - Vomiting
 - Fainting

<input type="checkbox"/>	<input checked="" type="checkbox"/>
--------------------------	-------------------------------------

- Hit hard in head, in last year
- Headaches began/worse after blow

<input checked="" type="checkbox"/>	<input type="checkbox"/>
-------------------------------------	--------------------------

- Similar headaches in past
- Age >50

<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>
STOP	<input type="checkbox"/>

- Definite Dx. in past 2 years
- On protocol-acceptable regimen
- Acceptable relief
- Seeks refill *Refill*

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

- Sx occurring near onset:
 - Flashes/spots before eyes
Dx vascular headache
 - One eye gets red/tearful
 - Weakness of hand/arm/leg
 - Difficulty speaking

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

- Pain deep behind only one eye
- Throbbing/pounding pain
- Often when resting after hard work
- Usually nausea or diarrhea with HA
- Usually begins on one side

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------

- Hx of MD-diagnosed "migraine"

<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input type="checkbox"/>

- Pain over frontal/maxillary sinuses
- Chronic nasal/postnasal drip
- Awakens congested

PHYSICAL EXAMINATION

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

- Temperature >100.0 _____
- BP >200 systolic or >105 diastolic _____

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

- One eyelid drooping
- Cloudy cornea(s)
- Red/tearful conjunctiva
- Asymmetric pupils

<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

- Headache at this moment
- Acutely tender sinus(es)
Dx acute sinusitis
- Redness/edema over sinuses
Dx acute sinusitis
- Purulent discharge *Dx acute sinusitis*

<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

- Stiff neck
- Arm drift

IMPRESSION

STOP	<input type="checkbox"/>
STOP	<input type="checkbox"/>

- Any reds *Consult MD*
- Will consult MD for other reasons

<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

- Dx of acute sinusitis *Rx*
- Any greys: *Dx chronic sinusitis, Rx*
- >1 blue *Dx vascular headache*

<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/>	<input checked="" type="checkbox"/>
STOP	<input type="checkbox"/>

- Dx vascular HA *Rx*
- Dx muscular HA, Rx*
- Taking birth control pills
- HAs worse since starting pills
Consult MD

PLAN (Rx regimen on back)

STOP	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

- Allergy/contraindication to Rx
Consult MD
- ASA _____
- Ergotamine _____
- Diazepam _____
- Hot packs/massage _____
- Psychiatric evaluation _____

Figure 2

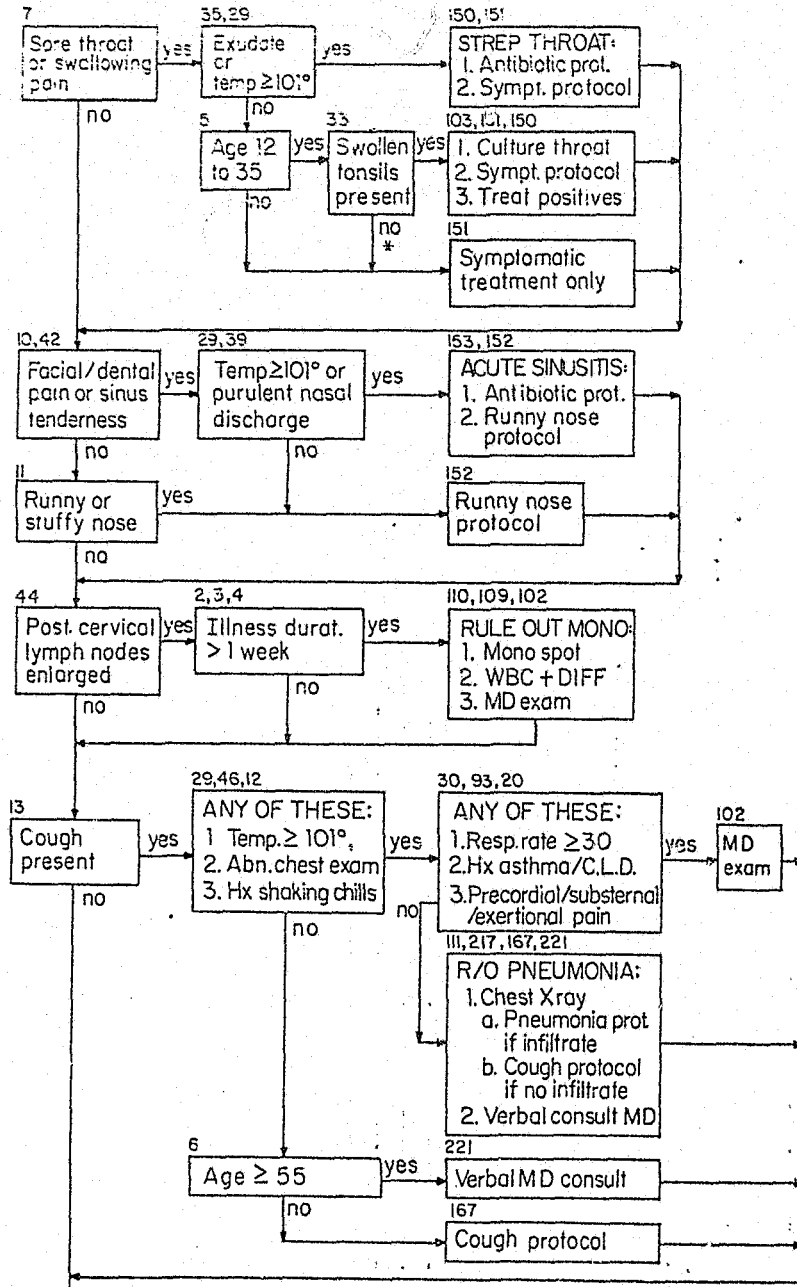
DYSMENORRHEA PROTOCOL

- A. SUBJECTIVE: Chief Complaint _____
1. Age _____ Occupation _____ Cultural Background _____
 2. Gynecological History
 - a. Menarche began at age _____.
 - b. Date of last menstrual period _____.
 - c. Cycle: _____ days; Duration: _____ days; Flow: _____ pads or tampons used in a day.
 - d. Last Pelvic Exam _____; Pap Smear _____; GYN Surgery _____
 - e. Onset of menstrual discomfort began at (check one):
 1. 1-2 years after onset of menarche _____ (primary dysmenorrhea)
 2. 5+ years after onset of menarche _____ (secondary dysmenorrhea)
 - f. Symptoms: (circle the ones present)
lower abdominal pressure, backache, premenstrual headaches, breast tenderness, feeling of bloating, mood change, weight gain prior to period (____ lbs.), nausea, vomiting, diarrhea, other: _____.
 - g. Menstrual Symptoms: (check one)
 1. relieved by menstruation (within 24-48 hrs. after the onset of a period) _____ (primary)
 2. lasts throughout total length of period _____ (secondary)
 - h. Onset of symptoms:
symptom: _____ days before period _____
symptom: _____ 12-24 hrs. before period _____
symptom: _____ with onset of period _____
 - i. On a scale from 1-10, how severe is your discomfort? _____
(1 = mild cramping; 10 = total incapacitation)
 3. Other Problems: anemia, constipation, fatigue, thrombophlebitis, other: _____
 4. Sexual History
 - a. Sexually active? No ___ Yes ___
Are you satisfied? ___ dissatisfied? ___
 - b. Gravida _____; Para _____; Abortions _____
 - c. Contraceptive method used: _____
 - c. Hx of venereal disease: No ___ Yes ___
 5. Explanation of body functions during menstrual cycle: No ___ Yes ___
 6. Family Hx _____
 7. Social Hx "stress" factors: home, school, work, etc. _____
 8. Allergies to medication, food, etc. _____
 9. Previous modes of therapy used _____ effectiveness _____
 10. What does patient do to relieve the discomfort? _____

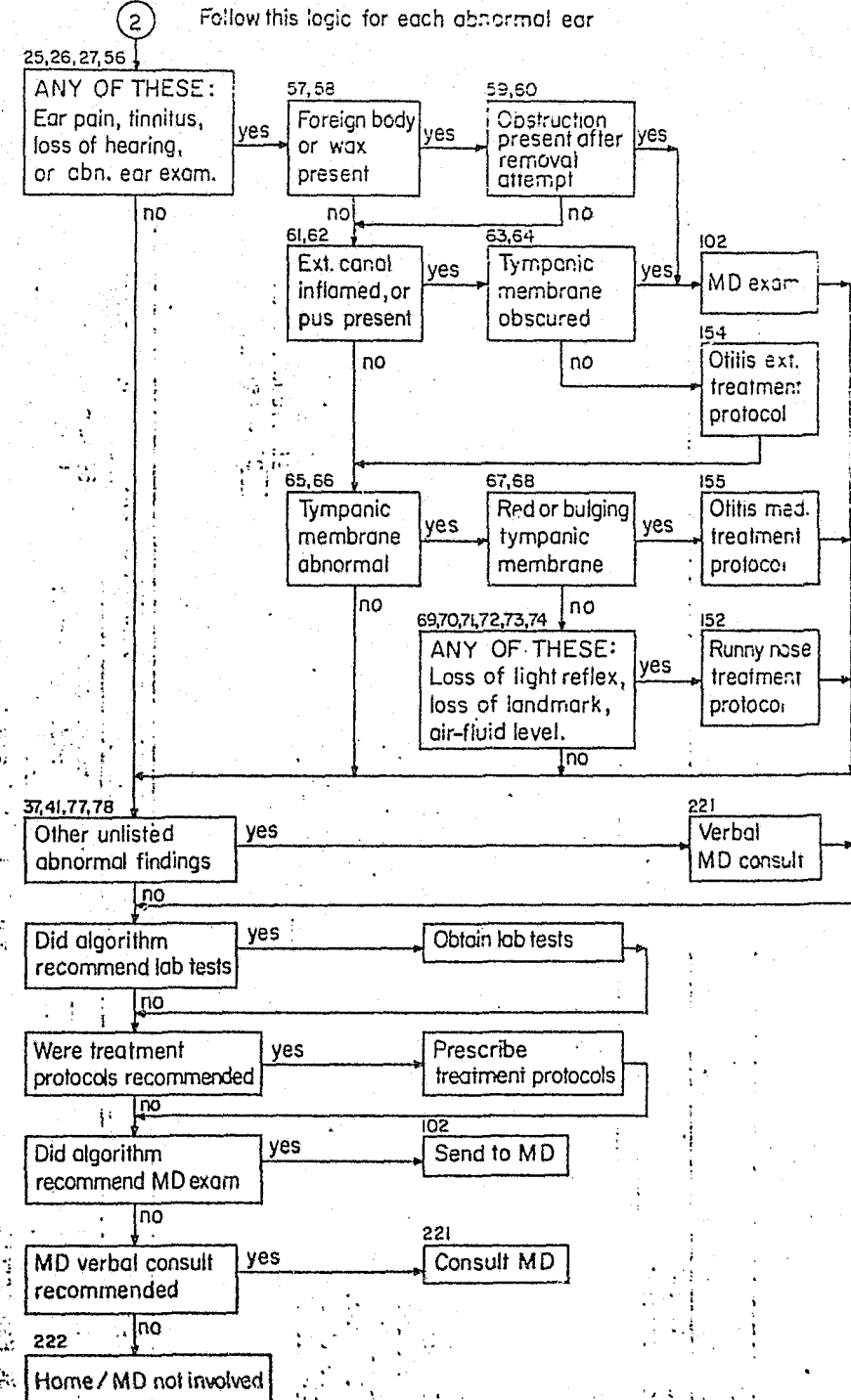
- B. OBJECTIVE: Physical Exam
- Temperature _____ Pulse _____ Weight _____ Height _____
- General Appearance _____
- Secondary Sex Characteristics _____
- Hair Growth and Distribution _____
- Posture _____
- Breast Exam: Tender _____ Lumps _____
- Nodes (specify) _____
- Abdominal Exam: Tenderness _____ Mass _____

Figure 4

URI/COUGH/EAR PROBLEMS ALGORITHM #13



URI/COUGH/EAR PROBLEMS ALGORITHM #13



2

In large, very busy health care settings, it is generally someone's responsibility to sort out, or triage, incoming complaints so that those who need care immediately do not have to wait. The triaging function also provides a systematic means of determining which patients may be seen by non-physician care providers and how soon the condition should be evaluated. An example of a protocol that was developed solely to aid in the sorting and routing of patients' complaints is seen in Figure 5. It too is primarily a decision-making tool.

As can be discerned from the example protocols, their uses fall into two general categories--those protocols used for treatment and those used for triage. More detailed information regarding these two types of clinical protocols are found in Section D of this chapter.

Figure 5

TRIAGE PROTOCOL - ABDOMINAL PAIN

Abdominal pain is pain anywhere below the ribs and above the groin in the front half of the body. The back may also hurt, but if the pain is confined to the back, triage under the back pain algorithm. At times, it may be difficult to distinguish pain in the upper abdomen from that in the lower chest. If there is any question, send the patient to the PA.

*Answer determined by observing patient.

1. Severe abdominal pain should be sent to the Dr/PA immediately, so the patient can be evaluated for serious disease and treated promptly.

Is pain severe (patient bent over clutching abdomen)? *

- 1. Yes
- 2. No

→ Dr/PA STAT

2. Abdominal pain frequently accompanies nausea/vomiting/diarrhea, and evaluation by that sequence is appropriate.

Is there nausea, vomiting or diarrhea?

- 1. Yes
- 2. No

→ Triage as Nausea/Vomiting, Diarrhea

3. Black or bloody stools may indicate serious internal hemorrhage. The patient needs immediate evaluation.

Is there black or bloody stools?

- 1. Yes
- 2. No

→ Dr/PA STAT

4. Abdominal pain associated with recent trauma could indicate a life-threatening situation such as a ruptured spleen.

Abdominal trauma within 72 hours?

- 1. Yes
- 2. No

→ Dr/PA STAT

5. Abdominal pain of more than seven days duration usually indicates a chronic problem that is best evaluated at the clinic on a routine basis.

Duration over 7 days?

- 1. Yes
- 2. No

Make appt. with Dr/PA/NP within 1 week.

Is patient uncomfortable now?

- 1. Yes
- 2. No

Dr/PA/NP within 24 hrs.

B. Why Use Protocols in
Prison Health Care
Delivery?

This question leads immediately to another question. Are there more health problems and/or requests for health services than the available physician(s) can manage? If the answer is in the negative, then there is absolutely no reason to use protocols. If this is the case, the remainder of this Manual will likely be of little value.

If the answer to the question is affirmative, however, clinical protocols are used in prison health care delivery for the same reasons that they are used in other settings. Commonly, protocols are used to:

- Provide data collection and decision-making tools for non-physician care providers.
- Set a minimum standard of care for common acute and chronic health conditions.
- Assure uniformity and consistency when health care is provided by multiple personnel with differing levels of education and experience.
- Facilitate audit of care and performance.
- Improve the thoroughness and accuracy of documentation.
- Provide a standard data base for health information systems.
- Improve control of institutional resources.
- Put the responsibility for medical decision-making only in the hands of persons licensed to practice medicine.

C. Advantages and
Limitations of
Protocol Use

Tools for Data Collection and Medical Decision-Making

No health care provider can be expected to remember to ask every history question or to complete every part of the examination that should be done for every health condition. The most well-trained and competent practitioners will omit items on occasion. In some cases, important information may be ignored due to inadequate training. In either

instance, the availability of a data collection guide precludes the human inability to remember every detail. Thus, one of the primary functions of clinical protocols is to provide a mechanism for insuring thoroughness of the data collection process.

In several settings clinical protocols have been used specifically as educational tools in the process of teaching what data needs to be collected in a given clinical situation (Charles et al., 1974; Sox et al., 1973; Sullivan, 1976; Yarnall, 1975). For use as pre-service and in-service training aids, protocols have great potential for enhancing the skills of care providers in correctional settings. It is assumed that, once learned, the protocols and the skills required to use them will be incorporated into daily practice. Thus, the thoroughness with which inmates' health complaints are explored is improved and potentially severe problems are identified and managed early.

Complete and accurate data collection is a vital component of medical care but the decision making involved in clinical diagnosis and selection of appropriate treatment is the most difficult. Medical schools exist to educate people in precisely these skills. In recent years, however, the emergence of a host of non-physician health practitioners has altered our notions of who may deliver medical care. Many functions, previously the sole responsibility of physicians, are being delegated to others. Repeatedly, nurses, physicians assistants, and other properly trained personnel have been shown to provide quality medical care, at least in terms of patient outcome and patient satisfaction (Charles et al., 1974; Grimm et al., 1975; Hastings, 1976; Komaroff et al., 1976; Vickery et al., 1975; Thompkins et al., 1977).

In most instances, research has also demonstrated that care provided by these non-physicians is less costly, or at least no more costly, than care provided by doctors. These advantages plus the difficulties in physician recruitment for correctional institutions makes utilization of non-physician care providers not only essential but also desirable (Brecher and Della Penna, 1975).

Protocols Vs. Standing Orders

In delegating certain functions to other personnel, physicians have always relied on written orders with the expectation that those orders would be carried out. Sometimes these orders become so commonplace and repetitive they take the form of standing orders. This type of management tool is highly useful when a diagnosis has already been made, when a diagnosis must be made and treatment started instantaneously (e.g. cardiac care units), or when therapy is not necessarily initiated as a result of a medical diagnosis (e.g. immunizations).

Effective and responsible non-physician management of the acute and chronic problems seen in primary care practice requires more than standing orders, however. There must be guidelines available to assist with the diagnostic process as well as the therapeutic. The portions of this medical decision-making function that are committed to writing are clinical protocols. In this sense then, protocols are like elaborate standing orders. They are physician-generated rules for how certain health conditions are to be managed. The use of clinical protocols by non-physician care providers is a matter of intelligently carrying out expanded physicians orders. In this manner, diagnostic and therapeutic decisions remain with only those individuals legally sanctioned to make them.

Protocols and Quality of Care

In the course of delegating medical responsibilities, physicians are fully aware of the responsibility they retain over the quality of care ultimately delivered. For this reason, the responsible physician and the potential protocol users should inspect the protocol (if written by someone else) and use it only if they agree with the medical judgments involved. Once agreed upon, the protocol becomes like a physician's order to be used as standing orders have been used in the past.

Published protocols such as those in Common Acute Illnesses: A Problem-Oriented Textbook With Protocols, edited by Komaroff and Winickoff, have received extensive testing with hundreds of patients and have each been revised many times. It is obvious that these represent highly refined

versions quite different from the originals. Because of this continuous refinement, it is recommended that published protocols be given first consideration when the decision is made to begin implementation of a protocol system.

These protocols are in a state of constant evolution, however, and it is the responsibility of the physician and the protocol user to make certain they are using the most current version. If they have written their own, it remains their responsibility to change the content over time to reflect the newest medical knowledge.

It has been suggested that protocol use can encourage practitioners to conform to current standards and that non-physician providers, backed by physician consultants, can deliver care of quality which is comparable to care by physicians. But how good are those standards? All health practitioners tend to practice by unwritten, internal protocols in the process of patient care. Ideally, individual decision-making is based on current, sound, scientifically derived information. However, due to the inexactness of current knowledge, many important clinical questions are left unanswered. The only recourse is to make educated guesses based upon the best available information at the time. Protocols, too, are subject to limitations reflecting not truth, but the current state of the art. Careful research of protocol logic, however, has contributed not only to validation of the logic and therefore the usefulness of the protocol, but also has added new knowledge to the art and science of patient care. Protocols are not at all infallible but should represent the most current, accurate, and complete scientific information.

Good patient care is certainly more than following protocols, however. Patient care is both an art and a science. Protocols can assist the practitioner in systematic collection of data and in sound, rational decision-making based upon scientifically produced strategies for approaching patient problems. In doing so, protocols help free the provider to engage in creative and resourceful management of the patient, the art of patient care. Good patient care requires not only good science, but it requires sensitivity, the ability to convey competence, confidence and warmth, as well as skill in explaining the problem and its

management. Utilizing protocols does not mean a mechanical, depersonalized approach to patient care as some would say. Instead, it means assistance with the rational science of patient care toward the real art of caring.

Contrary to the opinion of some, protocols are not rigid paths to be followed by unthinking, programmed providers (Ingelfinger, 1973). As Komaroff (1977) indicates, a protocol should be a floor under, not a ceiling over, the practitioner. It should serve as a support not a constraint. Although a protocol indicates the history questions to be asked with regard to a specific problem, information should be acquired according to the natural flow of conversation, not as dictated by questions on a sheet of paper. If at any point the patient demands to see a physician or the practitioner believes there is a reason to deviate from the protocol, the practitioner should not be inhibited from following a different course of action. To only follow the protocol or ignore the human aspects of care is to provide inadequate, inhumane, and negligent care (Komaroff, 1977).

Clinical Protocols and the Health Record

Appropriateness and effectiveness of medical care is generally assessed by review of the health record. Whether examined by peer review for quality assessment or in court through the process of litigation, the health record is viewed as reflecting the quality of care provided to an individual. All too frequently, information offered by the patient, examinations that were done or other data pertinent to the case are omitted. Many individuals, institutions, and whole correctional systems have suffered the consequences of poor documentation. The old adage, 'what wasn't recorded, wasn't done' rings all too true.

In correctional settings, the health record often becomes the inmate's best communication link when seen by several care providers or when transferred to another institution. If all necessary information is not available, receiving care from another practitioner or in a different setting will likely disrupt the care process. Continuity can only be assured by a complete health record available at all times.

Clinical protocols offer the potential for resolving the documentation problem. Used properly, protocols allow for a complete and legible

progress note perfectly suited to a problem-oriented record system. The resulting progress note generally contains complete subjective data, describes what was found through physical examination and lab procedures, indicates the probable diagnosis based on the presenting information, and suggests an appropriate plan. The logical, lucid flow of information plus any additional comments from the care provider allows for as complete and reliable a record as possible.

Additional Benefits

Physicians working in settings that utilize non-physician care providers and clinical protocols report a high degree of professional satisfaction. Because they are afforded a support staff that can manage common problems, physicians are allowed more freedom to manage the more difficult and perhaps, the more interesting patient problems. Likewise, for non-physician providers, increased involvement in patient management and responsibility for a major portion of patient care heightens their sense of professional satisfaction. All providers are encouraged by working in a health care setting that is effective, rational, and coordinated. These characteristics can decrease the emotional and physical toll of working in correctional institutions and improve the professional esteem sensed by care providers. Such benefits would seem to have positive implications for the recruitment of qualified personnel.

There remain, as yet, unresolved legal questions about non-physicians making diagnostic and therapeutic decisions despite the fact that protocols have been in use for many years. The medical-legal opinions to date, however, indicate that there are legal safeguards if protocols clearly spell out and defend a particular course of action. Several states have recently changed their nurse practice acts and physician assistant laws to encourage the development and use of jointly agreed upon protocols (Washington State Board of Nursing, 1974). Therefore, it appears the legal atmosphere is positive and supportive of the concept. As protocols are continually tested and refined, this support is expected to increase.

D. Treatment and
Triage Protocols

Treatment protocols function initially as data collection guides, defining specifically what information about the patient is to be obtained.

Included are the history questions, the elements of the physical exam, and those laboratory tests which need to be done in order to manage the problem. Protocols not only indicate what data needs to be collected, they also identify that data which need not be collected. Dependent upon the particular characteristics of each patient (e.g. age, sex, past medical history, severity of the problem, and associated symptoms), branching decision points or logic rules enhance individualizing the process of care for each patient. For example, the type of data to be collected would be quite different for two patients complaining of cough, one with no fever and needing only cough medicine, and the other who comes in febrile.

Another important feature of protocols is sensitivity to unusual conditions. Protocols indicate specifically those clinical findings which are worrisome or questionable enough to require referral or consultation with a physician. This characteristic renders protocols particularly useful to non-physician care providers in correctional settings who are frequently responsible for deciding under what circumstances the physician is to be called in or consulted.

Lastly, protocols offer precise rules for arriving at diagnostic impressions and for making management decisions including additional evaluation, therapy, and patient education. In contrast to this well-defined process are the standing orders available in most clinical settings. Standing orders only identify the treatment plan for a specific problem and are subject to variable interpretation by different practitioners.

One of the major difficulties faced by large correctional facilities is the management of sick call and triaging of inmates' complaints. Whether sick call is held in a central location or takes place in the institution's living units, problems and requests need to be sorted out so that those persons needing care can, in fact, receive it. A systematic means of sorting requests, especially at times of peak attendance, is mandatory

if there is any expectation of maintaining orderliness and sanity. There must also be an available means of insuring that limited physician time is not taken up with requests that are more appropriately handled by another level of care provider.

Several groups around the country have developed and tested protocols specifically to be used for the triaging of sick call. These were designed to aid in the routing of patients, dependent upon severity of the condition, to the appropriate level care provider. One example, relevant to the correctional setting is the triage protocol system by Dr. Barry Wolcott and associates that was designed to assist the management of military sick call at Fort Sam Houston, Texas (U.S. Army Health Services Command, 1978). The triage protocols were written in such a way that serious or life-threatening conditions can be quickly screened and referred to a physician. However, they also include the branching logic rules that permit individualization of the patient's disposition to several other care sources including self-care, pharmacy for over-the-counter medications, or referral to a mid-level care provider.

The military's experience has many implications for triaging of prison or jail sick call. Most noteworthy is that the protocols were designed to be used by persons with little or no formal medical or nursing training. The only skills required are being able to read, being familiar with the content and vocabulary, and being able to follow directions. Thus, they can be used by health aides or assistants or others with only brief preparation.

It is also envisioned that triage protocols can be used by correctional officers during those times that care providers are not available or in settings such as field units, where access to health care is limited. While not necessarily acceptable or desirable, the fact remains that officers in some facilities are often faced with having to make decisions about an inmate's health. In situations such as this, providing the tools by which an officer can make informed, rational decisions would be of tremendous benefit to both the officer and the inmate.

The experience at Fort Sam Houston and in other health care settings has demonstrated the role non-professional personnel can play in the process of delivering health care. For the many states whose correctional

institutions rely on non-licensed (although, oftentimes experienced) personnel, utilization of well-substantiated triage methods can offer not only a systematic approach, but can help to provide validation in the event of litigation against non-licensed care providers.

E. Audit of Protocol Use

Auditing is the process of monitoring the use of clinical protocols and is as important an issue as the protocols themselves. To develop and implement protocols without a parallel auditing mechanism would greatly limit the usefulness of the new system. If non-physicians are to be given the responsibilities of providing medical care, then there must be a way of insuring that instructions and rules in the protocol were carried out explicitly.

Audit of the Practitioner

The primary purpose of the audit is to detect omissions of important clinical data, and to detect situations in which the actions taken by the protocol user were not in keeping with the instructions of the protocol.

One of the most important reasons for implementing the use of protocols in the first place is to improve the thoroughness of the health record data base. Too often subjective and objective data are omitted leaving an uncertain clinical picture and no rational chain of information. Audit of information that is collected by each care provider will indicate exactly what information is missing. On-going audit will also determine whether the omission is an oversight or whether there is a pattern. For example, a particular care provider is noted to consistently neglect recording (or examining for) the presence or absence of enlarged lymph nodes in patients with sore throats. Protocols are developed to include the data that must be collected for a given condition. Audit helps to assure that the data was, in fact, collected.

The second purpose of the audit is to detect situations in which the care provider did not take action in compliance with the rules of the protocol. For instance, audit can determine that an antibiotic was given for sore throat in the absence of a positive throat culture or that

back x-rays were ordered without indication. Once again, protocols are developed to indicate exactly those situations in which the throat culture and back x-rays are appropriate and those for which they are inappropriate. Without audit, controlling this aspect of the quality of care is impossible.

Without question there are limitations to the value of auditing. Anyone can record information that actually was not obtained from the patient and anyone can record information in such a way that it appears every patient with a sore throat requires an antibiotic. Audit is simply no substitute for honesty--nothing is.

Auditing also does not indicate those situations in which a care provider does not possess a particular skill, such as taking blood pressure properly or auscultating the chest. It remains the responsibility of all protocol users and the responsible physician to be certain that competencies are in keeping with the requirements of the protocol.

Several other advantages of audit for the correctional health services delivery system may be gleaned from the previous paragraphs. Omissions of data and inappropriate action should indicate immediately the need for in-service programs, retraining, or other educational approaches. The focus and content of those programs can be developed in response to a documented educational need.

The audit also helps to control institutional resources. Many x-rays and laboratory procedures are rather expensive. Performing them only when absolutely necessary could result in substantial savings. Even dramatically decreasing the use of the less expensive procedures, such as throat cultures, will result in large savings over a long period of time.

Finally, audit of protocol use also lends itself to the compiling of utilization data. Number of patients seen, diagnoses and disposition, numbers and types of diagnostic procedures, etc. are examples of the kinds of information audit can yield. Planning for future resource needs, evaluations of health care, and health care delivery are enhanced with the information available through protocol audit.

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CHAPTER 3

THE PROGRAM DEVELOPMENT PROCESS:

LEVEL I INITIATE PLANNING

Objective: To initiate the formation of a committee responsible for the development and implementation of clinical protocols in a particular setting and to provide guidelines for systematic program development.

Overview of Level I

Task 1 - Problem Clarification

Task 2 - Setting Goals and Objectives

Task 3 - Analysis of Institutional Setting

Step A: Organizational Structure and Functioning

Step B: Analysis of Factors Affecting Organizational Change

Task 4 - Resource Assessment

Task 5 - Establishment of Support Within System

Task 6 - Development of a Plan of Action

While the interest and enthusiasm of one person may serve as the stimulus for change, it is extremely difficult and probably impossible for any single individual to initiate large-scale change in a complex system. A cooperative, collaborative effort on the part of many persons is necessary if any new program or procedure is to be useful and successful. The most appropriate mechanism for eliciting this broad base of organizational support is the formation of a planning committee (or task force).

Since the planning committee has a large, difficult task to accomplish, the work of many persons committed to implementing the new program can make the job easier. Gathering input from various categories of personnel can also positively affect the survival of the program. Additionally, the committee can provide the day-to-day implementers with a support base for carrying out their tasks and provide initial direction for their efforts.

The Organization and Functioning of the Planning Committee

Although initially only one health care provider or administrator may be familiar with the use of clinical protocols, others must soon become interested and involved. Persuasion efforts in the form of casual conversations, staff meetings, or in-service programs can plant the idea and allow it to grow. Ultimately, a small group of people will emerge who share a common interest and the motivation to actually plan, develop, and implement the use of protocols in a particular setting. It becomes the responsibility of this interest group to obtain official sanction for the organization of a formal planning committee.

In the process of establishing a planning committee, several guidelines should be kept in mind:

- A. The personnel selected for the committee should be committed to implementing the utilization of clinical protocols.
- B. The committee should be comprised of line and administrative staff including representatives of all types of personnel who would be affected by the change.
- C. The group should generally not be larger than twelve members.
- D. A planning committee may be established on a state-wide basis (i.e. representatives from various institutions). In addition, committees should be established within the institution where the program is to be implemented.

In order to do its work effectively, the committee must be able to operate as smoothly and efficiently as possible. Therefore, part of the energy expended by the committee must be used to enhance its own functioning. Clarifying certain procedural issues early in the life of the committee will help insure the long-term survival of the group as well as to help to make the group more productive.

The following are minimal areas to be considered:

Membership

The committee should discuss the following issues regarding membership:

- a. Will membership be open to any other persons? (i.e. those interested in the program or those who might have valuable contributions to make such as knowledge or experience.)
- b. Are there other individuals who should be requested to participate because of the unique contribution they may be able to make?
- c. What are the members expected to do, minimally?

Leadership

- a. Who will coordinate the activities of the committee?
- b. If a chairperson is named as coordinator, is this position to be appointed, elected?
- c. How long will chairperson serve?
- d. Are other officers needed? (i.e. if minutes to be taken, recorder needed.)

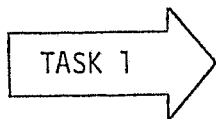
Process and Procedures

- a. How often will meetings be held? Where? What time?
- b. How will members be informed about meetings?
- c. Will agendas be circulated prior to meetings?
- d. Will minutes of meetings be recorded? If yes, will they be circulated to committee members? Others?
- e. Will special effort be made to communicate with important administrative persons? If yes, how will this be done?

Establishing the working ground rules early in the life of the committee will help to prevent difficulties later. The committee is encouraged to periodically discuss and assess its own functioning to determine if changes in membership, leadership, or process are needed.

Tasks of the Planning Committee

The primary responsibility of the planning committee is to establish a "blueprint" for the planning, development, and implementation of an alternative health services delivery method, i.e., the utilization of clinical protocols. This committee will: 1) analyze problems in the current service delivery system, 2) determine which problem areas might be improved via the use of clinical protocols, 3) make initial decisions regarding the scope and content of the protocols to be used, 4) propose measures to determine the effectiveness of the new program, and 5) explore strategies for the smooth integration of new procedures into the existing health care delivery system.



Problem Clarification

To begin the planning phase, it is first necessary to determine the nature of the problem to be addressed. Clarification of the problem is essential in beginning to assess the applicability of protocol use in a particular setting and to define the scope of a new program.

In attempting to clarify the problem, the planning committee should first determine those conditions which presently exist with respect to the provision of health services. The assessment of present conditions should then be compared to an appraisal of conditions as they "should" exist. In other words, the status quo should be compared to the ideal. The discrepancy between:

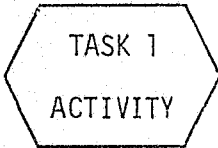
EXISTING
CONDITIONS
(Status Quo)

and

DESIRED
CONDITIONS
(Ideal)

represents the general problem at issue. By identifying the discrepancy between the status quo and the ideal, the planning committee can start to

define the overall scope of the intended program, basic needs and priorities, and the level of commitment to program purposes and goals.



Problem Clarification

Directions: The following worksheet is intended to assist in clarification of the problem. Individually, the planning committee members should first list service delivery/personnel/or other problems as they exist currently. Then the committee chairperson should have the group members share and discuss the problems they cited. A list should be completed of the major or most frequently identified problems.

Working Notes

Problem Clarification Worksheet

Service Delivery/Personnel/Or Other Problems As They Currently Exist

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.

Major or Most Frequently Identified Problems

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.

Committee Members:

Since not every problem cited will likely be amenable to improvement by using clinical protocols, discuss and identify the two or three most significant problem areas for which protocols may offer a solution.

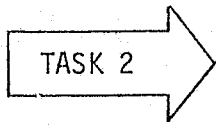
List these:

1.

2.

3.

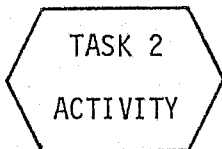
This brief list of problem areas will help direct subsequent decisions that must be made regarding the content and scope of a protocol system.



Setting Goals and Objectives

The establishment of goals and objectives should evolve from the health service delivery problems identified in the problem clarification exercise. The group may establish a goal for the program by expanding on the anticipated benefits envisioned as an end product of the program. The program goal statement may be described as a broad statement of intent describing what is to be achieved by the establishment of a specific program.

The program objectives are used to attain the goal. There may be any number of objectives that will be used to obtain the desired goal. Goals and objectives are dynamic concepts. Revision and refinement in them can occur at any time with the addition of new or more detailed information. The planning committee may wish to periodically re-evaluate the statement of goals and objectives. If there has been a shift in focus, a new statement should be written so that all members retain a clear understanding of what they are trying to accomplish.



Statement of Goals and Objectives

Directions: The following worksheet is intended to assist in preparing a statement of the goal(s) for initiating the use of clinical protocols and the objectives by which the goal(s) will be realized. Using the results of the problem clarification exercise, prepare a tentative goal statement. Specifically include:

- a) the type of protocols to be developed and used,
- b) by whom,
- c) for what purpose, and
- d) to begin within what time frame.

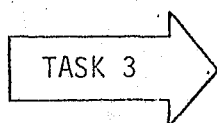
The steps in the process of accomplishing the goal become the objectives. Discuss what these steps will be and list them.

Statement of Goals and Objectives Worksheet

Goal Statement:

Objectives:

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.
- 10.



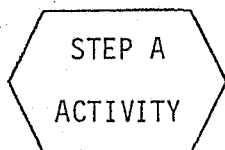
Analysis of Institutional Setting



Organizational structure and functioning.

Initiating the use of clinical protocols in the correctional setting will generally require persons to alter some aspects of how they do their job and to whom they are directly responsible. Changes of this nature are tremendously difficult to promote and they rarely occur easily.

For these reasons, the planning committee should review the organizational structure, identify lines of authority, and begin to anticipate future difficulties. Preparing for this early will help the committee to capitalize on the facilitating factors of the organization and minimize the limiting factors.



Analysis of Organizational Structure

Directions: The following worksheet is intended to assist with the analysis of the organization. Draw an organizational chart and identify lines of authority. Minimally include all branches of personnel who will be affected by the introduction of protocols into the health service delivery system (e.g., physicians, nurses, assistants, dentists, lab and x-ray personnel, etc.).

Analysis of Organizational Structure Worksheet

Organizational Chart:

Will lines of authority be altered because of the proposed goal? How?
Discuss methods of facilitating smooth transitions and record for later
reference.

STEP B

Analysis of factors affecting organizational change.

STEP B

ACTIVITY

Directions: There are many organizational factors that can influence the progress of program development and implementation. Assess some of those factors listed on the following worksheet. Discuss strategies for how the facilitating factors can be maximized and limiting factors eliminated or minimized. After completing this exercise, identify any changes that should be made in the statement of goals and objectives.

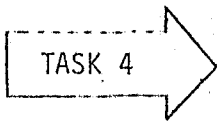
Factors Affecting Organizational Change Worksheet

FACILITATING

- External authority requires your organization to support your effort (i.e. courts).
- External support available (outside agencies, persons).
- Administration support of involvement.
- Supervisor involvement.
- Good staff relationships.
- Physical facilities aid the effort.
- Knowledgeable personnel.
- Motivated staff.
- Funds available if needed.
- Effective leadership.
- Clear organizational goals and priorities.
- Other: _____

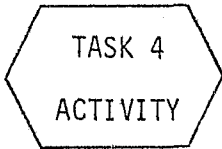
LIMITING

- Lack of power or authority of the organization.
- Unclear or shifting goals, programs, or assignments.
- Lack of administrative support.
- Lack of supervisor support.
- Difficulties in staff relationships, cohesiveness, communication, etc.
- Lack of funds.
- Lack of necessary physical facilities.
- Ineffective leadership.
- Inadequately trained personnel.
- Other: _____



Resource Assessment

Planning any organizational/service delivery change requires careful assessment of the resources required to implement the change. It is important to take account of those resources that are available as well as those that are needed.



Resource Assessment

Directions: The categories of resources listed on the following worksheet must be assessed:

Working Notes

Resource Assessment Worksheet

Information/Input

Do you need more information about clinical protocols in order to make further decisions?

Are there persons from whom further input is needed (administrators, care providers, etc.)? What input is needed?

What information is already available upon which decisions can be based?

Other:

Materials/Supplies/ ? /Personnel

Is the proposed goal affordable?

What materials/supplies will be needed?

What materials/supplies are available?

What are the personnel requirements of the stated goal?

Are additional personnel needed?

Will current personnel be given different responsibilities from those they already have? If yes, how will they be prepared for their new responsibilities?

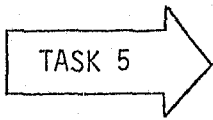
Other:

Time

Do the planners and implementers of the proposed goal have enough time to devote to their tasks?

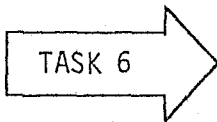
How can tasks/responsibilities be shifted so that time is made available?

Other Resources



Establish Support Within System

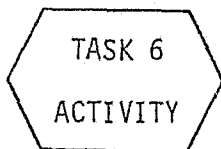
For institutional change to occur, it is essential to secure the support of key administrators and other correctional personnel that will be involved in any level with the proposed incorporation of clinical protocols into health service delivery. The first step in this process is to identify all the people that will need to be contacted. The planning committee can then assign the tasks of contacting these persons to its members.



Development of a Plan of Action

Utilizing the steps identified as necessary in order to accomplish the proposed goal (see worksheet for statement of goals and objectives), a plan of action can be developed.

The plan of action will function as the guide by which the planning committee will perform its duties. The plan should include a total listing of tasks to be assigned and accomplished within specific time frames.



Action Plan

Directions: The following worksheet is intended to assist in developing the plan of action. As tasks are completed they can be checked off. As additional tasks become necessary, they can be added to the list and assigned to a committee member.

As a group, discuss and list all of the major steps that will have to be taken in order to implement the goal as stated. (Use the statement of goals and objectives as a tentative list.) Be sure to consider resource needs, communication with other personnel (administrators, care providers), and decisions that must be made before proceeding, etc.

Prioritize the list to determine the order in which tasks should be accomplished.

Determine a time line for accomplishment of tasks. Set interim goals or benchmarks so that progress can be easily measured.

As a group, review the list of tasks and check for completeness. Assign each task to a member of the committee. Review the time frames within which each task must be completed.

Priority Ranking	Task	Time Frame	Assignment
	A. B. C. D. E. F. G. H. I. J. K. L. M. N. O. P. Q.		

CHAPTER 4

THE PROGRAM DEVELOPMENT PROCESS: LEVEL II PROGRAM DEVELOPMENT STRATEGIES

Objective: To reach decisions with regard to the specific protocols to be used, the relationship between the protocol system and the health record, staff orientation, and program evaluation.

Task 1 - Identify the Content and Format of Clinical Protocols to Be Utilized

Step A: Determine number and variety of protocols

Step B: Analyze the characteristics of the health care setting

Step C: Assess care providers' skills

Task 2 - Determine Method for Incorporating Protocols into the Health Record

Task 3 - Plan for Staff Orientation

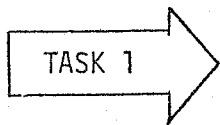
Task 4 - Prepare Audit Design

Task 5 - Prepare Evaluation Design

Task 6 - Review Program Development Tasks

To develop a system for the use of clinical protocols which will be effective and efficient, attention must be given to several special issues because of their potential for influencing the success of the program. Included are decisions that must be made regarding the protocols to be used, the method of incorporating them into the existing service delivery structure, strategies for informing and preparing personnel, and preparation of an evaluation and audit design.

The issues and strategies discussed in this chapter are an extension of the process initiated in the Program Planning Phase, Chapter 3. The goals, objectives, and plan of action developed in the initial planning stages should provide the direction and impetus for the next stage, Program Development. The planning committee remains the primary decision-making body but may, at this time, desire the input and involvement of additional persons including other health service personnel, outside agencies, and/or consultants.



Identify the Content and Format of the Clinical Protocols to Be Utilized

The unique features of the clinical setting will dictate the content and format of the protocols that will ultimately be used. Protocols developed for one setting may be partly or entirely inappropriate when used in another setting. Consequently, a process of adaptation or modification must occur to individualize protocols to reflect the characteristics of the setting in which they will be implemented.

Just as protocols cannot be "borrowed" from a different setting in total, the opposite extreme should also be avoided. That is, no one should feel compelled to start from scratch in developing their own protocols. Many groups around the country have expended countless hours and large sums of money to develop, test, and refine protocols covering the majority of common acute and chronic health conditions. To not capitalize on these efforts would be an unfortunate oversight.

The task of adapting existing protocols is not an easy one. The process will require a cooperative, collaborative effort on the part of many persons. In particular, the care providers who will be using the protocols and the responsible physician must have input into their development.

STEP A

Determine number and variety of protocols.

It is encouraged that development and implementation of clinical protocols start on a small scale. As already discussed in Chapter 3, utilizing protocols may alter considerably the way in which persons accomplish their responsibilities. Introducing one or two protocols initially, then adding others later, may help to avoid the resistance most of us experience when confronted with a change in the way we do things.

The characteristics of the patient population served by an institution will influence the variety of protocols used. A review of the age range, sex, and the health problems most frequently encountered should readily indicate the kinds of protocols that will be most helpful. For instance, protocols to be used in an institution for female offenders would likely cover genitourinary conditions and health maintenance strategies such as breast exams and pap smears. Those used in a facility for young people should include a protocol for acne and other skin conditions. If the inmate population tends to be somewhat older, protocols for chronic conditions such as hypertension and diabetes should be considered.

One useful way to determine what protocols are needed is to keep a log of every chief complaint presented for a period of time, such as two or three weeks. Protocols to manage the four or five most frequently noted conditions will likely account for a large percentage of health service requests.

A common procedure is to introduce one or two protocols for common acute/self-limiting conditions, such as upper respiratory infection and headache, and one or two flow sheets for chronic conditions, such as hypertension and diabetes. The usefulness of these protocols can serve to demonstrate the benefits of the program and can also indicate problematic areas that may need some attention.

STEP B

Analyze the characteristics of the health care setting.

A host of factors characterizing the practice setting will have an effect on the nature of the protocols implemented. Of critical importance is the availability of physician consultation. In those settings where a physician is readily available, the complexity of the protocol may be diminished and referral to the physician can be included at an earlier point in the management process. In contrast, highly detailed diagnostic strategies, specific treatment plans, and stringent guidelines for physician referral should be included in those protocols used by practitioners without close physician support.

Many protocols require the availability of laboratory or x-ray services. The types of services available on-site, the demand placed on those services, and costs involved must be considered. While experience in some settings has indicated a noticeable decrease in the demands for certain procedures (e.g. throat cultures), utilization patterns may change. Involvement of key support service personnel in the planning process is strongly advised so that difficulties may be anticipated or even avoided.

STEP C

Assess care providers' skills.

Regardless of the variety, content, or format of the clinical protocols used in a particular setting, there should ultimately be a close "match" between the skills required by the protocols and those demonstrated by the protocol users. It would be a tremendous waste of time and energy to proceed with the planning and implementation of a set of protocols without first doing a careful assessment of providers' skills.

Since nearly all clinical protocols require obtaining a history of the presenting condition, skill in history-taking and recording is imperative. Most protocols also require the care provider to perform an examination of the patient. Depending on the specifics of the protocol, the physical exam skills required could range from taking temperatures and measuring blood pressures to auscultating the chest. Certain protocols require that simple laboratory procedures be done. For example, the protocol user may be asked to prepare a slide for microscopic

examination. Whatever skills a particular protocol requires, it must be ascertained that the potential protocol users do, in fact, possess those skills.

A suggested method of assessing providers' skills is to carry out the following two-step assessment. The first step involves having each care provider assess their own skills. The second requires having the skills verified by a supervisor, in-service instructor, or other resource person.

To prepare the skills inventory, a complete listing of the skills required by the protocol(s) must be completed. For example, by reviewing the Low Back Pain Protocol in Figure 1, it can be determined that the following skills are required in order to use this particular protocol:

- obtain history of presenting problem
- observe gait
- inspect and palpate abdomen
- percuss for CVA tenderness
- perform neurological examination of lower extremities (knee jerk, ankle jerk, sensation)
- perform musculoskeletal examination of lower extremities
- obtain urinalysis and culture

Figure 1

LOW BACK PAIN PROTOCOL[®] (6/76)

ID #:

Date:

Name:

Birthdate:

Phone:

Protocol User:

yes no SUBJECTIVE

	<input checked="" type="checkbox"/>	Seen <4 wks ago for same problem
A	<input type="checkbox"/>	Improved

Duration of pain _____

	<input type="checkbox"/>	Any previous episodes
	<input type="checkbox"/>	Age ≥ 60

	<input type="checkbox"/>	Located in central back
	<input type="checkbox"/>	Right side
	<input type="checkbox"/>	Left side
	<input type="checkbox"/>	Groin <i>Do urinalysis & culture</i>
	<input type="checkbox"/>	Abdomen
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Buttock (which side? _____)
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Thigh (which side? _____)
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Below knee (which side? _____)

	<input checked="" type="checkbox"/>	Tried bed rest (3 hrs, firm mattress, on back or side)
	<input type="checkbox"/>	Some relief during bed rest

<input checked="" type="checkbox"/>	<input type="checkbox"/>	Made worse by coughing/sneezing
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Numbness/paresthesias below waist
	<input type="checkbox"/>	Blow (direct trauma) to low back in past 3 months
	<input type="checkbox"/>	Diarrhea
	<input type="checkbox"/>	Constipation
	<input type="checkbox"/>	Rectal bleeding
	<input type="checkbox"/>	Fecal/urinary incontinence
	<input type="checkbox"/>	Trouble urinating in last 12 hrs
	<input type="checkbox"/>	Unable to walk

	<input type="checkbox"/>	Dysuria <i>Do urinalysis & culture</i>
	<input type="checkbox"/>	Urinary frequency <i>Do urinalysis & culture</i>
	<input checked="" type="checkbox"/>	Male
	<input type="checkbox"/>	Urinalysis ordered
	<input type="checkbox"/>	Urethral discharge

OBJECTIVE

A	<input type="checkbox"/>	Pt appears in severe pain
	<input type="checkbox"/>	Temperature ≥ 100 _____
	<input type="checkbox"/>	Scoliosis/pelvic tilt
	<input checked="" type="checkbox"/>	Normal heel walking
	<input checked="" type="checkbox"/>	Normal toe walking
	<input checked="" type="checkbox"/>	Abdominal pain by Hx
	<input type="checkbox"/>	Abdominal tenderness by Px

	<input type="checkbox"/>	Unilateral CVA tenderness <i>Do urinalysis and culture</i>
	<input type="checkbox"/>	Tenderness in back <i>Describe location</i>
	<input checked="" type="checkbox"/>	Localized to sacroiliac joint

right	left	
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Sciatic notch exam normal
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Straight leg raising normal
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Big toe elevation normal
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Sensation in foot normal

<input type="checkbox"/>	<input type="checkbox"/>	Knee jerk
<input type="checkbox"/>	<input type="checkbox"/>	Ankle jerk

<input type="checkbox"/>	<input type="checkbox"/>	Any reflex 4+
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Knee jerks about equal
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Ankle jerks about equal

PLAN

STOP	<input type="checkbox"/>	Any reds <i>Consult MD</i>
STOP	<input type="checkbox"/>	Will consult MD for other reasons

	<input checked="" type="checkbox"/>	Return visit
	<input type="checkbox"/>	Signs better <i>Advance Rx</i>
STOP	STOP	<i>Consult MD</i>

	<input type="checkbox"/>	Urinalysis ordered
	<input type="checkbox"/>	<i>Do UTI protocol, return</i>
	<input type="checkbox"/>	Dx of UTI
	<input type="checkbox"/>	<i>Dx Low Back Strain</i>
	<input type="checkbox"/>	<i>Rx Bed Rest</i>

	<input checked="" type="checkbox"/>	Any grays <i>Dx Low Back Strain</i>
	<input type="checkbox"/>	<i>with possible root irritation</i>
	<input type="checkbox"/>	<i>Rx Bed Rest Return in 3 weeks</i>

STEP C
ACTIVITY

1. Provider Self-Assessment

Directions: Using the example skills noted above, the following checklist can be developed. The checklist is then distributed to each potential care provider to be used as a self-assessment.

Inventory of Individual Care Provider's Skills
Worksheet

Skills Required by Protocol (Examples)	Can Perform Without Supervision	Can Perform But Need Assistance	Unable to Perform Need Training
1. Obtain history of presenting problem			
2. Observe gait			
3. Inspect and palpate abdomen			
4. Percuss for CVA tenderness			
5. Perform neurological examination of lower extremities (knee jerk, ankle jerk, sensation)			
6. Perform musculoskeletal examination of lower extremities			

STEP C

ACTIVITY

2. Instructor Assessment

Directions: Taking the completed self-assessment forms, the instructor or other person responsible for verification must then actually observe each care provider in the performance of those items identified in the "Can Perform" column. Ideally, this is done in the clinical setting during routine activities. If this is not possible, time may have to be set aside for an in-service session.

The provider self-assessment and instructor assessment, taken together, should offer a fairly clear picture of the clinical capabilities of the potential protocol users. With this information on hand a decision must then be made regarding how to improve the "match" between the skills required and the documented skills care providers actually possess.

One approach would be to eliminate those items in which most care providers demonstrated knowledge or skill deficits. This strategy would likely decrease the need for educational programs but would also reduce to the lowest common denominator the expectations placed on personnel. It would also decrease the number of patients who could be managed without physician referral. For these reasons this is not considered the best strategy.

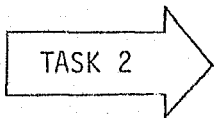
The second approach involves improving and expanding the skills of care providers so that all personnel progress to a higher level of clinical competency. In-service programs, community college courses in physical assessment, and/or peer tutoring are all possible means of improving skills. The skills inventory should assist in planning for which skills on which to focus and assures some identifiable, documented evidence of proficiency.

A Case in Point:

One state correctional system is taking the concept of the skills inventory one step farther. Using a system of protocols standardized throughout all state institutions, care providers are expected to be able to perform all of the functions required to use the protocols. Once the individual care providers have demonstrated a pre-determined level of competency, certificates are awarded credentialing them to work within

that state system. It is also anticipated that re-certification will be required at regular intervals and will prompt health care personnel to maintain and update their skills.

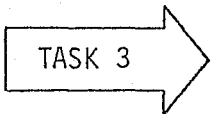
A list of suggested resource material for enhancing history taking and physical exam skills is included in the reference section of this Manual.



Determine Method for Incorporating Protocols Into the Health Record

A decision that must be made at some point in the program development phase regards the incorporation into the health record of information from the protocols. The planning committee should discuss this issue early in this phase although a final decision will be influenced by many factors. Once the content and format of the protocols are established and the audit design is prepared, the decision may be an obvious one.

Involvement of the health records administrator is strongly suggested at this point. The planning Committee should not make a final decision on this particular matter until the impact of the use of protocols on the health record is assessed.



Staff Orientation

At this point in the program development process, it may be too early for the actual activities involved in staff orientation. However, informing staff prior to implementation of protocols will be absolutely necessary and therefore, the planning committee is requested to discuss strategies for staff participation.

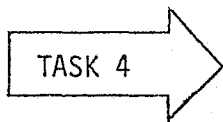
As has been emphasized earlier, using protocols will undoubtedly require a change in the way people do their work. It is critical that time and attention be devoted to becoming familiar and comfortable with that change.

The most effective method of preparing staff and overcoming any resistance is for as many persons as possible to be involved in program planning and development from its inception. This is not always practical, however, so alternative routes must be identified.

The purposes of staff orientation are two-fold. First, it will be important for all persons involved in or affected by the implementation of protocols to have an understanding of why they are going to be utilized. Secondly, staff must know how to use them. Knowing how to use protocols encompasses knowing when to use them.

Staff meetings or in-service education sessions are useful as methods for staff orientation although being lectured to is not nearly as interesting and motivating for adult learners as actually performing. To foster maximum participation, role-playing with one staff person as patient and one as care provider is suggested as an instructional methodology. Other staff members can observe and critique the role-play until they have the opportunity to be an actor too.

This type of learning environment enhances knowledge/skill competencies because it requires active learning. Lectures, on the other hand, do not necessarily require active participation. Because the use of protocols is a behavioral and cognitive change, staff orientation to the use of protocols should be a practical, useful experience.



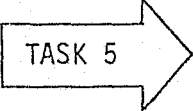
Prepare Audit Design

As important a task as the development of protocols is the development of an audit procedure. The format of the protocols used will dictate to a large degree the structure of the audit. Whatever the design, the audit must include a process for determining that all data required by the protocol was collected and recorded and that the actions taken by the protocol user were in compliance with the rules of the protocol.

In most systems, audit will be done by hand by an appointed person or persons. The responsibilities include actually determining the errors or omissions of each care provider using the protocols and then giving feedback directly.

The planning committee must address this issue and determine the procedure for audit prior to actual implementation of the protocols. The procedure must then be made familiar to the persons who will be doing the audit.

NOTE: IT MAY NOT BE NECESSARY TO AUDIT EVERY HEALTH RECORD EACH TIME A PROTOCOL IS USED. HOWEVER, A RANDOM SELECTION OF EACH PROTOCOL USER'S RECORDS SHOULD BE AUDITED REGULARLY.



TASK 5

Prepare Evaluation Design

The planning committee should also begin designing an evaluation component to determine the interim and overall effects of protocol use on the health services delivery system. A detailed description of this component can be found in Chapter 6. Preliminary discussion should begin to consider the following:

- a) Who will conduct the evaluation?
- b) Who will participate in the evaluation?
- c) When will the evaluation take place?
- d) Where will the evaluation take place?
- e) What will be evaluated?
- f) What will be included in the evaluation?
- g) How will the evaluation results be used?



TASK 6

Review Program Development Tasks

1. Review and revise goal statement and objectives, if necessary (Chapter 3).
2. Review and update action plan worksheet (Chapter 3). Add new tasks, assignments, needed resources, etc., as necessary.

CHAPTER 5

THE PROGRAM DEVELOPMENT PROCESS: LEVEL III: PROGRAM IMPLEMENTATION

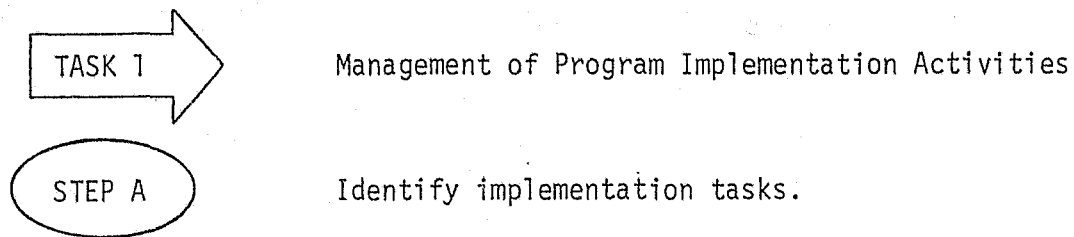
Objective: To establish systematic procedures for managing and monitoring the implementation of a clinical protocol program.

Task 1 - Management of Program Implementation Activities

- Step A: Identify implementation tasks
- Step B: Prepare management time line

Task 2 - Monitoring Program Implementation

- Step A: Determine information needs.
- Step B: Monitor and document program implementation process



To implement the planned system of clinical protocols in an effective and efficient manner, attention must be given to managing specific aspects of the implementation process. Essentially this involves identifying each of the major tasks and sub-tasks required during this phase, designating individual work assignments, and finally, preparing a detailed management time line.

The major steps to be undertaken at this level are actually an extension of some of the procedures initiated as a part of the program planning phase (Chapter 3). At this juncture in the program development process, the action plan was prepared which identified general categories of significant tasks related ultimately to the initiation and use of clinical protocols. The purpose of the action plan was to serve as a planning tool and progress measure by indicating those tasks that were necessary to accomplish the goal identified by the planning committee. A portion of the action plan included estimated time frames during which the tasks were to be completed.

It is now necessary to also prepare a management time line for program implementation activities. The function of the management time line is two-fold. First it serves to display, in a non-linear fashion, all of the necessary tasks to be completed in carrying out a particular phase of the program development process. Secondly, by outlining program tasks in this way, those responsible for managing the program can determine the relative status of the program by referring to the estimated dates assigned to each individual task.

Step A consists of reviewing the action plan and identifying in detail those tasks which must be completed to properly implement a system of clinical protocols in an organized fashion. The program planning committee must carefully consider all of the anticipated events and activities which must necessarily occur during the implementation.



Specification of Implementation Tasks

Directions: The planning committee, working as a group, should identify all significant tasks which need to be performed during the implementation phase of the program development process. While it is not necessary at this time to order the tasks with respect to their anticipated sequence, it may be helpful to group sub-tasks according to major categories.

Sample:

Implementation Tasks

- I. Staff Orientation
 - A. Arrange release time
 - B. Schedule meeting place
 - C. Contact health administrator
 - D. Etc.
- II. Printing and Distribution of Protocols
 - A. Finalize content and format of protocols
 - B. Arrange for typing, printing, and/or duplication
 - C. Distribute protocols to units
 - D. Etc.
- III. Design Audit Procedures
 - A. Finalize items to be included in audit
 - B. Develop audit tally sheet and provider feedback form
 - C. Etc.

Program Implementation Tasks Worksheet

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.
- 15.
- 16.
- 17.
- 18.
- 19.
- 20.

STEP B

Prepare management time line.

Once the planning committee has identified the major tasks to be undertaken during the implementation process, the next activity should be to display this list of tasks in a management time line. As mentioned, the management time line is similar to the action plan worksheet, but contains more detail and includes specific personnel assignments. In general, Step B involves organizing and refining the list of implementation tasks, estimating completion dates, and assigning tasks to particular members of the program planning committee.

STEP B

ACTIVITY

Preparation of Management Time Line

Directions: Having completed the list of tasks related to the program implementation process, the planning committee should review the list of overlapping or redundant task descriptions. Next, an attempt should be made to sequence the major task categories in a linear time frame.

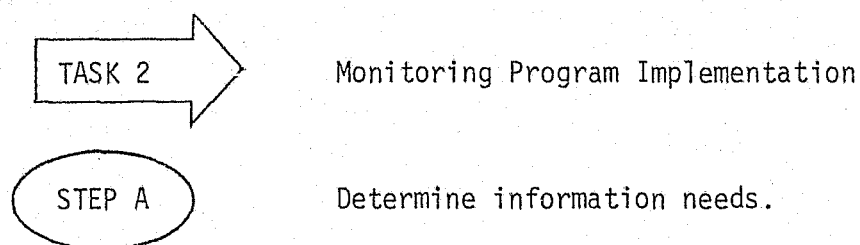
The list of program implementation tasks should then be displayed on the Time Management Form provided on the next page and information with regard to the anticipated completion dates and personnel assignments recorded.

Management Time Line Sample

TIME TASK	March	Completed April	Completed May	Completed June	Completed July	Completed August	Completed September	Completed	Staffing Assignments
	I. Staff Orientation								
A. Arrange release time		7							Johnson
B. Schedule meeting place	29								Smith
C. Contact health administrator			2						McWilliams
II. Printing and Distribution of Protocols									
A. Finalize content and format of protocols			9						Smith
B. Arrange for typing, printing, and/or duplication			12						Merson

Management Time Line Worksheet

TASK												TIME											
												March											
												Completed April											
												Completed May											
												Completed June											
												Completed July											
												Completed August											
												Completed September											
												Completed											
												Staffing Assignments											



Monitoring program implementation activities is primarily a management/evaluation function to ensure that initial program plans are being properly discharged and major program goals met. More specifically, the methods and procedures outlined below are designed to document and describe on-going program activities. The purpose is to provide program planners with current information for determining program status and the need for revisions. In this sense, such monitoring procedures are directly related to both formative and summative evaluation as will be further discussed in Chapter 6.

The first step in designing an appropriate implementation monitoring strategy is to assess basic information needs. What types and how much information should be collected in monitoring the program implementation activities? In making this judgement, it could be kept in mind that monitoring program implementation involves the collection of two broad categories of information:

1. descriptive data related to program materials, events, and administrative functions, and
2. back-up data to substantiate the program events described.

In deciding the information needs of a particular program, the planning committee should consider what aspects of the program are most critical for their specific purpose. This decision will obviously be based, in part, on the time and resources available. It will also depend on the scope and complexity of the program and the intended recipients of the information.

Secondly, determining program information needs requires that program planners consider the quality and quantity of the back-up data to be collected. This decision centers on the question of how much evidence is desired to verify the program description information. Again, time, resources, and the nature of the program will be the central factors.

STEP A
ACTIVITY

Determining Information Needs

Directions: The program planning committee should work together to decide specific information needs regarding the procedures for monitoring the implementation process. First, a decision should be reached on what elements of the program to monitor and at what level of detail to report these findings. This can be accomplished by ascertaining which elements of the program context need to be described and which program activities require assessment. Using the sample given below as a guide, the planning committee should complete the Program Implementation Information Needs Worksheet.

NOTE: IT IS IMPORTANT TO REMEMBER THAT THESE DECISIONS SHOULD BE BASED ON THE AGREED-UPON PURPOSE OF THE MONITORING PROCEDURES, AND ON THE NATURE AND INTENT OF THE PROGRAM.

Sample: Program Implementation Information Needs

Program Context Information	Program Activity Information
1. Number and type of protocols developed.	1. Adaptation and/or development of protocols.
2. Personnel involved.	2. Provider's skills inventory.
3. Resources utilized (e.g. instructional materials, published protocols, etc.)	3. Staff orientation (e.g. instructional methods, etc.)
4. Site of implementation (i.e. description of facility, staffing patterns, inmate population, etc.)	4. Administrative arrangements (e.g. decision-making process)

Program Implementation Information Needs Worksheet

Program Context Information	Program Activity Information
1.	1.
2.	2.
3.	3.
4.	4.
5.	5.
6.	6.
7.	7.

STEP B

Monitor and document program implementation process.

After having decided on the nature and scope of the implementation monitoring procedures to be employed, the planning committee must next decide on the methods for collecting the required program information. In other words, given the specific type of questions to be asked, how will the information be obtained.

The purpose of Step B is to assist in making the above decisions. Various methods for data collection are suggested below. Using this information and the resulting decisions made during Step A, the planning committee should attempt to match the appropriate method with the appropriate information category on the forms provided.

Alternative Data Collection Methods*

I. Examine Program Records

Examples of records useful for this purpose include: memorandums, instructional plans, attendance records, program reports, management time lines, budget records, participant profiles, sick call records, etc.

II. Conduct Observations

Program personnel can be assigned to systematically observe various activities of the program and prepare summary reports on an on-going basis.

III. Self-Reports

Program personnel and participants (e.g. instructors, administrators, consultants, aides, students, etc.) can provide detailed descriptions of various program activities. Information of this kind can be collected through the use of interviews, survey questionnaires, or structured reports. In general, this method is most often employed when attempting to verify findings from other sources.

*For further explanation of data collection methods, refer to Chapter 6.

SAMPLE
DATA COLLECTION PROCEDURES

Information Category	Methods	Source
<u>Program Context Information</u> 1. Physical Resources 2. Program Personnel 3. Etc.	I. Observation II. Progress records III. Self-report I. Program Records	I. Observation check lists II. Program reports III. Personnel survey I. Program reports, memo's, etc.
<u>Program Activity Information</u> 1. Utilization of Materials	I. Observation II. Self-report	I. Observation check lists II. Staff and participant surveys

WORKSHEET

DATA COLLECTION PROCEDURES

Information Category	Methods	Source

CHAPTER 6

THE PROGRAM DEVELOPMENT PROCESS:

LEVEL IV PROGRAM EVALUATION

Objective: To develop methods and procedures for assessing the effectiveness and efficiency of the use of clinical protocols.

Overview of Level IV

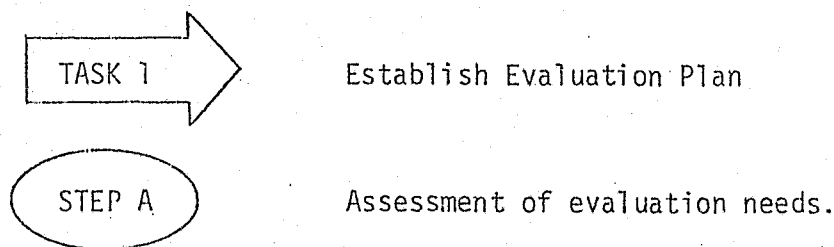
Task 1 - Establish Evaluation Plan

Step A: Assessment of evaluation needs

Step B: Identification of evaluation measures and information sources

Task 2 - Develop Evaluation Instruments

Task 3 - Report Evaluation Findings



The evaluation process is an integral part of any systematic program development strategy. Properly designed and implemented, program evaluation can assist in assuring the successful accomplishment of program goals and objectives and promote effective and efficient program operations.

The basic purpose of program evaluation is to provide valid and reliable information for making various types of programmatic decisions. Such decision-making information is necessary to all levels of the program development process: from planning through final program implementation.

In evaluating the use of clinical protocols thought should be given to both formative and summative evaluation procedures. Program evaluation conducted during the developmental stages is called formative evaluation. The process of formative evaluation concerns the systematic collection of information to assess the effectiveness of program methods and materials prior to the final installation of the program. Assessing selected program components as they are designed and developed allows program planners and decision makers to make necessary revisions and improvements with the least amount of cost in time and effort. This type of an evaluation also insures the quality of the final product by identifying program weaknesses and omissions before the program is actually established.

Formative evaluation normally consists of field-testing various aspects of the program using a representative sample of the intended target audience or qualified program consultants. The judgments must be made as to which aspects of the program need to be evaluated in this way. These decisions should be based on the nature of the program activity to be evaluated, its significance in terms of program outcomes, and the cost of revisions after the program has been implemented.

The other major program evaluation activity which needs to be considered is summative evaluation. The purpose of summative evaluation

activities is to measure the final outcomes of the overall program. In other words, to assess the extent to which stated program goals and objectives were accomplished.

This type of evaluation should be conducted after the program has been implemented. While the process of formative evaluation is meant to assess specific components of the program on an on-going basis during the various developmental stages, summative evaluation is designed to provide information regarding the effectiveness and efficiency of the total program.

The first step in constructing a sound evaluation design for the implementation of protocols is to determine the intended purpose of the evaluation. Depending on how the evaluation information is to be used, the design and scope of the evaluation procedures can vary significantly from program to program. A small-scale program, for instance, may require very little in terms of evaluation activities and be intended only to keep immediate staff members informed as to the status and results of the program. On the other hand, a large-scale program designed for replication throughout the system could require much more extensive documentation of program operations and results as well as detailed reports to various decision makers throughout the system.

Thus, the planning team must agree on a general statement of purpose with respect to program evaluation activities. This statement of purpose should include the specific goal(s) of the evaluation effort and the intended recipients for the evaluative information.

Following this, the planning committee should determine precisely what is to be measured. As has been emphasized, it is extremely important to identify clearly defined program goals and objectives. These goals and objectives can then serve as a basis for establishing program evaluation questions. It should be noted that the program evaluation questions should be based not only on program objectives but also can include various other programmatic features considered significant in assessing the program.

STEP B

Identification of evaluation measures and information sources.

After having identified the major evaluation questions, the next step in designing an evaluation plan is to attempt to determine the appropriate methods for gathering data related to these questions. This involves deciding what measures will be employed in documenting each program activity specified. As discussed in the preceding chapter, there are three main categories of evaluation measures which can be employed. Such measures include: (1) program records, (2) observations, and (3) self-report measures (see page 63, Chapter 5).

During this step, the planning committee should give careful consideration to exactly what type of measures will be utilized and what will be the source of the evaluation data. To assist in this task, a number of alternative evaluation measures have been listed below:

<u>Participant Performance</u>	<u>Program Procedures</u>	<u>Implementation Process</u>
Knowledge test	Staff ratings and reports	Observers' reports
Skill Performance Test	Observers' ratings and reports	Staff reports
Interviews	Attitude Measures	Rating scales
Questionnaires	Performance tests	Questionnaires
Rating Scales	Questionnaires	
Attitude Measures		

STEP A & B
ACTIVITY

Directions: The planning committee should outline their evaluation design by completing the evaluation plan worksheet supplied below.

Program Evaluation Plan

Sample

Statement of Purpose:

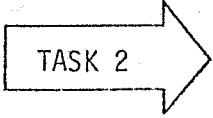
Program Objective	Evaluation Question	Measure	Information Source
1. All hypertensive patients will have the Hypertension Flow Sheet recorded in their health record each visit.	Are Flow Sheets in each hypertensive patient's charts? Do the records show evidence of on-going management and therapy?	Chart review	Health records
2. Mid-level care providers will find protocols assist in data collection.	To what extent do mid-level care providers find the protocols an enhancement to the data collection process?	Staff ratings	Unit staff

Program Evaluation Plan

Worksheet

Statement of Purpose:

Program Objective	Evaluation Question	Measure	Information Source



TASK 2

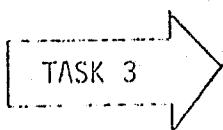
Development of Evaluation Instruments

As mentioned above, there are a variety of evaluation techniques and instruments that can be employed to assess the outcomes of the use of clinical protocols. The difficulty lies in selecting the proper instrument and technique for the collection of specified information. If trained personnel are not available within the organization, it is recommended that outside consultants be used to assist in the selection and development of the most appropriate measurement devices.

It is recommended that the following factors be kept in mind in making decisions about the use of particular evaluation instruments.

1. The selection of the most appropriate evaluation instruments and methods for collecting information should be considered in view of the particular group being evaluated and the conditions under which the evaluation will take place.
2. The evaluation instruments should be as brief as possible and be designed to measure specific program objectives or other critical variables.
3. Directions for administering and collecting information should be clear and concise.
4. Whenever possible, responses to the evaluation instruments should be kept confidential.

Validity, reliability, and utility of the evaluation instruments is also a primary concern. It is important that the evaluation instruments measure what they are intended to measure and that there become evidence of this fact. Secondly, there must be overall consistency and stability in terms of the evaluation devices. Lastly, the evaluation measures selected should have utility; should be practical in terms of the circumstances of the program in question. How realistic for the program staff to design and produce evaluation instruments? Will the information gathered be used and reported in an appropriate way? These questions are important, a program can be over-evaluated and thus a proper balance must be maintained.



Report Evaluation Findings

After the evaluation design has been completed, instruments for the collection of data selected and program evaluation information collected, the next step is to systematically tabulate, analyze, and disseminate program evaluation information to the appropriate decision makers. Most often this will take the form of a series of program status reports and a final report which reports an overall assessment of the project. In developing such reports, it is imperative that they be written in a concise, clear, and attractive format. The following is a brief outline of a typical evaluation report. It should be noted that information contained within the evaluation report should be consistent with the intent and purpose of the evaluation and the time and resources available.

- I. Summary
 - A. Program Title
 - B. Purpose of Evaluation
 - C. Significant Findings and Recommendations
- II. Overview and Context of Program
 - A. Program Setting
 - B. Program Origins
 - C. Program Goals and Objectives
 - D. Historical Background
 - E. Program Target Group
 - F. Program Personnel
 - G. Program Management Procedures
 - H. Budget Summary
- III. Program Description
 - A. Program Methods
 - B. Methods Rationale
- IV. Evaluation Methods
 - A. Purpose of Evaluation
 - B. Evaluation Measures and Data Collection Methods

V. Evaluation Findings

A. Overview and General Considerations

B. Specific Findings and Conclusions

In summary, the method used for reporting evaluation findings should be carefully prepared in light of its importance to the on-going program efforts. To expend the kind of energy and time necessary to properly evaluate a program and then to report the results in a less than appropriate fashion, is not only costly but may well jeopardize the program's success. The evaluation report can serve to disseminate essential decision-making information, promote the accomplishments of a successful program, gain wider support for program activities, and provide valuable insights and justification for improving, or extending the program.

APPENDIX A

AN ANNOTATED BIBLIOGRAPHY

BIBLIOGRAPHY

Acuna, H. R. The physician's assistant and extension of health services. Bulletin of the Pan American Health Organization, 1977, 11(3), 189-194.

This speech, delivered to the Fifth Conference on Health Practitioners, very clearly underscores the utility of programs involving the delivery of services by auxiliary health personnel (i.e., medical and physician's assistants) to populations typically not treated directly by physicians. Such programs appear to offer services which are at once expedient and economically feasible for remote, poor, or disadvantaged peoples.

Alexander-Rodriguez, T. Could prison nursing be the specialty for you? Nursing 78, March, 94-97.

Ms. Alexander-Rodriguez presents an interesting and positive overview of prison nursing.

Bottom, P. A., Bottom, W. D., DiMicco, W. A. P., Elledge, C. D., Retief, Z. M., Setzer, F. B., Stephens, G. G., Thompson, R. W., & Young, W. O. Interdisciplinary health care: Adjunct to family medicine. Alabama Journal of the Medical Sciences, 1978, 15(2), 134-136.

This brief report summarizes the methodological and philosophical buses of interdisciplinary health care programs. Receiving particular emphasis are the needs for patient education, and for supplanting crisis-oriented intervention with continuity in health care delivery.

Derro, R. A. Admission health evaluation of inmates of a city-county workhouse. Minnesota Medicine, 1978, 61(1), 333-337.

This report discusses the design and implementation of a protocol intended to facilitate the expedient detection and treatment of health problems in prisoners. Additionally, comparisons of incidence and prevalence of a variety of diseases and disorders between inmate and general populations are offered.

Engebretson, B. & Olson, J. W. Primary care in a penal institution: A study of health care problems encountered. Medical Care, 1975, 13(9), 775-781.

Health problems of inmates reporting to sick call were identified indicating a large number of psychosocial problems and a wide diversity of problem categories. The questionable suitability of the medical model for health care in this type setting is discussed. The implications for primary care delivery and education are also considered.

CONTINUED

1 OF 2

Freeman, F. R. Computer diagnosis of headache. Headache, 1978, 8(1), 49-56.

This article reports the development of a relatively simple computer algorithm which has proved useful in the diagnosis (i.e. classification of headaches. The author also emphasizes the utility of algorithm writing as a means of forcing one to elucidate the logical processes involved in medical diagnosis and decision making.

Goldsmith, Seth B. The status of prison health care. Public Health Reports, 1974, 89(6), 569-575.

A review of the literature to date indicating that the organization and delivery of health services within penal institutions is less than satisfactory. Reviews national, state, and local studies of prison health care delivery systems and studies of inmate health status.

Golladay, F. L., Miller, M., & Smith, K. R. Allied health manpower strategies: Estimates of potential gains from efficient task delegation. Medical Care, 1973, 11(6), 457-469.

This study analyzes the potential impact of physician extenders on the productivity of primary care practices and considers consequent implications for future health manpower requirements.

Greenfield, S., Anderson, H., Winickoff, R. N., Morgan, A., & Komaroff, A. L. Nurse-protocol management of low back pain: Outcomes, patient satisfaction, and efficiency of primary care. Western Journal of Medicine, 1975, 123, 350-359.

This article presents an algorithm employed by nurses in diagnosing and in treating low back pain. The validity of the instrument was evaluated by comparing a nurse-protocol treated group with a group treated in the regular manner by physicians. The groups were indistinguishable insofar as symptom relief was concerned and greater patient satisfaction was reported by the nurse-protocol group.

Greenfield, S., Bragg, F. E., McCraith, D. C., & Blackburn, J. Upper-respiratory complaint protocol for physician-extendere. Archives of Internal Medicine, 1974, 133, 294-299.

This report discusses the development and testing of an algorithm designed for the diagnosis of upper-respiratory illness and the referral (e.g., to physician or to home and self-treatment) of patients with these illnesses. Both the efficiency and the safety of this protocol appear to be excellent.

Greenfield, S., Friedland, G., Scifers, S., Rhodes, A., Black, W. L., & Komaroff, A. L. Protocol management of dysuria, urinary frequency, and vaginal discharge. Annals of Internal Medicine, 1974, 81, 452-457.

The authors discuss the design and evaluation of an algorithm used in diagnosing and referring patients with dysuria, frequent urination, and vaginal discharge. The instrument proved useful in terms of saving time, and almost without exception did not lead to treatment or outcome differences relative to individuals treated by a physician.

Greenfield, S., Komaroff, A. L., & Anderson, H. A headache protocol for nurses. Archives of Internal Medicine, 1976, 136(10), 1111-1116.

This report discusses the utility of a nurse-administered protocol designed to aid in the differential diagnosis and treatment of various classes of headaches. A group of patients seen by nurses armed with this protocol were compared with a similar group of patients seen by physicians not aided by the protocol. The groups did not differ in terms of symptom relief, and the group seen by nurses expressed greater satisfaction with the care they had received than did the control group patients.

Kennedy, J. A. Health care in prison: A view from inside. American Journal of Nursing, 1975, 75(3), 417-420.

An ex-inmate and nurse described the attitudes, values, and policies of one prison community and how they affected the health care prisoners received or did not receive.

King, L., Reynolds, A., and Young, Q. Utilization of former military medical corpsmen in the provision of jail health services. American Journal of Public Health, 1977, 67(8), 730-734.

Dr. King describes how utilization of medical corpsmen has been associated with improved rates of medical delivery, infectious disease control, and more appropriate utilization of physician services.

Komaroff, A. L. Protocols for new health practitioners: Implications and experience. In M. Kallstrom & S. Yarnall (Eds.), Design and Use of Protocols. Seattle: MCSA, 1975.

Dr. Komaroff offers a definition of protocols and contrasts the elements of protocols, general guidelines, and standing orders. He also describes use of protocols in specific clinical situations stating benefits and limitations of their use.

Komaroff, A. L., Black, W. L., Hatley, M., Knopp, R. H., Reiffen, B., & Sherman, H. Protocols for physician assistants: Management of diabetes and hypertension. New England Journal of Medicine, 1974, 290(6), 307-312.

Report of a randomized study in which patients on return visits were seen either by a physician or a physician assistant using a protocol. Thirty-seven percent of the patients seen by the assistants over eleven months went home without seeing a physician with physicians accepting the protocol disposition in ninety-four percent of the cases. Patient acceptance was also determined as reflected by their attendance rate at the clinic.

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This chapter elucidates the sequence of operations in protocol use, from design, to implementation, to evaluation, and back to improvement in design.

Litt, I. & Cohen, M. Prisons, adolescents, and the right to quality medical care. American Journal of Public Health, 1974, 64(9), 894-897.

Described in this article is a comprehensive medical program that was established in a teenage detention facility. Although detained for short periods of time, much was accomplished with the youth in terms of prevention and treatment.

Massachusetts Department of Public Health. Prison health services. New England Journal of Medicine, 1974, 290(15), 856-857.

Offered in this article is a discussion of some of the special problems in correctional health care and some changes that have occurred in the Massachusetts Prison Health Project.

McDowell, H. M. Leadership at the cell-block level. American Journal of Nursing, 1975, 75(3), 423-424.

A nurse educator describes her experiences offering in-service education to nursing personnel in a correctional facility.

Murtha, R. Change in one city's system: It started with a director of nursing. American Journal of Nursing, 1975, 75(3), 421-422.

Ms. Murtha describes her experiences as she assumed responsibilities as the Director of Nursing Prison Health Services in New York City.

Newport, J. Review of health services in correctional facilities in the United States. Public Health Reports, 1977, 92(6), 564-569.

This report summarizes a rather extensive examination of health care in this country's penal systems. With few exceptions, the findings were that health services in correctional institutions are sorely lacking in terms of organization, personnel, and facilities. Potentially valuable avenues of improvement, including periodic program evaluation and the use of paraprofessional personnel (e.g., ex-corpsmen) are suggested.

Ptak, A. Replacing pill pushing with nursing. American Journal of Nursing, 1975, 75(3), 427-428.

Mr. Ptak describes his experiences as a nurse in a prison setting including changes he has helped institute to improve health care delivery.

Rector, M. G. Prisons of the future. New York State Journal of Medicine, 1975, 1087-1090.

Presented as a paper to the Medical Society of the State of New York, Dr. Rector discusses his philosophy of corrections and current trends and issues regarding the purpose and usefulness of prisons. Indicating that future prisons will house only dangerous offenders he challenges the medical profession to continue research into methods of identifying those inmates who are "dangerous".

Rowe, D. J. R. Medical and health care services in Canada's federal prisons. Canadian Medical Association Journal, 1978, 118(5), 578-587.

This article describes a recent federally-appointed investigation of health care in Canada's penal system, with the finding that while currently undergoing some improvement, personnel are under-qualified and services are generally inadequate. As a consequence of the investigation, prison health centers are gradually being restaffed by R.N.s.

Sox, H. How to write a clinical algorithm. In M. Kallstrom and S. Yarnall (Eds.), Design and Use of Protocols. Seattle: MCSA, 1975.

Dr. Sox offers step-by-step guidelines to be used in either writing protocols or modifying existing protocols for use in particular clinical settings.

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American Journal of Public Health, 1977, 67(8), 720-722.

Dr. Weisbuch offers a timely and illustrative discussion of the role health professionals must play in both delivery and administration of correctional health care services.

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