PRIMARY CARE EVALUATION:  
A STUDY OF A COMMUNITY CLINIC

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ABSTRACT

This thesis presents a discussion of Primary Care Evaluation using a specific quality of care evaluation as a case study. The nature of Primary Care is discussed and a brief review of quality assessment methodology is presented. The issue of process versus outcome evaluation as it is presented in the literature is discussed.

The study itself is a quality of care assessment undertaken in an urban, multi-disciplinary community family practice clinic. Using an indicator condition approach, and explicit process criteria for chart auditing developed for the Burlington Randomized Control Trail (BRCT), we reviewed randomly selected charts demonstrating episodes of care given in seven specific indicator conditions: otitis media; hypertension; urinary tract infection; care of the newborn (up to 12 months of age); prenatal care; depression; and childhood immunization. The study period was specified as July 1, 1981 to June 30, 1982.

Of the 583 total charts available for study (i.e. charts "active" during the study period), 103 (17.7%) fit the criteria for the indicator conditions chosen. The final study sample represented 8.6% of the 1200 charts randomly selected from the total of 6,923 charts available in the record-room. The work of all seven (5 doctors and 2 nurses) practitioners active during the study period was surveyed.

The 103 charts contained 124 episodes of care in the seven indicator conditions. Interrater reliability was determined and overall agreement between two observers (one physician, one non-physician) was 85%, with agreement beyond chance (KAPPA) of .66.
Overall, 83 (66.9%) of the 124 episodes of care studied were rated adequate or superior, and 33.1% rated inadequate, using the criteria as given. Reinterpretation of the prenatal component, to adjust for episodes which had features of superior and inadequate care increased the proportion of episodes judged adequate or superior to 70.2%. Across the seven indicator conditions the proportion of episodes judged adequate or superior ranged from a low of 33.3% for hypertension to 80.9% for care of the newborn.

Comparison with the results obtained with these seven indicator conditions (using the same criteria) in the two clinic groups studies in the BRCT revealed that the study clinic had a higher proportion of episodes rated adequate or superior than either BRCT clinic group for otitis media and urinary tract infection; had a proportion of episodes rated adequate or superior, which was intermediate between the two BRCT groups, for hypertension, depression, care of newborn, and immunization; and had fewer episodes rated as adequate or superior than either of the two BRCT clinics for prenatal care. In terms of overall proportions of episodes rated adequate or superior, a test of proportions found that the study clinic was not significantly different from either of the BRCT study groups.

The reasons for inadequacy and the implications of these findings for quality assurance activities at the study clinic are discussed.

Finally, the general relevance of process evaluations, such as the one applied at the study clinic, as a policy tool is discussed.
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INTRODUCTION

The purpose of this thesis is to present the results of a quality of care evaluation of a particular care setting - an urban community clinic - in the context of evaluation methodology in general and Primary Care evaluation in particular. Questions had been raised about the quality of care delivered by the study clinic and, because it is directly funded by the B.C. Ministry of Health, it was essential for the clinic to conduct an external objective quality of care evaluation. This is not a dissimilar situation from that facing many organizations who increasingly are required to justify not only what they do, but often their very existence.

With the increasing public concern about the current economic situation, more accountability is being demanded of service providers at all levels from practitioners to policy makers and politicians. Popular "buzz words" these days are "cost containment", "retrenchment", "fiscal responsibility", "financial accountability". Regardless of the validity of the perception that human service costs are "spiralling" and "out of control", nevertheless that is the perception (or at least, the assertion) of many from policy makers, politicians and practitioners to members of the general public. Hence, many social services and programs, which for years have enjoyed a certain immunity from public scrutiny, are now being examined in terms of their efficiency and effectiveness and are being subjected to cost/benefit analyses. As governments at all levels attempt to cope with the task of allocating resources in some rational, just, way, many of their major programs - such as health care services - are obvious targets for evaluation.
Evaluation has been defined as "a social process of making judgments of worth..."\(^1\). While this may appear to be a rather vague, general definition of evaluation, it is in fact extremely useful for it captures the sense that evaluation has more to do with value setting - which is a social/political process - than with making decisions about what is a "worthwhile" service or program based on hard scientific analyses of data, costs, benefits, etc. This latter process is more in the domain of evaluative research which has been characterized as referring "to those procedures for collecting and analyzing data which increase the possibility of proving rather than asserting the worth of some activity"\(^1\). The distinction between evaluation and evaluative research is significant because it may be that some service or program will have its worth asserted for some political or social-value reason, even if there is no conclusive proof that it is in fact worthwhile - i.e. has an impact.

A major part of the evaluation of health care services has been directed at measuring the quality of care delivered, on the assumption that better quality of care leads to better health in the individual and thus, in the population as a whole. Quality of care assessments have long been conducted in hospitals as part of quality assurance programs, in order to meet accreditation requirements. Quality assessment - measuring the quality of care delivered - has only recently been focussed on Primary Care.

This thesis addresses these issues using a quality of care evaluation of a specific Primary Care setting. The format is as follows:

Chapter 1 examines the scope of Primary Care and looks briefly at the impetus for the evaluation of Primary Care.
Chapter 2 focuses on the advancement of evaluation methodology by looking historically at the major conceptual developments and how those concepts were operationalized and applied.

Chapter 3 describes the study setting and the specific method used to conduct the quality of care evaluation.

The results of the study clinic evaluation are presented in Chapter 4; Chapter 5 is a discussion of the study clinic results and the methodology as applied to the study clinic.

Finally, in Chapter 6, the more general policy issues of quality of care evaluations, their feasibility and relevance will be discussed.
INTRODUCTION - NOTES

1.1 What is Primary Care?

Primary Care as a recognized discipline of medicine is a relatively recent development. It was not until 1974 that Index Medicus gave the term the rank of a major subject heading.\(^1\)

Attempts have been made to define what the practice of Primary Care consists of. For example the World Health Organization describes Primary Care in very general terms of almost infinite scope:

Primary health care consists of the advice given to a person or a group of persons for preventative or therapeutic purposes by one or more members of the health or related professions, acting alone or as a team.\(^2\)

On the other hand the British Medical Association attempts to narrow the focus and specify the characteristics of Primary Health Care that distinguishes it from other types of health care:

...primary care deals with the work of the doctor whom the patient first approaches when he wants advice or medical treatment. The discipline of primary medicine is based on a particular synthesis of knowledge drawn from clinical and social (including preventive) medicine, psychology and sociology. The clinical skills of the primary physician should enable him, not so much to attach a diagnostic label as to unravel the undifferentiated, clinical problem, which is often a complex of physical, emotional and social factors, and to take immediate and appropriate action.\(^3\). (emphasis added)

Others have attempted to define Primary Care indirectly by describing the activities of Primary Care providers, for example,
He must be capable of establishing a profile of the total needs of the patient and his family. This evaluation should include social, economic and psychological details as well as the more strictly 'medical' aspects. He should then define a plan of care, deciding which parts are to be carried out by himself and which by others. The plan should have a long-range dimension. It should be understandable to the patient and his family and it should include a follow-up on whether they have been effective\(^4\). (emphasis added)

A textbook on general practice is even more exhaustive on the role of the Primary Care physician:

The general practitioner provides personal, primary and continuing medical care to individuals, families and a practice population, irrespective of age, sex and illness. He will attend his patients in his consulting room and in their homes, and sometimes in a clinic or hospital. His aim is to make early diagnoses. He will include and integrate physical, psychological and social factors in his considerations about health and illness. He will make an initial decision about every problem which is presented to him. He will undertake the continuing management of his patients with chronic, recurrent or terminal illness. He will practice in cooperation with other colleagues, medical and non-medical. He will know how and when to intervene through treatment, prevention and education to promote the health of his patients and their families. He will recognize that he also has a professional responsibility to the community\(^5\). (emphasis added)

What emerges from the above quotations derived from varied sources are the operative words which have been underlined. It is these words which convey the sense of what Primary Care is about.

The word "primary" has the sense of first or basic. As such, according to Stephen\(^6\) it must be accessible and readily available. Access relates to potential barriers to health care. Penchansky and Thomas\(^7\) have discussed the concept of access in terms of five dimensions:

1. **Availability**, the relationship of the volume and type of existing services (and resources) to the clients' volume
and types of needs. It refers to the adequacy of the supply of physicians, dentists and other providers; of facilities such as clinics and hospitals; and of specialized programs and services such as mental health and emergency care.

(ii) **Accessibility**, the relationship between the location of supply and the location of clients, taking account of client transportation resources and travel time, distance and cost.

(iii) **Accommodation**, the relationship between the manner in which the supply resources are organized to accept clients (including appointment systems, hours of operation, walk-in facilities, telephones, services) and the clients' ability to accommodate to these factors and the clients' perception of their appropriateness.

(iv) **Affordability**, the relationship of prices of services and providers' insurance or deposit requirements to the clients' income, ability to pay, and existing health insurance. Client perception of worth relative to total cost is a concern here, as is clients' knowledge of prices, total cost and possible credit arrangements.

(v) **Acceptability**, the relationship of clients' attitudes about personal and practice characteristics of providers to the actual characteristics of existing providers, as well as to provider attitudes about acceptable personal characteristics of clients. In the literature, the term appears to be used most often to refer to specific consumer reaction to such provider attributes as age, sex, ethnicity, type of facility, neighborhood of facility, or religious affiliation of facility or provider. In turn, providers have attitudes about the preferred attributes of clients or their financing mechanisms. Providers either may be unwilling to serve certain types of clients (e.g., welfare patients) or, through accommodation, make themselves more or less available.

In Canada, while the concept of access has been expanded to include the elimination of financial obstacles to obtaining medical care through two federal acts - the **Hospital and Diagnostic Services Act** of 1957 and the **Medical Care Act** of 1966 - which provide for universal comprehensive health insurance for all Canadians, the other dimensions of accessibility still need to be addressed. Geographical distribution of health care resources and physician specialty distribution are two obvious examples.

In that Primary Care represents the first and most basic medical care given, it functions as the point-of-entry into the entire health care system;
referrals to specialist and hospital care are generated at the Primary Care level. In a classic paper entitled "The Ecology of Medical Care", Kerr White and colleagues demonstrated that from a base population of 1000, 250 persons (33% of the 750 "sick") will consult a general practitioner one or more times a month, while only 9 per month (1.2% of the "sick") will be admitted to hospital and 5 per month (0.7% of the "sick") will be referred to another physician (see Figure 1). Clearly the bulk of medical care is delivered by the care giver of first contact. The current terms of "primary", "secondary" and "tertiary" care are easily applied to White's model. The movement of the patient to more intense levels of care - secondary and tertiary - is generally at the discretion of the Primary Care provider (excluding occurrences like hospital admissions through emergency wards). For this reason the Primary Care provider - i.e. the general or family practitioner - has considerable influence on the extent to which the entire health care system is utilized, and therefore, how it evolves. This is particularly true in Canada where conventional medical practice requires that consultation with a specialist is through referral by a family physician.

The Primary Care provider acts not only as the gatekeeper to the entire health care system, controlling the flow of patients to other parts of the system - hospitals, specialists, diagnostic services and laboratories, but also as a guide for the patient through the labyrinth of available care. Tonkin illustrates how confusing the health care system can be to the patient/client (Figure 2). For this reason Titmuss says patients need a family doctor to protect them from the excesses of specialized technocracy: to defend them against narrow-mindedness; and to help them humanely to find their way among the complex maze of scientific medicine.
FIGURE 1 - MONTHLY PREVALENCE ESTIMATES OF ILLNESS IN THE COMMUNITY AND THE ROLES OF PHYSICIANS, HOSPITALS AND UNIVERSITY MEDICAL CENTERS IN THE PROVISION OF MEDICAL CARE (ADULTS SIXTEEN YEARS AND OVER)

1000 - Adult population at risk

750 - Adults reporting one or more illnesses or injuries

250 - Adults consulting a physician one or more times

9 - Adults admitted to hospital

5 - Adults referred to another physician

1 - Adults referred to a University Medical Center

ADAPTED FROM: White, K. et al, The Ecology of Medical Care, NEJM, 1961;265 (18):885
FIGURE 2 - PATIENT MODEL OF HEALTH CARE

... (looks) after people as people and not as problems...
His function is to meet what is really the primary medical need. A person in difficulties wants in the first place the help of another person on whom he can rely as a friend — someone with knowledge of what is feasible but also with good judgement on what is desirable in the particular circumstances, and an understanding of what the circumstances are. The more complex medicine becomes, the stronger are the reasons why everyone should have a personal doctor who will take continuous responsibility for him and, knowing how he lives, will keep things in proportion — protecting him if need be, from the zealous specialist.

However, Cartwright makes the point in referring to the above statement that continuity of care means more than just having the same doctor for several years, referring for example to McKeown's concept of a "medical friend". It is interesting to note that in her study of General Practice in the U.K., Cartwright notes that 87% of the general practitioners interviewed saw their role as "medical friend" encompassing problems other than strictly medical.

In summary, the scope of Primary Care emerges as the first point of contact with the health care system encompassing basic, continuous and comprehensive care.

1.2 Why evaluate Primary Care?

The evaluation of Primary Care would appear to be important from several perspectives. Firstly, since most people's first (and in most cases only)
encounter(s) with the health care system is with a Primary Care provider, from the point of view of the individual patient/client it is essential that this level of care be of the highest quality. Subsequent encounters with the health care system are generally via the Primary Care level, the nature and quality of which are, as noted above, to a significant degree determined by the Primary Care provider.

From the point of view of enhancing the "professional" image, of Primary Care providers, evaluation feeding into Continuing Medical Education is of significant and increasing importance.

Thirdly, since the bulk of medical care occurs at the Primary Care level or is generated at this level, the structure and functioning of the entire health care delivery system is affected by what occurs at this level. An understanding of any health care delivery system must begin with an evaluation and analysis of the activities that comprise Primary Health Care.

Finally, if the bulk of medical care is either delivered or generated at the Primary Care level, then the majority of health care costs are a result of what happens at this level of health care. In the context of a publically funded health care system, it is important from a cost/benefit analysis point of view to know more precisely what occurs at the Primary Care level.

1.3 Thrust for Primary Care Evaluation

The thrust for the evaluation of Primary Care has come from several areas. Evaluations of hospital in-patient care have been in existence in the U.S. for many years under The Hospital Standardization Program and since 1952 under the
Joint Commission on Accreditation of Hospitals (JCAH)\(^\text{18}\). As a result of the requirement for hospitals to conduct evaluations of inpatient care, emergency rooms eventually came under scrutiny. Several studies of emergency room use of large inner-city hospitals indicated that these facilities were more frequently being used by the poor and working classes for the majority of their Primary Care\(^\text{19}\). Evaluation studies of these emergency facilities\(^{19-23}\) indicated, generally, great discrepancies in diagnostic and therapeutic processes and followup, resulting in overall low quality of care, and thereby emphasizing the need to evaluate further the quality of care received by people seeking this kind of medical help.

As a result of these and other evaluation studies indicating low quality of care at the Primary Care level, the focus of the quality issue shifted, in the U.S., to the Health Maintenance Organizations (HMO's) which had emerged in the 1960's as alternative providers of Primary Care. The regulatory requirement for the evaluation of Primary Care originated in the U.S. with the Health Maintenance Organization (HMO) Act of 1973\(^\text{24}\). This Act requires an ongoing quality assurance of ambulatory care on the part of each participating HMO.

Professional Standards Review Organizations (PSRO) were established in the U.S. in 1972 in order to cover the gap left by the JCAH - private office practice. Of the PSRO's, Jonas says

> for the first time a law - with some fairly sharp teeth in it - required peer review of individual instances of physician delivery of medical care\(^\text{16}\).

Initiatives have also come from associations, both institutional and professional. The Accreditation Association for Ambulatory Health Care and the Federal Bureau of Community Health Services requires its voluntary affiliates
to conduct internal quality assurance programs\textsuperscript{24}. The medical profession itself has undertaken a peer review process for the purposes of Continuing Education. Indeed the American Academy of Family Practice requires a certain number of hours of continuing medical education for continued membership\textsuperscript{25}. More recently the American Society of Internal Medicine has proposed that formal review of physician performance in ambulatory care be the basis for renewal of hospital privileges, relicensure, renewal of professional association membership and recertification for specialty practice\textsuperscript{24}.

1.4 How to evaluate Primary Care?

The justification of and regulatory requirement for the evaluation of Primary Care having been established, researchers were faced with the problem of how to accomplish it. The difficulty is compounded by the fact that Primary Care appears to be the area of medical care least well grounded in scientific rationale. For many of the decisions a provider must make, there may exist no hard evidence to guide the decision-making process. The Primary Care provider operates in a context of high diversity and low specificity. S/he is often faced with a wide array of symptomology which must be filtered in order to converge towards some diagnostic outcome. By the time patients reach either a specialist or hospital much of the diagnostic focussing has already been done.

Another difficulty with evaluating Primary Care is that the kinds of problems seen in Primary Care are quite different from those of hospital in-patients; patients with acute life-threatening diseases are rare and care
typically involves acute, self-limited disease, chronic disease, psycho-social problems and preventive care\textsuperscript{24}. Within the context of extremely high volumes, the Primary Care provider must discriminate between substantive and self-limited disease, often in the face of uncertainty and inadequate data. Cartwright\textsuperscript{13} makes a very interesting statement on that point:

Methods of evaluating standards of care need to be developed which count as good care the non-investigation of symptoms which clear up quickly and spontaneously as well as the adequate investigation of conditions which need it.

Palmer and Nesson\textsuperscript{24} have identified four major components of Primary Care:

i) solution of problems patients complain about (e.g. sore throat, earache).

ii) case finding for asymptomatic disease (e.g. hypertension).

iii) application of preventive measures (e.g. pap tests, well baby care, immunization).

iv) management of diagnosed chronic disease (e.g. diabetes mellitus, arthritis).

However, as noted in the opening discussion, Primary Care requires more than competent medical care. It requires, as well, interpersonal skills of clear communication, listening, rapport and support. All of this makes the evaluation of Primary Care an enormous task, much of which has yet to be undertaken. What follows is a review of the developing methodology for the evaluation of Primary Care.


8. *Hospital Insurance and Diagnostic Services Act, April 12, 1957, and Regulations, 5-6 Elizabeth II* (Ottawa: Queen's Printer, 1957)


15. The term "ambulatory care" appears consistently in the literature. One definition given for this term is: "It is personal or combined health care service given to a person who is not a bed patient in a health care institution" [Jonas, S., Ambulatory Care. In Jonas, S. and contributors, Health Care Delivery in the United States (New York: Springer Publishing Company, 1977), p.120.] While the term "ambulatory care" may encompass a greater scope of medical care than connoted by the term "primary care", for the purposes of this discussion these terms will be considered synonymous.


2.1 Early Studies

Evaluation of the quality of medical care in this century goes back to the work of Codman\(^1\) who in 1912 examined the success of surgery one year after operation on the basis of physiological and functional status and mortality. Indeed, much of the early work evaluating the quality of medical care focused on the outcomes of various surgical procedures performed in hospitals\(^2, 3\).

It was not until the mid 1950's, however, that evaluation studies of Primary Care began to emerge. The Health Insurance Plan of Greater New York commissioned an evaluation\(^4\) in terms of prematurity and perinatal mortality rates of prenatal and obstetric care given in different practice settings - group practice versus private fee-for-service. Peterson\(^5\) conducted the first, and to date the only, large scale observational study in the early 1950's of physician care in private practice office settings in North Carolina relating the quality of care rendered to various physician factors such as education, methods of practice, practice setting, etc. His results indicated considerable deficiencies in basic skills. A Canadian study\(^6\) was conducted in the early 1960's using the method developed by Peterson, comparing a practice setting in Nova Scotia with one in Ontario. It arrived at the same conclusions as the Peterson study.

Interest in Primary Care evaluations increased in the late 1960's, particularly after the establishment of neighbourhood health centres in several large North American cities\(^7, 8\), when financial accountability was required
of agencies spending large amounts of money on the urban poor. In the early 1970's, Hulka et al.\textsuperscript{9,10} and Romm et al.\textsuperscript{11} conducted an extensive multifaceted review of private office practice. Their results showed that the best indicator of final health status was initial disease status, indicating a negligible impact of medical care on the health of patients. These results also highlighted one of the difficulties in conducting quality of care evaluations, that is, the selection of components of medical care that can be shown to have a positive effect on the health of the patient. Despite the improvement in evaluation methodology in recent years, this continues to be one of the major limitations of process evaluations.

After the passage of The Health Maintenance Organization Act in 1973, establishing the regulatory requirement for the evaluation of ambulatory care delivered by HMO's, it became imperative to advance the methodology for Primary Care Evaluation. Several conceptual developments were instrumental in defining and clarifying this methodology.

2.2 Development of the Methodology

The earliest efforts to place the evaluation of the quality of medical care within a conceptual framework is represented by the work of Sheps\textsuperscript{12} who outlined three categories of the care system in hospitals that are amenable to evaluation: assumed prerequisites for quality care (facilities organization, staff, standards); elements of the performance of the care provider(s) collectively termed "effort"; and outcome of care or "effect".

Donabedian\textsuperscript{13}, in a paper that remains a classic, refined these categories proposed by Sheps to include three specific areas - structure, process and outcome. The rationale behind these categories is that in general, one can assess or evaluate three broad components of the care system: its
structure, i.e. staffing patterns, numbers of professionals, accessibility, etc.; its process, i.e. procedures done, charting, laboratory tests utilization; and outcome, i.e. improvement in individual health, prevention of sequelae, activities of daily living, etc.

Donabedian is very careful to point out that these categories are not mutually exclusive. Indeed, they are interrelated in very complex ways. In a later paper Starfield\(^1\) illustrated this concept of structure-process-outcome (Figure 3).

In order to conduct evaluations with any kind of generalizability and comparability, standards of care had to be established. Donabedian saw standards as arising in two ways:

(i) **Empirical Standards** - that is standards which derive from actual practice and which generally conform to attainable levels of care. (Presumably these standards are shaped by factors in addition to academic training, such as practice setting, staffing patterns, physician personal characteristics, etc.)

(ii) **Normative Standards** - which Donabedian says derive, in principle, from the sources that legitimately set the standards of knowledge and practice in the dominant medical care system. In practice, they are set by standard textbooks or publications, panels of physicians, highly qualified practitioners who serve as judges or a research staff in consultation with qualified practitioners. Normative standards can be put very high and represent the "best" medical care that can be provided, or they can be set at a more modest level signifying "acceptable" or "adequate" care\(^5\).
FIGURE 3 - DYNAMICS OF HEALTH OUTCOME

STRUCTURE

PERSONNEL
FACILITIES
EQUIPMENT
ORGANIZATION
INFORMATION SYSTEMS
FINANCING

PROVISION OF CARE

PROBLEM RECOGNITION
DIAGNOSIS
MANAGEMENT
REASSESSMENT

PROCESS

PATIENTS

UTILIZATION
ACCEPTANCE
UNDERSTANDING
COMPLIANCE

RECEIPT OF CARE

LONGEVITY
ACTIVITY
COMFORT
SATISFACTION
DISEASE
POTENTIAL
RESILIENCE

SOCIAL AND PHYSICAL ENVIRONMENT

OUTCOME


- 22 -
He distinguishes normative standards from empirical standards saying, 

"...their [normative standards] distinctive characteristic is that they stem from a body of legitimate knowledge and values rather than from specific examples of actual practice. As such, they depend for their validity on the extent of agreement concerning facts and values within the profession or, at least, among its leadership. Where equally legitimate sources differ in their views, judgments concerning quality become correspondingly ambiguous."

The development of normative standards was an important contribution to the advancement of quality of care evaluation methodology. Indeed, the concept of standards of care was not a new one. By the mid-1950's Lembcke had already established the concept of valid care criteria for hospital care. They were to embody the principles of objectivity, verifiability, uniformity, specificity, pertinence and acceptability. Payne later expanded Lembcke's concept to optimal care criteria. Working with panels of specialists he eventually established optimal care criteria for 51 different conditions covering 135 ICDA diagnoses encompassing ambulatory as well as hospital care. The rationale behind the concept of optimal care criteria is to select a few, valid, specific dimensions of care within specified diagnostic categories rather than to conduct general evaluations of unspecified dimensions of care, which is not only imprecise but also marginally instructive in terms of corrective action. This concept is the foundation of the medical audit which Lembcke defines as

the evaluation of medical care in retrospect through analysis of clinical records.
It was the concept of normative standards that established the medical audit as an acceptable evaluation tool. In a more recent paper Sanazaro characterizes the medical audit as having two basic features:

(a) selecting an important element of performance
(b) comparing the observed level of performance with predetermined criteria or standards.

However, Sanazaro outlines several criticisms of the medical audit: first, there is an assumption that there is some relationship between the information recorded in the patient chart and actual quality of care received; second, there is no way of knowing which of the recorded diagnostic or therapeutic procedures is essential; and finally, many studies have shown either weak or no correlations between recorded processes and patient outcomes. These continue to be weaknesses in the medical or chart audit method.

While structure-process-outcome is a useful conceptual model, considerable work was required to operationalize this concept and to provide practical methods of measuring the multiplicity of variables which influence each of these components of care. Recent evaluative studies have greatly enhanced the clarity with which quality of care assessments have been conceived by comparing methodologies.

In particular, Brook and Appel delineated and compared five different peer-review methods of assessing the quality of medical care: implicit process (which resembles Donabedian's empirical standards); implicit outcome; implicit process/outcome combined; explicit process (which corresponds to Payne's optimal care criteria and Donabedian's normative standards); and explicit outcome. The major difference between the implicit and explicit methods was that, for the former, professional judgments were made as to whether...
or not the process of care and/or patient outcomes were acceptable; for the latter actual process items and patient outcomes were compared with preset process criteria and predetermined estimates of acceptable outcomes. Their results showed that for the same patient sample judgments of the quality of care rendered ranged from 63.2% acceptable when implicit outcome judgments were used to 1.4% when explicit process was used. Since explicit process is the method inherent in the external medical audit (although not always used), it is clear that the most widely used evaluation methodology produces the "severest judgments" of quality of care.

Several researchers have conducted evaluation studies in outpatient clinics of large urban hospitals, focussing on the application of preset explicit criteria for diagnostic and therapeutic processes and outcomes. Others have done similar studies in various Primary Care settings such as neighbourhood clinics and private office practices. Several general conclusions can be drawn from these studies: a very low level of care is being provided at considerable cost; because of the lack of adequate patient follow-up, ineffective and/or inappropriate behaviour of physicians (especially young physicians) may be reinforced; diagnostic process is as important as therapeutic process; and finally - perhaps most importantly for the development of evaluation methodology - better links must be established between items of the medical care process and patient outcomes - i.e. explicit process items must be limited to those which have been conclusively demonstrated to have an effect on patient outcome. This last point continues to be the bete noire of quality of care evaluation.

The most notable recent Canadian Primary Care evaluation using explicit process criteria was the Burlington Randomized Controlled Trial conducted by
investigators at McMaster University in Hamilton\textsuperscript{26-28}. While this study was primarily a comparison of the quality of care delivered by nurse practitioner/physician teams and by conventional physicians, it is an excellent example of an applied methodology - i.e. an explicit-process-criteria chart audit. The study had the additional merit in that the researchers also attempted to link patient outcomes to the explicit process care items.

Methods for developing explicit criteria lists have been explored using

(i) textbooks and expert panels\textsuperscript{18,25}

(ii) small groups of practicing physicians\textsuperscript{28,29}

(iii) questionnaires mailed to larger groups\textsuperscript{30}

(iv) a Delphi technique which generates consensus through a feedback of group responses\textsuperscript{31}.

Several other practical difficulties of conducting Primary Care evaluations still needed to be addressed. For instance, it became critical to develop a unit of measurement of care since single visits or procedures are not entirely consistent with the concept of Primary Care. The conceptualization of "episodes of care" by Solon et al\textsuperscript{32,33} encompassing diagnosis, treatment and follow-up for a single presenting complaint provided for a practical unit of measurement. Episodes of care will encompass different time frames for different conditions: for example an episode of care for otitis media may cover 2-4 weeks from the initial diagnosis through to the disappearance of all symptoms; for prenatal care the episode of care includes the entire prenatal period. Episodes of care, however, are more difficult to define for care of chronic conditions, such as hypertension and diabetes mellitus.
It also became important to develop a method for identifying appropriate samples of care without having to assess the care given in every conceivable medical condition. Kessner provided the framework for this by refining and describing the concept of "tracers" or indicator conditions. This was not a new idea; the concept of tracers had been implicit in the work of Williamson and Brook who studied the quality of care delivered in hospital emergency rooms to patients presenting with specific conditions, e.g. gastrointestinal complaints, hypertension and urinary tract infection. Indeed hypertension as a "tracer" condition was used in some of the earliest evaluations of Primary Care done in hospital outpatient clinics and neighbourhood clinics. However, it was not until 1969 that the Institute of Medicine of the National Academy of Sciences focused on the use of tracers.

A tracer in the context of health care is a discrete, identifiable health problem which can be used to analyze the health delivery system. The rationale underlying the tracer method is that how a physician manages certain ailments common to all Primary Care settings will be an indicator of the general quality of care delivered overall. Although controversial, in that questions have been raised about generalizability to overall quality of care when only a few "tracer" conditions are evaluated, the clinical breadth of the conditions chosen and their representativeness in specific clinic settings can be determined, and the number and kind of "tracer" conditions adjusted accordingly for each care setting. For example, if prenatal care comprises a large bulk of the care given in a specific care setting, an evaluation of that clinic would most appropriately assess more prenatal care than (say) care of
hypertension. The ideal would be to evaluate the care given in selected indicator conditions in the proportions in which they make up the care load. Tracers are an important addition to the chart audit method which is primarily a measurement of the activities of health professionals. Therefore, a tracer condition should most importantly be one for which the management of care has an impact on health outcome. For that reason conditions unlikely to be treated and those that cause negligible functional impact are not useful. Tracer conditions should also be easily defined, be reasonably prevalent, and be those for which there are well established minimal standards of care.

Kessner gives guidelines for the development of criteria for treating tracer conditions

We believe criteria for treating the tracer conditions could avoid rigidity if they were formulated on three premises: they should outline minimal, or base-line, care; they should be pragmatic, taking into account unavailability of sophisticated diagnostic equipment; and they should be periodically revised and updated.34

In summary, the concepts of structure-process-outcome, implicit/explicit process/outcome, episodes of care and tracer conditions represent the major conceptual stepping stones in the developing methodology for the evaluation of Primary Care. Much of the recent work has been concerned with the application of these concepts in field studies7,11,20,23-26,31. Several important issues have arisen out of these field studies including:
(i) what is quality in medical care?

(ii) process versus outcome evaluations.

(iii) the emergence of patient characteristics—compliance, satisfaction, health belief, health status as important components for evaluation.

A brief discussion of these issues follows.

2.3 What is quality in medical care?

Any evaluation of the quality of medical care is necessarily based on a conceptualized and operationalized—however implicit—definition of "quality".

One of the earliest definitions of quality care was written by Lee and Jones:

Good medical care is the kind of medicine practiced and taught by the recognized leaders of the medical profession at a given time or period of social, cultural, and professional development in a community or population group.

They base their concept of quality on what they call certain "articles of faith":

1. Good medical care is limited to the practice of rational medicine based on the medical sciences.
2. Good medical care emphasizes prevention.
3. Good medical care requires intelligent cooperation between the lay public and the practitioners of scientific medicine.
4. Good medical care treats the individual as a whole.
5. Good medical care maintains a close and continuing personal relation between physician and patient.
6. Good medical care is coordinated with social welfare work.
7. Good medical care coordinates all types of medical services.
8. Good medical care implies the application of all the necessary services of modern scientific medicine to the needs of all the people.

Given that this was written in 1933, these statements are remarkably enlightened in their presentation of a "holistic" approach to medical care.

Rather than being positivist statements as to what quality medical care is, these
"articles of faith" are really normative statements as to what it should be. Donabedian points out they are nothing more than value judgments that are applied to several aspects, properties, ingredients or dimensions of a process called medical care. As such, the definition of quality may be almost anything anyone wishes it to be, although it is, ordinarily, a reflection of values and goals current in the medical care system and in the larger society of which it is a part.

Definitions of quality have, by and large, been left up to the providers, i.e. physicians; have, for the most part, been equated with technical standards of care (implicit in the search for explicit process criteria is the search for quality care); and have been employed primarily through peer review.

The major problem with defining "quality" in health care is that the definition depends almost entirely on who is doing the defining and at what "level of concern" their definition comes from. At the individual patient-provider level, "quality" may indeed be defined most appropriately in terms of technical medical standards of care, with the addition of psychosocial skills such as rapport, counselling, listening, etc. At the level of the health care delivery system, the concept of quality expands to include continuity, comprehensiveness and access. Finally, at the level of society as a whole, "quality" most certainly is associated with issues of not only access, but also more importantly the equitable allocation of health care resources - human, physical, technological and financial - which, of course, directly affects access.

Havighurst and Blumstein take the discussion of quality in medical care a step further, with their argument that whoever controls the definition of
need (as opposed to demand) for health services also controls the definition of quality. They say that it is the health care providers who have controlled the definition of need and that conflict arises with those responsible for allocating resources because

....need is defined in terms of what is technically feasible, without specific regard to dollar cost, a resource-allocation problem is sharply presented. In fact, need appears to be the standard by which "quality of care" is evaluated: any failure to meet professionally defined needs is ipso facto inadequate quality41.

Clearly, following from this argument, as non-medical professionals have and do become more influential in the health care field - planners, policy-makers, administrators, health economists, and practitioners other than physicians - the definition of need and hence, quality has expanded and become more complex and will continue to do so.

Donabedian very succinctly pointed out that the major difficulty with what he calls the "multipartite nature of quality" is

that of determining the degree to which there are internal conflicts or incompatibilities among the various components. This implies that the achievement of quality in one component of care may be associated with a tendency to deterioration in another. Is it possible, for example, that technical excellence may tend to be associated with fragmentation and impersonality of care? If this were true, special attention might need to be directed, in the process of appraisal, to those dimensions of quality that appear to be in conflict. Such possibilities also have important implications for the organization of service. Services ought to be organized so as to minimize such conflicts. In some situations it may be difficult to achieve comparable levels of excellence in all components of care. Priorities may need to be set up and difficult choices may have to be made42.
2.4 Process vs Outcome Evaluation

Much debate has gone on in the literature\textsuperscript{15,36,43-47} in the last ten years around the question of whether process or outcome evaluations of the quality of medical care are more valid, reliable and feasible\textsuperscript{48}.

It is generally accepted that the underlying goal of any health care system is the maintenance/improvement of the health status/health outcome of the individual/population. But health outcome is an extremely difficult entity to define let alone measure\textsuperscript{49}. As Brook\textsuperscript{36} points out:

- Measurement of outcome necessitates measurement of "health" itself, or some aspect of it.

He goes on to delineate the problems of assessing health outcome even when outcome measures are developed:

- (i) The outcomes most frequently used, such as death or incidence of major complications, may be so uncommon that detection of significant differences in these outcomes between patient groups requires a sample so large that the feasibility of the study is limited.

- (ii) "Ultimate" outcomes or end results such as death or restoration of normal function often occur so late in the course of treatment that timely evaluation is impossible.

- (iii) Such commonly used measures as mortality or return to function are heavily influenced by intervening factors such as genetic makeup and the physical and social environment that are beyond the control of the medical care system.

- (iv) Information about many outcomes is not readily available or contained in the patient's medical record, requiring the use of follow-up interviews. These are expensive to conduct and may be difficult to complete for the entire patient population.

- (v) Information on the breadth of the outcome criteria that should be used in assessing quality of care is absent. Should outcome assessment be limited to physical and physiologic measures, or should it include psychological measures such as sexual function following a radical mastectomy for breast cancer?
And finally he summarizes:

In summary, there exists a paradoxical situation in which policy demands that operational quality assurance systems use the outcome method to assess quality of care, while there is a dearth of valid and reliable outcome criteria and standards and no method of proven feasibility by which they can be applied.

In contrast, process criteria are well developed, although Brook says their validity has not been adequately tested. The underlying assumption, of course, in conducting process evaluations is that outcome is linked to process – i.e. good process will result in a good outcome. The immediately obvious weakness in this assumption, as noted above, is that outcome may be affected by a myriad of other factors – genetics, health belief, compliance, health status, the social/political/economic climate – so that "good" process may in fact lead to "poor" outcome, or a "good" outcome may result from a "poor" process. Many studies have been done specifically on the linkage between the process of care and patient outcomes, with variable and not universally accepted results. Establishing positive associations between process and outcome variables is the next major step in the developing methodology of quality of care evaluations. Process variables, which are easier to define and measure, if clearly linked to patient outcomes could then be used as surrogate measures for outcome variables.

Aside from the problem of linkage between process and outcome, one of the major practical problems with conducting process evaluations is their reliance on the patient chart for data. Questions have been raised as to the validity and reliability of this data source. Patient charts are not only often illegible and highly idiosyncratic but also there is no way to verify that
what has been recorded as having been done has actually been done. There is no evidence that computerized medical records eliminate this basic limitation of the chart audit. Typically, however, process evaluations are easier and cheaper—therefore, perhaps more feasible—to conduct. In that process evaluations are basically a measure of the activities of health care providers, they indicate very little about patient characteristics.

2.5 Patient Characteristics

In the last ten years, with the emphasis on prevention and health promotion, there has been a growing interest in studying patient characteristics that may affect health outcome. Studies have been done on compliance with treatment, satisfaction with treatment, health belief and health behaviour and finally on developing health profiles on self-perceived health status.

Certainly these studies are valuable in completing the picture of Primary Care. However, they do not really help if the object is to measure and assess the activities of health care providers. Kessner is very quick to point out the difference between health outcome and health status:

Outcome refers to the effect of medical care on the patients health, whereas (health) status may be affected by genetic, social, cultural and economic factors.

If the question of interest is about the ability of the health care system to deliver services in an efficacious way, then process and outcome studies are relevant. If, however, the question of interest is the nature of health itself and how to quantify, measure and facilitate it, then the studies on patient characteristics above are most relevant and provocative.
2.6 **Summary**

Two themes emerge from the preceding discussion:

1. The major conceptual developments in the evolving Primary Care Evaluation methodology -
   (i) structure - process - outcome
   (ii) implicit/explicit process/outcome criteria
   (iii) episodes of care
   (iv) "tracer" or indicator conditions

2. The on-going difficulties of adequately evaluating Primary Care -
   (i) the often spurious relationship between certain items of the medical care process and patient outcome
   (ii) the difficulty of defining "quality"
   (iii) the emergence of patient characteristics as components of the care process

The next three chapters describe and analyse a quality of care evaluation conducted in a specific Primary Care setting - an urban community clinic - within the context of these themes.
CHAPTER 2 - NOTES

1. Codman, E.A., A Study in Hospital Efficiency As Demonstrated by the Case Report of the First Five Years of Private Hospital, Thomas Todd Co., (Boston), 1918.


- 36 -
12. Sheps, M.C., "Approaches to the Quality of Hospital Care." Public Health Reports, 1953; 70: 877-886.

13. Donabedian, A., Evaluating Quality of Medical Care. Milbank Memorial Fund Quarterly, 1966; XLIV.


40. Recent developments in Canada with respect to the Federal Government's proposed policy on funding to provinces who allow physician extra-billing and hospital user charges highlights this issue. That the Honourable Monique Begin considers the issue of "access" as coming under her mandate is illustrated by the following quote from the Canada Health Act White Paper - Draft-2

Proposed definition [of access]

Accessibility refers to the provision of reasonable access to insured services for each resident of Canada. Reasonable access means that insured persons should be assured of adequate quantity, quality and distribution of insured health services on a prepaid basis, unimpeded by financial barriers. (emphasis added)


42. Donabedian, A., op.cit., note 37, p.10.


44. McAuliffe, W.E., Measuring the Quality of Medical Care: Process versus Outcome. Milbank Memorial Fund Quarterly, 1979; 57 (1): 118.


48. Validity - refers to the extent to which a measure actually measures what it purports to measure. 
Reliability - refers to the repeatability of a measure. 
Feasibility - refers to the ease or practicality of measurement.

49. For a concise depiction of some current outcome concepts see Brook, R.H., op.cit., note 36, Chapter III, Table 5.


52. Studney, D.R., personal communication, September, 1983.


CHAPTER 3
Study Clinic: The Methodology

3.1 Study Setting:

The Reach Community Clinic (hereafter referred to as Reach) is a non-profit society, funded by the B.C. Ministry of Health, and responsible to a Board of Directors elected by members of the society. The Clinic began in 1969 in a converted fruit and vegetable shop as a joint project of residents in the Grandview-Woodlands area (mainly through the Area Council) and the UBC Department of Pediatrics under Dr. Sydney Israels. Dr. Roger Tonkin was the organizer and first Executive Director of Reach.

Reach is situated on the East side of Vancouver in a multi-cultural, multi-racial, residential and light industrial area. Services provided include a medical clinic, a dental clinic and various community programs such as Pregnant Teen Program and a multi-cultural preschool program. Staff of the medical clinic include: 5 part-time salaried physicians (4 Full Time Equivalents), one of whom is the Medical Coordinator; 2 nurse practitioners (B.Sc.N.); 2 clinical coordinators (LPN); 1 pharmacist; 1 nutritionist; and 3 medical receptionists. Physical facilities include: 8 offices, 1 laboratory; 1 pharmacy; and a large reception area, which houses the records. The medical clinic averages approximately 1500 patient contacts a month.

Reach represents a unique alternative for the provision of Primary Care services, the majority of Primary Care in B.C., indeed in Canada, being delivered in private practice office settings. Other community clinics similar to Reach (although with different origins) include the James Bay Community
Clinic in Victoria, the Houston Community Clinic near Terrace and the Massett Community Clinic in the Queen Charlotte Islands.

3.2 Initiation of the Study

In September 1982, members of the Reach Clinic staff, representing the Board of Directors, approached Dr. Sam Sheps, of the Department of Health Care and Epidemiology, U.B.C., to discuss the possibility of conducting a quality of care assessment at the Reach Clinic. Further discussion over the ensuing weeks established that such an assessment was feasible, and in October 1982, a letter of agreement was signed stipulating the overall research approach, the responsibility of the researchers and Reach Clinic staff and Board, and the schedule for completing the assessment. (Appendix I)

The study described below was planned and carried out over the five month period, November 1982 - March 1983.

3.3 Selection of an Approach for the Reach Study:

After reviewing the literature, it was felt that the Burlington Randomized Controlled Trial (BRCT)\(^2\) represented a good model upon which to base the Reach Clinic Study. As mentioned in Chapter 2 the BRCT was designed to compare the quality of care delivered by nurse practitioner/physician teams (the Randomized Nurse Practitioner [RNP] group), care delivered by conventional family practice - a physician with an office nurse (the Randomized Control [RC] group), and care delivered by two conventional family physicians practising in close association with each other (the Community Control [CC] group). All three study groups were in Primary Care office practice settings. The method used was the application of preset explicit-process criteria to ten (10) indicator conditions, prescriptions of thirteen (13) drugs and referral decisions. The
evaluation was accomplished through a prospective chart audit in which information was abstracted from patient charts and judgments made as to the adequacy of care on the basis of the preset care criteria. The BRCT also examined patient outcomes in terms of physical, emotional and social function one year after care was received.

The BRCT model was chosen because in the first place, the BRCT used a practice setting very similar to that found at Reach, particularly with regard to the fact that both study settings employed nurse-practitioner/physician teams. Functionally, the operation of Reach resembles the RNP group, in that much of the preventive care, such as birth-control counselling, well-baby care, etc. is managed by the nurse-practitioners. Secondly, the BRCT employed explicit process criteria covering all aspects of care (i.e. diagnostic, therapeutic, and follow-up). Thirdly, a reasonable variety of indicator conditions were chosen for assessment; thus a number of general aspects of care could be evaluated. Fourth, the explicit process criteria developed for the BRCT were generated by family practitioners, not academic physicians. Fifth, the BRCT was undertaken in a Canadian context, and thus many general medical care issues (e.g. financing) would be similar to the Reach situation. Finally, the results of the BRCT provided an external comparison, based on identical case definition and criteria for assessment, with the results obtained in the Reach Study.

The method used was a retrospective randomized chart audit, using explicit process criteria developed by Sibley et al for the BRCT. The clinical staff at Reach were asked to submit a list of the conditions judged to be the most frequently encountered. This list was compared to the conditions included
in the BRCT and the following seven indicator conditions were chosen: otitis media, hypertension, prenatal care, care of newborn, immunization up to 24 months, depression, and urinary tract infection (UTI). Three indicator conditions used in the Burlington Randomized Trial — knee injury, pityriasis, and anemia — were not included in the present study because the Reach staff indicated these were infrequently encountered.

The seven indicator conditions chosen are also relevant in that they fall into four categories of care considered to be typical of all Primary Care:

1. Care of acute infectious disease: otitis media, UTI.
2. Preventive/wellness care: prenatal care, care of newborn, immunization up to 24 months.
3. Care of chronic diseases: hypertension, UTI
4. Care of psycho-social conditions: depression.

A pre-study chart survey of 50 randomly selected charts indicated that approximately 16% of the Reach charts recorded at least one episode of one of the seven indicator conditions chosen.

3.4 Study Period

The study period, July 1, 1981 to June 30, 1982 was chosen because it represented recent care given during a period of consistency in staffing. Prior to and after the study period staffing changes occurred and it was felt after discussion with the Reach Staff that it was important to undertake the evaluation during a period when staffing was stable. Also this study period represented care given at a time well before the initial plans for the study
were discussed; thus no bias in either practice or recording could have occurred.

3.5 Chart Selection

The number of charts at Reach as of November 22, 1982 totalled 6,923; charts are numbered in a chronological order according to the date of the patient's first visit to Reach (so that the newest patient will have the highest chart number), and are cross-referenced to names of patients on a cumulative alphabetized patient list. Each patient on this list was assigned a number from 1 to 6923 in alphabetical order. 1800 random numbers between 1 and 6923 were generated using a Random Number computer program and charts of those patients for whom a random number occurred were selected for study. Charts were reviewed for eligibility in groups of 200 proceeding through the cumulative patient list in alphabetical order. The original intention was to study 1800 charts but, because there was no way to identify which charts contained episodes of specific complaints or diagnoses, the chart selection process took longer than expected and, therefore, time constraints necessitated reducing this number to 1200. An analysis of each group of 200 charts indicated that there was no alphabetical bias in terms of the distribution of diagnostic or chart categories. Thus the reduction in the number of charts studied did not bias the selection process.

Eligible charts are those in which at least one episode of care occurred within the study period. This definition, however, may include care given before or after the study period. For example, if the last (first) prenatal visit occurred within the study period, the entire course of prenatal care was
evaluated, even though the bulk of care may have occurred prior to (after) the study period.

Ineligible charts were defined as follows: 1) Transient - any visit without any follow-up visit is considered by Reach to be a transient visit; 2) Inactive - a chart with the last recorded visit prior to September 1980 was considered by Reach to be inactive; 3) Time ineligible - these are active charts, but no recorded visit occurred within the study period (this also includes charts in which recorded visits started after July 1, 1982); 4) Condition ineligible - charts in which none of the recorded visits occurring within the study period were for one of the seven indicator conditions.

3.6 Abstraction of Data

Information was abstracted from the study eligible charts using abstract sheets developed by Sibley et al for the BRCT. For each condition a clear definition of an episode of care was provided. Care of the newborn and immunization were assessed in the same charts, although on separate occasions in order to minimize bias.

Judgments of the quality of care rendered for each episode of care studied were made according to explicit process criteria and definitions of "superior", "adequate" and "inadequate" care developed for the BRCT. A complete set of abstract sheets, explicit process criteria and judgment category requirements for each indicator condition studied appear in Appendix II.

3.7 Validity and Reliability:

Validity: The criteria for the BRCT were developed by a "Peer Advisory Group" of three family practice physicians, representing a range of community and academic experience, specifically to reflect community rather than
academic standards of care. Analysis in terms of internal consistency, comparison with external mortality and morbidity data and patient outcomes, suggest that the criteria are valid for the evaluation of primary care. While these criteria may differ from those considered necessary or sufficient by other physicians, time did not permit either the development of specific criteria or a reworking of the BRCT criteria for the Reach study, or a review of the BRCT criteria by the Reach clinical staff. However, process criteria developed elsewhere do provide an objective external quality of care measure (the BRCT results) against which to compare the care delivered at Reach.

**Reliability:** A pilot study to assess the reliability of the abstraction process was undertaken on 32 charts at the Family Practice Unit at the University of British Columbia. This produced an overall agreement of 81% (KAPPA = 0.62) between the two investigators (one physician, one non-physician). KAPPA is a mathematical method of determining the amount of agreement occurring beyond that expected by chance. Lardis and Koch state that KAPPA values between 0.61 and 0.80 indicates substantial agreement beyond that expected by chance, with values over 0.80 indicating essentially perfect agreement.

A second reliability study was conducted on the Reach charts using a randomly chosen sample of 34 (27.4%) of the 124 episodes of care, resulting in an overall agreement of 85% (KAPPA = 0.66) between the two investigators. This reliability study also revealed that the physician investigator tended to be the more severe judge: all of the five episodes of care in which there was disagreement were rated by the physician as inadequate and most of these were for care of the newborn. (See Appendix III for the determination of KAPPA values)
CHAPTER 3 - NOTES

1. Reach Community Clinic, _Eleven Years at Reach_ (Vancouver: Reach Community Clinic, 1970)
   for a more detailed review of the history and development of Reach Clinic see:


CHAPTER 4

Study Clinic: Results

4.1 Results of Chart Selection

The results of the chart selection process are shown in Figure 4. Of the 1200 randomly selected charts, only 103 (8.6%) were eligible for study. However, of all the charts considered to be time eligible (583), because one or more visits were recorded within the study period, 103 (17.7%) were condition eligible, in that these visits were for one of the indicator conditions chosen. Table 1 shows the number of episodes of care in each indicator condition and the distribution of these episodes in terms of the total number of time eligible and study eligible charts. Column 2 indicates that overall, 21% of the care delivered at Reach was sampled and that of all conditions seen at Reach about 5% are otitis media, about 4% are prenatal, etc.

As indicated in Column 3, of the 124 episodes of care evaluated, 25% were for otitis media, 7.3% were for hypertension, etc.

4.2 Reach Clinic

Table 2 shows the distribution of the quality of care judgements at Reach for the indicator conditions individually and overall. The results for prenatal care require further explanation. Some of the charts which were judged as inadequate on the basis of the strict criteria, also showed features of superior care. Where only one feature of the strict criteria was not met (e.g. missed one urinalysis) it was felt that a modification of the judgement from inadequate to adequate was justified if the rest of the chart was judged superior. These adjusted scores are shown in parentheses.
It is clear from the totals in Table 2, that there was an almost equal distribution among the three judgement categories when overall quality of care is considered: 1/3 of the care was judged superior; 1/3 adequate; and 1/3 inadequate. However, Column 3 of Table 3 indicates that the range of adequate or superior care was from 33.3% for hypertension to 80.9% for care of newborn.

4.3 Comparison of Reach Clinic with BRCT

Table 3 also shows the comparison between Reach and the two groups studied in the BRCT, a "randomized nurse-practitioner (RNP) group" comprised of nurse-practitioner/physician teams, and a "community control (CC) group", comprised of a conventional family practice.

As can be seen, for some indicator conditions Reach achieved a higher proportion of adequate or superior care than either of the BRCT groups -- i.e. otitis media, and UTI; for some the Reach score was lower -- prenatal; and for the rest the Reach score was between the RNP and CC groups -- hypertension, depression, care of newborn, and immunization. Overall, the Reach score for adequate or superior care was between that of the RNP and CC groups: 66.9% (adjusted - 70.2%) as compared to 70.5% and 59.8% respectively. The standard error of the mean for this sample of episodes of care (66.9%) is ± .038. Thus if different samples of 124 episodes of care were taken for the indicator conditions studied the overall proportion judged adequate or superior would be likely to lie between 59.3% and 74.5%.

A test of proportions (Table 4) showed that while the difference between the RNP and CC scores was significant, (z = 2.052, p = 0.04), we failed to find a significant difference between the Reach score and either the RNP score (z = 0.140, p = 0.52), or the CC score (z = 1.276, p = 0.20). This was true for both
unstandardized and standardized data.

4.4 Reasons for Inadequacy at Reach Clinic

Table 5 lists reasons for an episode of care receiving a judgement of inadequacy. Note that there are a total of 48 reasons for judging episodes of care as inadequate, thus some episodes had more than one reason.

In order to explore the data for patterns of inadequacy, the primary care categories, as noted above have been adapted (combining the four categories discussed by Palmer and Nesson into three categories), and specific clinical-functional areas (history-taking; physical exam; laboratory data; and management) which describe specific components of care have been delineated. The distribution of reasons for inadequacy along these two dimensions is presented in Table 6.

As can be seen, omissions of patient management accounted for nearly 50% of all of the reasons for inadequacy, being almost equally divided between acute infectious disease care and preventive care. Laboratory omissions, although accounting for only 18.8% of all of the reasons for inadequacy, represented 31% (9/29) of the omissions in preventive care, all of these occurring in prenatal care. Physical exam omissions were seen primarily in preventive care, but also in chronic disease care, while omissions in history-taking were strikingly concentrated in chronic disease care (5/7 = 71%).

Examining categories of Primary Care, it can be seen that the rate of omissions per 100 episodes is highest for chronic disease (50/100 episodes), although this figure is only somewhat higher than seen for preventive care.
(43.3/100 episodes). Care of acute infectious diseases has the lowest rate of omissions (26.8/100 episodes).
Figure 4
Details of Chart Selection

6923 Total No. Charts

1200 Randomly Selected (17.3%)

1097 Total Ineligible Charts (91.4)

75 Transient (6.3%)
300 Inactive (25.0%)
242 Time Ineligible (20.2%)
480 Condition Ineligible (40.0%)

103 Eligible (8.6%)

\[
\frac{\text{Study eligible charts}}{\text{Time eligible charts}} = \frac{103}{103 + 480} = \frac{103}{583} = 17.7\%
\]

*Transient - walk-in visit only.
Inactive - no visit recorded after September 1980.
Time Ineligible - no visit in study period July 1, 1981 to June 30, 1982.
Condition Ineligible - no episode of any of the seven indicator conditions within study period.
TABLE I

Distribution of Time and Condition Eligible Episodes
Reach Clinic Study

<table>
<thead>
<tr>
<th>Indicator Condition</th>
<th>No.</th>
<th>% Time Eligible (583)</th>
<th>% Study Eligible (124)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otitis Media</td>
<td>31</td>
<td>5.3</td>
<td>25.0</td>
</tr>
<tr>
<td>Hypertension</td>
<td>9</td>
<td>1.5</td>
<td>7.3</td>
</tr>
<tr>
<td>Prenatal</td>
<td>23</td>
<td>3.9</td>
<td>18.5</td>
</tr>
<tr>
<td>Care of Newborn</td>
<td>21</td>
<td>3.6</td>
<td>16.9</td>
</tr>
<tr>
<td>Immunization</td>
<td>23</td>
<td>3.9</td>
<td>18.5</td>
</tr>
<tr>
<td>Depression</td>
<td>7</td>
<td>1.2</td>
<td>5.6</td>
</tr>
<tr>
<td>UTI</td>
<td>10</td>
<td>1.7</td>
<td>8.1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>124*</td>
<td>21.1</td>
<td>99.9</td>
</tr>
</tbody>
</table>

* All 21 Care of Newborn charts were also eligible for the Immunization category raising the total episodes of care studied from 103 to 124.
### TABLE II

Number of Episodes of Care Assessed and Judgment of Adequacy by Indicator Condition

Reach Clinic Study

<table>
<thead>
<tr>
<th>INDICATOR CONDITION</th>
<th>TOTAL NO. CASES</th>
<th>SUPERIOR #</th>
<th>%</th>
<th>ADEQUATE #</th>
<th>%</th>
<th>INADEQUATE #</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otitis Media</td>
<td>31</td>
<td>17</td>
<td>54.8</td>
<td>7</td>
<td>22.6</td>
<td>7</td>
<td>22.6</td>
</tr>
<tr>
<td>Hypertension*</td>
<td>9</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>33.3</td>
<td>6</td>
<td>66.7</td>
</tr>
<tr>
<td>Prenatal**</td>
<td>23</td>
<td>11</td>
<td>47.8</td>
<td>0(4)</td>
<td></td>
<td>12</td>
<td>52.2</td>
</tr>
<tr>
<td>Care of Newborn</td>
<td>21</td>
<td>13</td>
<td>61.8</td>
<td>4</td>
<td>19.1</td>
<td>4</td>
<td>19.1</td>
</tr>
<tr>
<td>Immunization*</td>
<td>23</td>
<td>-</td>
<td>-</td>
<td>17</td>
<td>73.9</td>
<td>6</td>
<td>26.1</td>
</tr>
<tr>
<td>Depression*</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>5</td>
<td>71.4</td>
<td>2</td>
<td>28.6</td>
</tr>
<tr>
<td>UTI</td>
<td>10</td>
<td>1</td>
<td>10.0</td>
<td>5</td>
<td>50.0</td>
<td>4</td>
<td>40.0</td>
</tr>
</tbody>
</table>

* No superior category for these indicator condition.

** Numbers in parentheses represent adjusted scores. See results section for explanation.
TABLE III - Comparison of Number of Episodes of Indicator Conditions and Percentage Scored Adequate or Superior Between Reach Medical Clinic and the Burlington Randomized Controlled Trial Randomized Nurse Practitioner (RNP) Group and Community Control (CC) Group.

<table>
<thead>
<tr>
<th>INDICATOR CONDITION</th>
<th>BURLINGTON RANDOMIZED CONTROL</th>
<th>REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RNP</td>
<td>CC</td>
</tr>
<tr>
<td></td>
<td>#</td>
<td>%</td>
</tr>
<tr>
<td>Otitis Media</td>
<td>39</td>
<td>74</td>
</tr>
<tr>
<td>Hypertension</td>
<td>9</td>
<td>56</td>
</tr>
<tr>
<td>Prenatal Care</td>
<td>13</td>
<td>77</td>
</tr>
<tr>
<td>Care of Newborn</td>
<td>17</td>
<td>71</td>
</tr>
<tr>
<td>Immunization</td>
<td>10</td>
<td>90</td>
</tr>
<tr>
<td>Depression</td>
<td>37</td>
<td>81</td>
</tr>
<tr>
<td>UTI</td>
<td>24</td>
<td>42</td>
</tr>
<tr>
<td><strong>TOTALS</strong></td>
<td><strong>149</strong></td>
<td><strong>70.5</strong></td>
</tr>
</tbody>
</table>

+ These results are taken from Table 1 of the BRCT.12

* Adjusted Score - see results section for explanation.
Table IV

Comparison of Overall Judgment of Adequacy Between BRCT Groups and Reach Clinic Using Standardized * and Unstandardized Episode Frequencies

<table>
<thead>
<tr>
<th>BRCT</th>
<th>% Episodes Judged Adequate or Superior*</th>
<th>Test of Proportions</th>
<th>Reach Clinic (N=124)</th>
<th>Test of Proportions</th>
<th>Reach/RNP</th>
<th>Reach/CC</th>
</tr>
</thead>
<tbody>
<tr>
<td>RNP</td>
<td>70.5</td>
<td>2.05</td>
<td>0.04</td>
<td>66.9</td>
<td>0.14</td>
<td>0.52</td>
</tr>
<tr>
<td>CC</td>
<td>59.8</td>
<td></td>
<td></td>
<td></td>
<td>1.28</td>
<td>0.2</td>
</tr>
<tr>
<td>Unstandardized Data</td>
<td>73.2</td>
<td>3.26</td>
<td>0.001</td>
<td>66.9</td>
<td>1.13</td>
<td>0.25</td>
</tr>
</tbody>
</table>

* Frequencies for episodes found in the Reach Sample was used as the standard and BRCT frequencies adjusted accordingly.

* Proportions of charts rated adequate or superior as found in the BRCT were applied to adjusted episode frequencies.


<table>
<thead>
<tr>
<th>Indicator Condition</th>
<th>Total No. Episodes</th>
<th>Inadequate No. Episodes</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otitis Media</td>
<td>31</td>
<td>7</td>
<td>6 - no return visit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>*1 - previous drug sensitivity</td>
</tr>
<tr>
<td>Hypertension</td>
<td>9</td>
<td>6</td>
<td>4 - no family or personal history</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 - no repeat B.P. within 3 months</td>
</tr>
<tr>
<td>Prenatal (using strict criteria)</td>
<td>23</td>
<td>12</td>
<td>**9 - missed one or more urinalysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4 - no pelvic assessment when indicated</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4 - less than required no. of visits</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 - no DMP</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 - no complete physical within one year</td>
</tr>
<tr>
<td>Care of Newborn</td>
<td>21</td>
<td>4</td>
<td>3 - missed one or more weights</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 - immunization not up to date</td>
</tr>
<tr>
<td>Immunization</td>
<td>23</td>
<td>6</td>
<td>4 - no DTP booster</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 - only 2 DTP</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 - no notation re any immunization</td>
</tr>
<tr>
<td>Depression</td>
<td>7</td>
<td>2</td>
<td>1 - no family history</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 - no complete physical within one year</td>
</tr>
<tr>
<td>UTI</td>
<td>10</td>
<td>4</td>
<td>4 - no return visit for assessment and follow-up urinalysis</td>
</tr>
<tr>
<td><strong>TOTALS</strong></td>
<td><strong>124</strong></td>
<td><strong>41</strong></td>
<td><strong>48</strong></td>
</tr>
</tbody>
</table>

* Antibiotic prescribed where previous sensitivity to it had been noted.
** Some charts had more than one reason for inadequacy.
### TABLE VI

#### Distribution of Reasons for Inadequacy by Indicator Condition and Component of Care Category

Reach Clinic Study

<table>
<thead>
<tr>
<th>Category*</th>
<th>Indicator Condition</th>
<th>History</th>
<th>Physical Exam</th>
<th>Lab</th>
<th>Management</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute Infectious Disease:</strong></td>
<td>Otitis Media</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>UTI</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Subtotal</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td><strong>Preventive Care:</strong></td>
<td>Prenatal Care</td>
<td>1</td>
<td>5</td>
<td>9</td>
<td>4</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Care of Newborn</td>
<td>-</td>
<td>3</td>
<td>-</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Immunization</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Subtotal</td>
<td>1</td>
<td>8</td>
<td>9</td>
<td>11</td>
<td>29</td>
</tr>
<tr>
<td><strong>Chronic Disease:</strong></td>
<td>Hypertension</td>
<td>4</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Depression</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Subtotal</td>
<td>5</td>
<td>3</td>
<td>-</td>
<td>-</td>
<td>8</td>
</tr>
<tr>
<td><strong>TOTALS #</strong></td>
<td></td>
<td>7</td>
<td>11</td>
<td>9</td>
<td>21</td>
<td>48</td>
</tr>
<tr>
<td><strong>%</strong></td>
<td></td>
<td>(14.5)</td>
<td>(22.9)</td>
<td>(18.8)</td>
<td>(43.8)</td>
<td>(100)</td>
</tr>
</tbody>
</table>

* We have adapted Palmer and Nesson's typology by combining Chronic and Psycho/Social conditions because: 1) for our study we considered Depression as a form of chronic disease and 2) by combining Hypertension and Depression we can examine at least two forms of chronic disease.

CHAPTER 5
Study Clinic: Discussion

5.1 General

The previous two chapters have described the methodology and the results of a quality of care evaluation of a particular Primary Care setting. A specific evaluation methodology has been applied and care was taken that it be a random, valid and reliable application. The study has generated certain observations about and insights into the process of medical care at the study clinic and provided indications for where improvements might be made. In addition, important features of the methodology itself have been highlighted.

5.2 The Methodology

Several limitations of the indicator condition, explicit process, chart audit method need to be acknowledged and discussed.

First, since this is a process evaluation, no attempt is made to examine outcome; thus the results can, in no way, be extended to conclusions about patient outcomes, individual or overall. While the BRCT did include the assessment of outcome time did not permit this in the Reach Study. However, as discussed in Chapter 2, there appears to be no way to control for all the variables that affect patient outcome, and in fact, there are, as yet, few meaningful, quantifiable, widely accepted outcome measures. Thus, process evaluation, such as the one described here, emerges as an entirely valid and feasible option, rather than as a poor substitute for outcome evaluation.

In terms of feasibility, the study itself from start to finish took five months with the chart selection process, the data abstraction and the data
analysis being accomplished over a three and half month period utilizing a single researcher on a two day a week basis. Thus the evaluation instrument is feasible for use in short term studies and is relatively inexpensive in terms of research time and money. Furthermore, in undertaking evaluative studies of medical care it is, of course, a great advantage, for reasons of convenience as well as for comparability of data across study settings, to use existing instruments and methodologies. The experience with the Reach Clinic study demonstrated that the BRCT criteria were easy to use. The data collecting sheets were clear and criteria for making judgments of adequacy unambiguous. While Reach clinical staff may not concur with all the process criteria developed for the BRCT, the criteria used had enough latitude to allow for considerable individual practitioner variation.

For the study described here the method of process evaluation chosen was a chart audit. This in itself has limitations. In the first place, one of the major difficulties in conducting a chart audit evaluation lies with the data source - the patient chart. They are often illegible and can be highly idiosyncratic if standardized charting methods are not used. Also, if patient data are not cumulated in any way, such as by diagnostic category, as was the case in this study, the search for charts eligible for study can be very time consuming. Improvements in patient information systems would greatly enhance the feasibility of the chart audit.

However, a more serious limitation of the chart audit method as identified in Chapter 2, is that it relies entirely on the documentation in patient charts. In other words, there is no way to assess what may have been done, but not recorded. Romm and Putnam found significant discrepancies between
information contained in patient charts of a hospital general medicine clinic, and transcripts of audiotaped verbal interactions between patient and provider. They make the important observation that this incomplete recording of information partially explains low levels of performance on recommended care items found in quality of care studies. Without attempting to comment on the relative clinical significance of any of the reasons for inadequacy found in this study (Table VI), it would appear that many omissions may simply be a result of failures in charting. Standardization of charting protocol may minimize this problem.

Thus, while limited in some respects, a chart audit method may highlight important, but easily corrected problems in recording. Improvement in this area may not only enhance the validity and utility of the patient chart as a means of communication, but may also have an influence on patient outcomes, compliance and satisfaction. Clearly, future research should focus on these relationships.

Using patient charts as a way to evaluate the process of care has other implications. Patient charts are not only the provider's record of care; they are also an essential means for communication with colleagues, especially in a setting such as Reach which emphasizes a team approach to care. This crucial feature of the medical record is of course a _raison d'être_ of the chart audit method. Also, from a purely external, pragmatic point of view, patient charts are the only _legal_ record of care. Thus, from several perspectives it is both relevant and germane to examine the activities of care providers as they are recorded in the patient chart.
The "tracer" or indicator condition method requires some qualification. Since in effect one is sampling care given, generalizability may be a problem. While we must acknowledge this problem and thus be circumspect in our conclusions about the total care provided at Reach it is interesting to note Sibley et al's observation that

Primary Care practitioners cannot be expected to be uniformly "good" or "bad". Differences in score among indicator conditions ...are normative in Primary Care. (emphasis added)

We might expect, for example, a practitioner to be more interested in Prenatal Care than geriatric care; this difference in preference might show up in the quality of care provided for these two areas of Primary Care.

Finally, the methodology focuses primarily on the technical aspects of care and thus provides little scope for examining psycho-social issues which may be deemed important components of care in some clinical settings. It is interesting to note Berg and Kelly's finding in their study of audit protocols used in an urban multi hospital context, that only 4% of the criteria items related to patient education and 3% related to either psychosocial history, psychosocial consultation or the impact of illness on the patient. While this may be appropriate for hospital care, it may be that care protocols for Primary Care ought to include more non-medical criteria items. If Primary Care does encompass the "medical friend" concept as suggested in Chapter 1, then, clearly, this is an area where future work needs to be done.

The issues discussed above are intended, primarily, to be caveats in the interpretation and use of the data rather than major criticisms of the methods employed. The limitations in the methodology must also be tempered with Brook
and Appel's observation that explicit process evaluation produces the "severest judgment" of the quality of care when compared to other methods of evaluation.

5.3 The Results

While only 21% of all the care provided at Reach was sampled in this study, it was felt that the range of conditions studied was broad enough to be an adequate indicator of the overall quality of care. In examining the distribution of the indicator conditions in terms of how frequently they were encountered at Reach it is important to note that this does not necessarily reflect the amount of time spent on each condition; the care of an episode of otitis media, for example, may require only two visits, while prenatal care may require fifteen or more visits. The estimates in Column 2 of Table 1, may appear low to the clinician who may be more aware of the overall time spent on each indicator condition. The variation in the number of episodes of care evaluated in each indicator condition may have some bearing on the interpretation of the results. However, given the randomization process, this should represent an accurate profile of the case load at Reach.

Two-thirds of the care delivered by the study clinic has been shown to be judged either superior or adequate by the methodology as applied. Furthermore, areas where corrective action can be taken - at least in the charting of the process of patient care - have been indicated. Table VI shows that, for each of the differing categories of Primary Care, attention to different components of the medical care process - at least as they are recorded - is required. Thus, for acute infectious diseases, the clarification and explicit statement of management plans would seem to be important in enhancing the quality of care as
judged by this methodology. For preventive care, attention appears to be required in many areas - regular weighing (or charting of weight) of prenatal patients being the major omission. Finally, for chronic disease care, increased attention to the history and physical exam would seem to be warranted.

In terms of the comparability of the quality of care delivered by Reach with that delivered in other Primary Care settings, this study has shown that the present adequate or superior score for Reach appears to be similar to that of the BRCT groups (Table III). However, the failure to detect a difference between the Reach score and either of the BRCT scores (Table IV) may be a result of the smaller overall sample size achieved for Reach (reasons for the reduction of the sample size were outlined in the previous chapter). An indication that a possible difference exists is provided by Table IV, in which comparison of the standardized scores of Reach and the CC group shows a difference which nearly achieves statistical significance.

While this study does not allow for it to be said that Reach delivers a better quality of care than the CC group, neither is it likely that Reach delivers a significantly worse quality of care than the RNP group. Thus, it is probable that Reach delivers a quality of care at least as adequate as the BRCT groups. Whether or not this level of adequacy is acceptable in any absolute terms is another issue; what is important here is the comparability of the quality of care in different Primary Care settings.

5.4 Conclusion

The results indicate that: 1) Reach Community Clinic delivers a quality of medical care as measured which is most likely comparable to that demonstrated for a similar practice setting; 2) specific areas of practice or recording can be identified as requiring attention by clinicians and other staff, and thus can
be a focus of future evaluations of this practice setting; and 3) the methodology developed for the BRCT is easily adaptable and relevant to primary care settings other than reported in the BRCT.


6. For a discussion on the effect of sample size on the results of randomized controlled trials see:
6.1 **Preamble**

This thesis has presented the results of a quality of care evaluation of a community clinic in the context of a specific Primary Care evaluation methodology: an explicit-process-criteria, indicator-condition chart audit developed for the Burlington Randomized Controlled Trial. This study has allowed for the assessment of the utility of the process criteria developed for the BRCT. While the BRCT was primarily concerned with the comparison of nurse practitioners and physicians, it was felt that the process criteria developed for that study might be useful in more general evaluations of primary care. As far as can be ascertained from a thorough review of the literature no such wider application of these criteria has been reported to date. This study, then, illustrates the relevance and feasibility of the BRCT methodology in a community clinic setting.

Questions about the internal validity and reliability of specific methodologies need to be addressed by evaluators and researchers developing evaluation tools, and, indeed, is the focus of much of the current evaluative research, as discussed in Chapter 2. Techniques for establishing validity and reliability also need to be tested empirically and will not be dealt with here.

What is of interest here, to policy makers, who may be making significant policy decisions on the basis of evaluations and to organizations, who are required to conduct evaluations, is the feasibility and relevance of process evaluations.
6.2 Feasibility of Process Evaluation

The feasibility of the specific process evaluation methodology used in the study presented here has already been addressed in Chapter 5. In terms of the general feasibility of process evaluations, the major difficulty is in the development of the medical care criteria themselves. As has been discussed in Chapter 2, criteria should be ideally limited to those items of the medical care process that have been shown to be linked to positive patient outcomes, i.e. the efficacy of the care items chosen must be demonstrable. This is, of course, an inherent difficulty in process evaluations and will continue to be, as long as medical care is based on the prevailing normative standards of medical practice. As medical practice changes and evolves, quality of care criteria will have to be revised and refined. However, once developed, care criteria can be applied in a fairly straightforward way as shown by this study.

What is more important than knowing if a quality of care evaluation can be done easily and cheaply, is knowing if, when it is done, it tells us anything very relevant about our health care system.

6.3 Relevance of Process Evaluation

The major assumption at the basis of any health care system is that the desired end result is the improvement in the health of the population. But, what is health and what can be considered improvement?

Health can be defined on a spectrum from "the absence of disease" to the World Health Organization definition, "Health is a state of complete physical, mental, social and economic well-being...". While the latter definition may enshrine a noble ideal, it leaves much outside the realm of the current health
care delivery system. On the other hand, the former definition of health is obsolete, belonging to a time when the major infectious diseases were the concern of the health care system; it is no longer an operational definition, at least in the developed countries, where the major health problems are of a chronic degenerative sort - heart disease, hypertension, cancer - which have large psychosocial components.

Not only do we not have an operational definition of health, we also do not have a clear understanding of what the product of the health care system ought to be. "Improvement of health" seems an obvious one, but it is imprecise. It can mean anything from reductions in mortality/morbidity rates - the traditional way of assessing the efficacy of any intervention by the health care system, to the currently popular term "added quality-adjusted life years". Again, while the former is a crude measure, the latter opens up a Pandora's box of other issues - what is quality of life, and more importantly, who will define it. These questions border on the ethical and the theological and for the most part have not been addressed by the current health delivery system.

We would do well, too, to remember Kessner's warning that health outcome is not the same as health status. Improvement in health outcome has traditionally been the province of the health care system - for example, the lowering of blood pressure through diet and pharmaceutical regimes, the prevention of polio through mass vaccination programs, the reduction of perinatal risks through broad-base maternal-infant services and programs. Health status, on the other hand, has existed largely outside the health care system being dependent on myriad factors from genetics to lifestyle to health belief.
Lifestyle has to do with aspects of our personal behaviour that affect our health—smoking, drinking, wearing seat belts, exercise, nutrition, etc. The Lalonde Report, *A New Perspective on the Health of Canadians*, established the concept of lifestyle as an essential component of the health care package. Health belief is basically the concept that our beliefs about how healthy we are and about the efficacy of any treatment have a significant impact on both actual health status and health outcome.

The emergence of lifestyle and health belief as legitimate components of the health care system has initiated a whole range of new research areas as well as legitimizing several new health professions—health educators, lifestyle counsellors, etc. Health and health care has become everybody's business, in both senses of the word! However, there are those for whom these issues are red herrings, smacking of victim blaming and shifting of the responsibility for health from a social level to an individual level, thereby absolving government from responsibility.

All of the above is by way of a reflection on the difficulties of defining the product of the health care system in any easily quantifiable and measurable way, especially as our concepts of health continue to change and expand. So, if it is increasingly difficult to examine the outcome or product of the health care system we can at least look at what people do.

Donabedian loaned some credibility to this view when he said

> Conformity of practice to accepted standards has a kind of conditional or interim validity which may be more relevant to the purposes of assessment in specific instances.

Moreover, in a recent article the authors provide several compelling reasons why process evaluations may be even more useful to clinicians and policy makers, stating
...quality of care studies that focus only on structure or outcomes are unlikely to provide valid information about the real quality of care being delivered...

Indeed, much of the quality assurance activities undertaken by hospitals, in order to meet accreditation standards, is in terms of structure and administrative process. However, much evaluation of clinical process, both in and out of hospitals, remains implicit in the form of peer review, making it almost inaccessible to objective evaluation.

A very good case for the relevance of process evaluations is raised in a recent paper by Catherine Hewes of the Institute of Policy Sciences at Duke University. In looking at the use of outcome measures for the evaluation of long term care - which can perhaps be regarded as a special case of Primary Care - she looks at the whole concept of care as a process.

Health care, apart from the preventative aspects, is primarily a service industry, providing various types of highly personalized service. This means that the product is mainly consumed at its point of production and the act of giving care takes place at the same time and in the same place as the act of receiving it.

In other words, process cannot be separated from outcome as in most production systems. Of course, there is an assumption that there is a rationale underlying the activities of health care providers, i.e. what they do has some kind of positive effect. Weak as this link may sometimes appear, there is still relevance in looking explicitly at the activities of health professionals. This is especially true in the context of a publically funded health care system.

One of the major problems currently facing those who pay for health care is the allocation of scarce resources. As Stoddart says the question is:

Is this health procedure, service or program worth doing compared with other things we could do with these same resources? Are we satisfied that the health resources (required to make the procedure, service or program available to those who could benefit from it) should be spent in this rather than some other way?
It could be shown for example, that two different Primary Care service delivery packages - a community clinic and a private group practice - deliver comparable quality of care as determined by an explicit process evaluation. Given the social, political and economic context, policy makers may opt for the least costly delivery mode. This last statement, of course, raises issues beyond the scope of this thesis. What is important is that clearly defined medical care process evaluation can be a useful policy tool.

6.4 Summary

This thesis has demonstrated the utility of a particular evaluation methodology, and provided a context for the discussion of the function and significance of process evaluation. In addition the major areas where future work is required in the development of evaluation methodology have been highlighted.

Improved clinical data management needs to be developed, that is both acceptable to clinical and other staff and that can enhance the feasibility of quality of care evaluations. Current work on patient information systems at both the clinical and Ministry of Health level in B.C. is increasing the possibility of meeting this requirement.

Future developments in Primary Care evaluation methodology are needed in the application of the methodology used in this study to a greater diversity of practice settings to confirm its utility, the linkage of recorded activities and other factors such as patient satisfaction, compliance, etc., and continued development of process criteria correlated with positive outcomes.
In addition, there is an indicated need for further empirical demonstration of the utility of process evaluation as a medical care assessment methodology since its relatively low cost and ease of application make such an approach attractive when health care costs are of increasing concern.

And finally, in order for governments to know whether or not they are getting value for their money, they first need to answer some apparently simple questions - who is doing what to whom, where, when, how and why? As cost-effectiveness analyses become increasingly attractive to governments who bear the cost of health services, clearer definitions of outcome or the product of the health care system will need to be developed. Until widely accepted outcome measures are available, examining the activities of the health care system, or in Donabedian's terms the process of medical care, is a relevant endeavour and can provide useful data on some aspects of the effectiveness side of cost-effectiveness and related studies. The study presented here illustrates one of the ways that this can be accomplished.
CHAPTER 6 - NOTES


2. Department of National Health and Welfare

3. Donabedian, A., Evaluating Quality of Medical Care. Milbank Memorial Fund Quarterly, 1966; XLIV.

4. Department of Clinical Epidemiology and Biostatistics, McMaster University Health Sciences Centre, How to read clinical journals: VI. To learn about the quality of clinical care. CMAJ, 1984; 130: 377.

5. Hewes, C., Outcome Measures and Long-Term Care: Defining and Assuring Quality. Paper prepared for presentation at the Fifth Annual Research Conference.

BIBLIOGRAPHY


Brook, R.H., Studies of Process-Outcome correlations in Medical Care Evaluations. Medical Care, 1979; 17: 868.


Brook, R.H., et al., Effectiveness of Non-emergency Care via an Emergency Room: A Study of 166 Patients with Gastrointestinal symptoms. Annals of Internal Medicine, 1973; 78: 333.


Canada, Bill C-227, Medical Care Act, 1966, 14-15 Elizabeth II (Ottawa: Queen's Printer, 1966).

Hospital Insurance and Diagnostic Services Act, April 12, 1957, and Regulations, 5-6 Elizabeth II (Ottawa: Queen's Printer, 1957).


Codman, E.A., A Study in Hospital Efficiency As Demonstrated by the Case Report of the First Five Years of Private Hospital, Thomas Todd Co., (Boston), 1918.

Department of Clinical Epidemiology and Biostatistics, McMaster University Health Sciences Centre, How to read clinical journals: VI. To learn about the quality of clinical care. Canadian Medical Association Journal, 1984; 130: 377

Donabedian, A., Evaluating Quality of Medical Care. Milbank Memorial Fund Quarterly, 1966; XLIV.


Hewes, C., Outcome Measures and Long-Term Care: Defining and Assuring Quality. Paper presented for presentation at the Fifth Annual Research Conference.


McAuliffe, W.E., Measuring the Quality of Medical Care: Process versus Outcome. Milbank Memorial Fund Quarterly, 1979; 57 (1): 118.

McAuliffe, W.E., Response to Dr. Brook. Medical Care, 1979; 17: 874.


Reach Community Clinic, *Eleven Years at Reach* (Vancouver: Reach Community Clinic, 1970).


Sheps, M.C., "Approaches to the Quality of Hospital Care." *Public Health Reports*, 1953; 70: 877-886.


Phase II: December 13, 1982 - February 1, 1983
(a) The Chart Audit itself;
(b) Initial data analysis.

Phase III: February 2, 1983 - March 1, 1983
(a) Completion of data analysis;
(b) Preparation of the report;
(c) Presentation to the Board of Reach Clinic of one copy of the final report.

If, in our opinion, we are unable to present the final report to the Board as of March 1, 1983, we may request an extension, not to exceed three weeks, for the presentation of the final report.

(2) We will undertake said Chart Audit on the strict understanding that under no circumstances will the charts or any other identifiable medical information leave the premises of the Reach Clinic and all charts will be checked out of and returned to the Record Room of the Reach Clinic by a method to be devised by us and the Record Room staff.

(3) We will undertake that no patient names or other information clearly identifying any individual will be used in any report or other written document, including any potential journal articles, arising from this Audit.

(4) We will undertake that no information clearly identifying by name or in any other way any physician or other staff member at the Reach Clinic will appear in any report or other written document, including potential journal articles arising from the Audit.

(5) We will have the right to use the results of this Audit for publication in an adjudicated journal with the following stipulations:
(a) If, in the opinion of the Reach Clinic and us, the data suggest that the Reach Clinic does not compare favourably with data of a similar nature in the literature any publication of said data will not refer by name to the Reach Clinic; or
(b) If, in the opinion of the Reach Clinic or us, the data suggest that the Reach Clinic does compare favourably or is at least comparable with the performance of similar medical facilities as cited in the literature, the name Reach Clinic may be used in any publication.
(6) We will undertake to commit the equivalent of two days (16 hours) per week to this project.

(7) We will undertake to provide signed receipts for all monies paid to us.

B) We, Mr. John Richards, President of the Board of Reach Clinic, Ms. Marilyn Forster, Administrator of the Reach Clinic, and Dr. Ian Gummeron, Medical Coordinator of the Reach Clinic will:

(1) Provide access to all medical charts chosen for auditing.

(2) Support Dr. Sheps and Ann Robertson in any dispute regarding the project with any Reach staff unless the provisions of this letter of agreement are deemed to have been broken by Dr. Sheps and/or Ann Robertson and in the event of a concern about a violation of the terms of this agreement we will notify Dr. Sheps in writing regarding said violation and we will meet with Dr. Sheps and Ann Robertson regarding said violation.

(3) We agree to pay Dr. Sheps a total of five thousand dollars ($5000.00) in the following manner:

(a) A first installment of twelve hundred and fifty dollars ($1250.00) to be paid at a project review meeting held during the week of December 6 - 10, 1982 at the conclusion of Phase I: Initiation of Phase II is dependent upon payment of the first installment and non-payment of the first installment will be considered a termination of this agreement;

(b) A second installment of twelve hundred and fifty dollars ($1250.00) to be paid at a project review meeting held during the week of January 31 - February 4, 1983, i.e., at the conclusion of Phase II: Initiation of Phase III is dependent upon payment of the second installment and non-payment of the second installment will constitute an end to this agreement;

(c) A third installment of twenty-five hundred dollars ($2500.00) to be paid upon receipt of one copy of the final report of this project either on March 1 or if written permission is given for an extension (not to exceed three weeks) on receipt of the report of this project.

(4) We agree to the right of publication as stipulated above.
Appendix II

Criteria and Abstract Sheets
INDICATOR CONDITION #1 - OTITIS MEDIA

DEFINITION OF AN EPISODE - OTITIS MEDIA

Otitis Media episode begins when patient first consults physician or nurse about complaints related to the ear, or when diagnosis is recorded in the chart within the study period. This must be a new condition, or there must be reasonable evidence that a prior episode had been resolved satisfactorily. The episode ends on the last recorded visit concerning this problem or at the end of the study period, whichever occurs later.

CATEGORIES OF INTERVENTION

1. Follow-up visit within one month of initial episode
2. An appropriate antibiotic (Erythromycin, Penicillin, Sulpha, Ampicillin).
   An inappropriate antibiotic would be Tetracycline in a child under the age of 8, or Chloramphenical.
3. Consultation
4. Statement that patient is cured or a clear statement of patient’s status.
5. Continue antibiotics plus a further repeat visit.
6. Myringotomy plus further repeat visit.
7. Third or subsequent visits with evidence or a statement that hearing has been checked.
8. Follow-up or late consultation with audiometric examination.

SCORING

ADEQUATE

OPTION 1

1. Follow-up visit within one month of initial episode.
2. An appropriate antibiotic (Erythromycin, Penicillin, Sulpha, Ampicillin).
   An inappropriate antibiotic would be Tetracycline in a child under the age of 8, or Chloramphenical.

OPTION 2

3. Consultation

INADEQUATE

Less than adequate
OPTION 1

Adequate - plus

4. Statement that patient is cured or a clear statement of patient's status.

OPTION 2

Adequate - plus - any one of the following:

5. Continue antibiotics plus a further repeat visit.
6. Myringotomy plus further repeat visit.
7. Third or subsequent visits with evidence or a statement that hearing has been checked.
8. Follow-up or late consultation with audiometric examination.
OTITIS MEDIA

Episode begins when the patient first consults physician or nurse about complaints related to the ear, or when the diagnosis is recorded within the study period. This must be a new condition, with reasonable evidence that a prior episode has been resolved satisfactorily. The episode ends on the last recorded visit concerning the problem or at the end of the study period, whichever occurs later.

1 = YES
2 = NO
8 = NOT APPLICABLE
9 = UNKNOWN

I.D.  
0 1 2 3 4 5

R.T.  
0 1 2 3

STUDY CODE  
8 9 10 11

CATEGORIES OF INTERVENTION

- Follow-up visit (within one month)
- Antibiotics
  (Tetracycline for 8 years of age and under; Chloramphenicol - not to be used)
- Continue Antibiotics and repeat visit
- Myringotomy and repeat visit
- Three or more visits and hearing checked
- Follow-up or late consultation and audiometric exam
- Consultation
- Medical Status
DEFINITION OF AN EPISODE - HYPERTENSION

Episode begins with first record of assessment or management of hypertension in situations where the classification criteria of any of the three categories are met. The episode ends with the last visit related to this indicator condition in the period under surveillance.

Patients should be classified according to the level of diastolic blood pressure at the time episode begins.

DEFINITION OF CATEGORIES OF HYPERTENSION

1. Simple Hypertension - a diastolic blood pressure of 100 to 110, 55 years of age and under.
2. Intermediate Stage - Uncomplicated - Diastolic pressure of 111 to 120, 60 years of age and under.
3. Intermediate Stage - Complicated
   a) Diastolic pressure of over 120, regardless of age, OR
   b) Symptomatic hypertension with end organ damage, such as T.I.A., angina, shortness of breath, heart failure, azotemia, Grade III retinopathy (haemorrhages or exudates) OR
   c) A strong family history of one first degree relative having complications of hypertension. The patient under review would have a diastolic pressure of 110 or over, OR
   d) Recurrence of hypertension after special therapy, diastolic pressure 110 or over.

CATEGORIES OF INTERVENTION

1. Blood pressure
2. Evidence of enquiry re symptoms
   ("No symptoms" or "asymptomatic" acceptable)
3. Enquiry re family history
   ("Family history Neg." or "Positive" acceptable)
4. Enquiry re previous illnesses
   ("Not significant" or "Positive" acceptable)

Physical Examination

5. Cardiovascular examination
   ("C.V.Neg.", Comment on pulses, heart, acceptable as C.V.examination)
6. Repeat visit - either planned or taken place - within three months
7. Laboratory investigation - urinalysis
8. Referral for Consultation
**Special Attention**

9. Funduscopic examination
10. Enquiry re cigarette smoking
11. Life style, personal pressures and attitudes

**Physical Examination**

12. Blood pressure - both arms
13. At least two serial blood pressure readings on two separate visits
14. Blood Pressure - standing, plus one other position

**Special Investigations**

15. Serum electrolytes
16. I. V. P.
17. E. C. G.
18. Chest x-ray
19. Statement of renal function or a specific test, such as one of the following: B.U.N., Creatinine; Fishberg; Specific Gravity of urine; Urinalysis - Microscopic.

**Treatment**

20. a) Diet, exercise, drugs, or counselling with evidence that subsequent diastolic pressures are under 110,
    OR

b) A specific statement why no treatment had been initiated.

**SCORING**

1 - SIMPLE HYPERTENSION

**ADEQUATE**

**OPTION 1**

1. Blood pressure
2. Evidence of enquiry re symptoms
   ("No symptoms" or "asymptomatic" acceptable)
3. Enquiry re family history
   ("Family history Neg." or "Positive" acceptable)
4. Enquiry re previous illnesses
   ("Not significant" or "Positive" acceptable)
5. Evidence of cardiovascular examination
6. Repeat visit - either planned or taken place - within three months
7. Laboratory investigation - urinalysis
SCORING

2 - INTERMEDIATE STAGE - UNCOMPLICATED

ADEQUATE

OPTION 1

1. Blood pressure
2. Evidence of enquiry re symptoms
   ("No symptoms" or "asymptomatic" acceptable)
3. Enquiry re family history
   ("Family history Neg." or "Positive" acceptable)
4. Enquiry re previous illnesses
   ("Not significant" or "Positive" acceptable)
5. Cardiovascular examination
   ("C.V. Neg.", Comment on pulses, heart, acceptable)
6. Repeat visit - either planned or taken place - within
   three months
7. Laboratory investigation - urinalysis
8. Funduscopic examination
9. a) Diet exercise, drugs or counselling with evidence
    that subsequent diastolic pressures are under 110
   OR
   b) A specific statement why no treatment had been initiated

PLUS ANY FOUR OF THE FOLLOWING

10. Enquiry re cigarette smoking
11. Life style, personal pressures and attitudes
12. Blood pressure - both arms
13. At least two serial blood pressure readings on two
    separate visits
14. Blood pressure - standing, plus one other position
15. Serum electrolytes
16. I. V. P.
17. E. C. G.
18. Chest x-ray
19. Statement of renal function or a specific test, such as
    one of the following: B.U.N., Creatinine, Fishberg;
    Specific Gravity of urine; Urinalysis - Microscopic

OPTION 2

8. Referral for Consultation

INADEQUATE

Absence of any criteria as in adequate
S U P E R I O R

O P T I O N 1

1. Blood pressure
2. Evidence of enquiry re symptoms
   ("No symptoms" or "asymptomatic" acceptable)
3. Enquiry re family history
   ("Family history Neg." or "Positive" acceptable)
4. Enquiry re previous illnesses
   ("Not significant" or "Positive" acceptable)
5. Cardiovascular examination
   (Comment regarding pulses and heart acceptable
    as C. V. examination)
6. Repeat visit - either planned or taken place - within
    three months
7. Laboratory investigation - urinalysis
8. Funduscopic examination
9. a) Diet, exercise, drugs or counselling with evidence
    that subsequent diastolic pressures are under 110.
    OR
    b) A specific statement why no treatment had been initiated

P L U S A N Y S E V E N O F T H E F O L L O W I N G

10. Enquiry re cigarette smoking
11. Life style, personal pressures and attitudes
12. Blood pressure - both arms
13. At least two serial blood pressure readings on two
    separate visits
14. Blood pressure - standing, plus one other position
15. Serum electrolytes
16. I. V. P.
17. E. C. G.
18. Chest x-ray
19. Statement of renal function or a specific test, such as
    one of the following: B.U.N.; Creatinine; Fishterig;
    Specific Gravity of urine; Urinalysis - Microscopic

O P T I O N 2

T H E F O L L O W I N G A R E M A N D A T O R Y P R I O R T O C O N S U L T A T I O N

1. Blood pressure
2. Evidence of enquiry re symptoms
   ("No symptoms" or "asymptomatic" acceptable)
3. Enquiry re family history
   ("Family history Neg." or "Positive" acceptable)
4. Enquiry re previous illnesses
   ("Not significant" or "Positive" acceptable)
5. Cardiovascular examination
   (Comment regarding pulses and heart acceptable as C.V. examination)
6. Repeat visit - either planned or taken place - within three months
7. Laboratory investigation - urinalysis
8. Referral for Consultation

SCORING

3 - INTERMEDIATE STAGE - COMPLICATED

ADEQUATE

OPTION I

8. Referral for Consultation

OPTION II

1. Blood pressure
2. Evidence of enquiry re symptoms
   ("No symptoms" or "asymptomatic" acceptable)
3. Enquiry re family history
   ("Family history Neg." or "Positive" acceptable)
4. Enquiry re previous illnesses
   ("Not significant" or "Positive" acceptable)
5. Cardiovascular examination
   ("C.V. Neg."; Comment regarding pulses and heart acceptable as C.V. examination)
6. Repeat visit - either planned or taken place - within three months
7. Laboratory investigation - urinalysis
8. Funduscopic examination
9. Serum electrolytes
10. I. V. P.
11. E. C. G.
12. Chest x-ray
13. Statement of renal function or a specific test, such as one of the following: B.U.N.; Creatinine; Finsberg; Specific Gravity of urine; Urinalysis - Microscopic
20. a) Diet, exercise, drugs, or counselling with evidence that subsequent diastolic pressures are under 110, OR
   b) A specific statement why no treatment had been initiated
PLUS ANY TWO OF THE FOLLOWING

12. Blood pressure - both arms
13. At least two serial blood pressure readings on two separate visits
14. Blood pressure - standing, plus one other position

INADEQUATE

Absence of any criteria as in adequate

SUPERIOR

Not applicable in this category
**EPISODE -** Begins - with the first record of assessment or management of any of the three categories.  
Ends - with the last visit of the condition or the end of the study period.

**CATEGORIES OF HYPERTENSION**

1. **Simple hypertension (0201)**  
   - Patient 55 years of age or less with a diastolic blood pressure of 100 to 110.

2. **Intermediate Stage - Uncomplicated (0202)**  
   - Patient 60 years of age or less with diastolic blood pressure of 111 to 120.

3. **Intermediate Stage - Complicated (0203)**  
   - Diastolic pressure over 120, regardless of age  
   OR  
   - Symptomatic hypertension with end organ damage  
     i.e. T.I.A., angina, shortness of breath, heart failure, azotemia,  
     Grade III retinopathy (haemorrhages or exudates)  
   OR  
   - Strong family history of one first degree relative having complications of hypertension. The patient under review.  
   OR  
   - Recurrence of hypertension after special therapy, diastolic pressure 110 or over

| 1 = YES | I.D. | 1 2 3 4 5 |
| 2 = NO | R.T. | 6 7 |
| STUDY CODE | |
| 8 9 10 11 | |

**CATEGORIES OF INTERVENTION**

- Blood pressure

- Blood pressure - both arms

- Blood Pressure - standing and one other position
- 2 serial B.P. readings on 2 separate visits
- Enquiry re symptoms
- Family history
- History of previous illness
- Cardiovascular examination
  (Comment on pulses, heart, acceptable)
- Repeat visit - within 3 months
- Urinalysis
- Micro
- Consultation
- Funduscopic examination
- Enquiry re cigarette smoking
- Life style
- Serum electrolytes
- I.V.P.
- E.C.G.
- Chest x-ray
- Statement of renal function
- B.U.N.
HYPERTENSION (Cont'd)

- Creatinine
- Fishberg
- Specific Gravity (urine)
- Diet and (subsequent D.P. under 110)
- Exercise and (subsequent D.P. under 110)
- Medication and (subsequent D.P. under 110)
- Counselling and (subsequent D.P. under 110)
- Treatment (if treatment not given an explanation is acceptable)
INDICATOR CONDITION #3 - PRENATAL CARE IN PHYSICIAN'S OFFICE

DEFINITION OF AN EPISODE - PRENATAL CARE

Assessment of prenatal care will be of a period not less than five months of the gestation period, provided the five-month episode falls within particular definite dates that identify the interval of interest in the study.

A patient that was seen four months prior to beginning date of study could be included, and the last five months of the pregnancy assessed. A patient whose date of gestation fell four months past closing date of the study, could be assessed for the first five months. The period under study in the Burlington practices will be June 28, 1971 to June 30, 1972.

CATEGORIES OF INTERVENTION

1. Pelvic assessment - if no previous successful delivery
2. Past obstetrical history
3. Complete physical assessment - within two year period
4. At least one haemoglobin during prenatal period
5. Urinalysis on each visit
6. Frequency of subsequent visits
   Monthly or four weekly - 1st to 7th month
   two weekly - 8th month
   weekly - 9th month to term
7. Must be record of weight
8. Must be record of blood pressure
9. Must be record of Rh and S.T.S.
10. Must be statement of gestation
11. Evidence of a psycho-social interview (expressed fear or anxiety)
12. A meeting of the husband and wife together during the pregnancy
13. Pap smear
14. A two-hour P.C. sugar if there is a strong family history
   OR
   If there is glucosuria found,
   OR
   If there is a history of large babies.

SCORING

ADEQUATE

1. Pelvic assessment - if no previous successful delivery
2. Past obstetrical history
3. Complete physical assessment - within two year period
4. At least one haemoglobin during prenatal period
5. Urinalysis on each visit
6. Frequency of subsequent visits
   Monthly or four weekly - 1st to 7th month
   two weekly - 8th month
   weekly - 9th month to term
7. Must be record of weight
8. Must be record of blood pressure
9. Must be record of Rh and S.T.S.
10. Must be statement of gestation

INADEQUATE

Absence of any one of the above

SUPERIOR

Adequate - PLUS ONE OF THE FOLLOWING:

11. Evidence of a psycho-social interview (expressed fear or anxiety)
12. A meeting of the husband and wife together during the pregnancy
13. Pap smear
14. A two hour P.C. sugar if there is a strong family history
   OR
   If there is glucosuria found,
   OR
   If there is a history of large babies.

INTERMEDIATE STATE

SCORING

ADEQUATE

For the following specific conditions, the stated intervention must have been carried out in addition to the appropriate interventions itemized above (1 - 10).

INADEQUATE

Absence of any one of the above

SUPERIOR

Adequate as defined - PLUS ONE OF THE FOLLOWING:

11, 12, 13, 14, listed above.

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>INTERVENTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Albuminuria</td>
<td>1. Must have further urinary investigation or an adequate explanation.</td>
</tr>
<tr>
<td>B Hypertension -</td>
<td>2. A statement of concurrent urinary findings.</td>
</tr>
<tr>
<td>a diastolic</td>
<td></td>
</tr>
<tr>
<td>over 90 or 15</td>
<td></td>
</tr>
<tr>
<td>mm. over the</td>
<td></td>
</tr>
<tr>
<td>previous baseline.</td>
<td></td>
</tr>
<tr>
<td>C Excessive weight gain</td>
<td>3. Patient cautioned and/or dietary enforcement and/or more frequent visits and/or diuretics.</td>
</tr>
<tr>
<td>(over 5 lbs. per 4 weeks)</td>
<td></td>
</tr>
<tr>
<td>CONDITION</td>
<td>INTERVENTION</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>D 1. Hypertension and weight gain</td>
<td>4.1. Rest</td>
</tr>
<tr>
<td>D 2. Hypertension and albuminuria</td>
<td>4.2. Re-visit within 72 hours</td>
</tr>
<tr>
<td>D 3. Hypertension plus albuminuria plus weight gain</td>
<td>4.3. Salt restriction and/or diuretics</td>
</tr>
<tr>
<td>D 4. Weight gain plus albuminuria</td>
<td>4.4. Sedation (Phenobarb) - optional</td>
</tr>
<tr>
<td>D 5. Glucosuria</td>
<td>4.5. Either a blood sugar recorded or an adequate explanation for the glucosuria</td>
</tr>
<tr>
<td>E Discharge and/or pruritis - persistent or distressing</td>
<td>5. Culture and smear of the discharge</td>
</tr>
<tr>
<td>F Pyuria</td>
<td>6. Urine, culture and sensitivity</td>
</tr>
<tr>
<td>G Diagnosis of diabetes, either previously established or currently established</td>
<td>7. Consultation during pregnancy</td>
</tr>
<tr>
<td>H Possible German Measles contact</td>
<td>8. R. H. I. A.</td>
</tr>
<tr>
<td>I Established German Measles contact</td>
<td>9. Consultation</td>
</tr>
<tr>
<td>J Last trimester bleeding</td>
<td>10. Admission to hospital and consultation</td>
</tr>
<tr>
<td>K First trimester bleeding - not in the scope of this evaluation</td>
<td></td>
</tr>
<tr>
<td>L Premature rupture of membranes</td>
<td>11. Hospitalization immediately In labour within 12 hours, or Consultation</td>
</tr>
<tr>
<td>M Inadequacy of pelvis in primipara</td>
<td>12. Subsequent notation re disproportion</td>
</tr>
<tr>
<td>N Rising Rh Titre or anticipated Rh problem</td>
<td>13. Subsequent laboratory follow-up, or Consultation</td>
</tr>
</tbody>
</table>

INADEQUATE
The appropriate intervention for the specific condition was not carried out.
The patient must be under observation at least the last five months of gestation and the pregnancy must be concluded before the terminal date of the study.

<table>
<thead>
<tr>
<th>1 = YES</th>
<th>2 = NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.D.</td>
<td>R.T.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**STUDY CODE**

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**CATEGORIES OF INTERVENTION**

- Pelvic Assessment (or previous successful delivery)
- Obstetrical History
- Complete Physical (within 2 years)
- Haemoglobin
- Urinalysis at each visit
- Visits 1st - 7th month - monthly or q4 weeks
  - 8th month - q2 weeks
  - 9th month - term - q week
- Weight
- Blood pressure
- Rh
- STS
- D L M P
- Doctor's awareness of the presence or absence of family problems
- Meeting husband-wife together
- Pap Smear
- 2 hour pc (strong family history of diabetes, glucosuria, history of large babies)
PREGNATAL INTERMEDIATE STAGE

One of the conditions or problems associated with pregnancy.

1 = YES
2 = NO
8 = NOT APPLICABLE
9 = UNKNOWN

CATEGORY OF INTERVENTION

<table>
<thead>
<tr>
<th>Condition</th>
<th>Code</th>
<th>Further urinary investigation or explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albuminuria</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Hypertension - D.P. greater than 90 or greater than 15 mm Hg over previous baseline</td>
<td>30</td>
<td>Concurrent urinary findings</td>
</tr>
<tr>
<td>Excessive weight gain (over 5 lbs per 4 weeks)</td>
<td>31</td>
<td>Counselling</td>
</tr>
<tr>
<td>Hypertension + weight gain</td>
<td>32</td>
<td>Rest</td>
</tr>
<tr>
<td>Hypertension + albuminuria</td>
<td>33</td>
<td>Re-visit within 72 hours</td>
</tr>
<tr>
<td>Hypertension + albuminuria + weight gain</td>
<td>34</td>
<td>Salt restriction and/or Diuretics</td>
</tr>
<tr>
<td>Weight gain + albuminuria</td>
<td>35</td>
<td>Sedation (Phenobarb)</td>
</tr>
<tr>
<td>Condition</td>
<td>Code</td>
<td>Action</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Glucosuria</td>
<td>47</td>
<td>Blood Sugar or Explanation of glucosuria</td>
</tr>
<tr>
<td>Discharge or pruritis</td>
<td>48</td>
<td>Smear for culture</td>
</tr>
<tr>
<td>Pyuria</td>
<td>49</td>
<td>Urine - culture &amp; sensitivity</td>
</tr>
<tr>
<td>Diabetes</td>
<td>50</td>
<td>Consultation</td>
</tr>
<tr>
<td>Possible German Measles Contact</td>
<td>51</td>
<td>R.H.I.A.</td>
</tr>
<tr>
<td>Established German Measles</td>
<td>52</td>
<td>Consultation</td>
</tr>
<tr>
<td>Last trimester bleeding</td>
<td>53</td>
<td>Hospitalization &amp; Consultation</td>
</tr>
<tr>
<td>Premature rupture of Membranes</td>
<td>54</td>
<td>Hospitalized immediately and in labor within 12 hours OR Consultation</td>
</tr>
<tr>
<td>Inadequacy of Pelvis</td>
<td>55</td>
<td>Subsequent notation re disproportion</td>
</tr>
<tr>
<td>Rising Rh titre or anticipated Rh problem</td>
<td>56</td>
<td>Subsequent laboratory follow-up OR Consultation</td>
</tr>
</tbody>
</table>
DEFINITION OF ELIGIBILITY

Any child six months of age or under who enters the practice after June 28, 1971.

DEFINITION OF AN EPISODE

Episode begins with first visit of well child care in the patient's first year of life within the study period, and ends on the child's first birthday, or the end of the study period, whichever comes sooner. A child must be under surveillance for a minimum of five months during the study period for the episode to be eligible.

CATEGORIES OF INTERVENTION

1. Weight on every visit
2. Height and head circumference recorded twice in the first year of life or at least once every six months.
3. Immunization programme completed and recorded by seven months to include D.P.T.P. (If not completed, should be adequate explanation or evidence of illness)
4. An obstetrical history
5. Anaesthetic history at the time of delivery
6. Maternal medication during pregnancy
7. Any intercurrent diseases which occur during mother's pregnancy
8. Evidence of a psycho-social approach to the family unit
9. Recording of the landmarks of growth and development
10. Evidence of health education in the mother regarding hazards to child
11. Evidence of more than one notation about change in diet during the first year
12. Haemoglobin recorded or commented on
13. Urinalysis recorded or commented on
14. Hearing - evidence of being tested - statement made or recorded
15. Vision - evidence of having been tested - statement made concerning vision, or recorded

SCORING

ADEQUATE

1. Weight on every visit
2. Height and head circumference recorded twice in the first year of life or at least once every six months.
3. Immunization programme completed and recorded by seven months to include D.P.T.P. (If not completed, should be adequate explanation or evidence of illness)

INADEQUATE

Absence of any of the above
SUPERIOR

ANY THREE OF THE FOLLOWING:

4. An obstetrical history
5. Anaesthetic history at the time of delivery
6. Maternal medication during pregnancy
7. Any intercurrent diseases which occur during the mother's pregnancy
8. Evidence of a psycho-social approach to the family unit
9. Recording of the landmarks of growth and development
10. Evidence of health education in the mother regarding hazards to the child
11. Evidence of more than one notation about change in diet during the first year.
12. Haemoglobin recorded or commented on
13. Urinalysis recorded or commented on
14. Hearing - evidence of being tested - statement made or recorded
15. Vision - evidence of having been tested - statement made concerning vision, or recorded
A child entering the practice during the first three months of life and who remains in the practice up to and including the 12th month. It is the responsibility of the Family Practitioner to be aware of and record all care given though he may not administer it himself, i.e. immunization, well baby care.

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>YES</td>
<td>I.D.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NO</td>
<td>R.T.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STUDY CODE</td>
<td></td>
</tr>
</tbody>
</table>

- Weight (every routine visit)
- Height & head circumference (q6 months)
- Immunization programme (completed by 7 months or explanation)
- Obstetrical history
- Anaesthetic at time of delivery
- Maternal medication during mother's pregnancy
- Intercurrent disease during mother's pregnancy
- Doctor's Awareness of the presence or absence of family problems
- Landmarks of growth & development
- Health education re hazards (to mother)
CARE OF THE NEWBORN (Cont'd)

- More than one notation of change in diet

- Macroglobulin

- Urinalysis

- Hearing

- Vision
INDICATOR CONDITION #5 - IMMUNIZATION PROGRAMME UP TO THE END OF 24 MONTHS OF AGE

DEFINITION OF ELIGIBILITY

Any infant who is not less than 12 months and not over 18 months as of June 28, 1971

DEFINITION OF AN EPISODE

The episode ends at the second year of age or the end of the study period, whichever comes sooner. There must be evidence that immunization has been completed according to schedule.

CATEGORIES OF INTERVENTION

1. Three D.P.T.P. with one booster shot
2. Measles vaccination (after 12 months) either given or a specific explanation as to why it has not been given
3. Measles vaccination given prior to 12 months
4. Smallpox vaccination given prior to 24 months unless there is evidence that international travel is intended

SCORING

ADEQUATE

1. Three D.P.T.P. with one booster shot
2. Measles vaccination (after 12 months), either given or a specific explanation as to why it has not been given

INADEQUATE

ABSENCE OF:

1. Three D.P.T.P. with one booster shot
2. Measles vaccination (after 12 months) either given or a specific explanation as to why it has not been given

OR PRESENCE OF:

3. Measles vaccination given prior to 12 months

OR

4. Smallpox vaccination given prior to 24 months unless there is evidence that international travel is intended

SUPERIOR

There is no superior classification here.
There must be evidence that the child is a long term patient, and not more than 24 months old during the period of the study. He must have had at least one visit during the study and before reaching the age of 24 months.

1 = YES
2 = NO

I.D.
R.T.
STUDY CODE

CATEGORIES OF INTERVENTION

- D P T P

- D P T P (booster)

- Measles Vaccination (after 12 months or explanation why not given)

- Smallpox Vaccination

- Evidence of international travel
INDICATOR CONDITION #6 - DEPRESSION

ELIGIBILITY - An adult patient 22 years of age and over presenting with three or more of the following symptoms, or stated diagnosis of depression.

1. A feeling of depression
2. Fatigue
3. Sleep disturbance
4. Apathy or 'turned off'
5. Stated nervousness
6. Constipation
7. Loss of libido
8. Loss of appetite
9. Irritability
10. Muscular skeletal discomfort
11. Chronic recurring headache

EPISODE - begins 1. the first indication of a diagnosis of depression or the combination of symptoms as listed above. OR 2. pre-existing and continuing depression at the start of the study.

ends - at the conclusion of the study period or on the last recorded visit for depression.

CATEGORIES OF INTERVENTION

1. A general physical examination (done within 6 months)
   If negative - at least a statement should be made such as "O.E. Neg.", "Phys. exam Neg.". If positive - positive findings to be recorded.

2. Medical history - family history, past illness, present complaint.

3. Doctor's awareness of the presence or absence of problems.
   (Record is not as important as the evidence that appropriate examination and enquiry has been done).

4. Evidence of enquiry concerning drugs, either prescribed or self-administered.

5. Consultation or referral to a psychiatrist (immediate if evidence of suicide.)

6. Evidence of psychological support.

7. At least one follow-up visit in a month.

8. Treatment by family physician up to one month if there is a) evidence of structured therapy b) no deterioration
9. Treatment by family physician up to three months if there is evidence of improvement.

10. Hospitalization (immediate if evidence of suicide)

11. Treatment by family physician longer than one month if there is evidence of improvement to Grade II level.

GRADE I - Depression without evidence of impaired function or complication

OPTION I

ADEQUATE

1. A general physical examination (done within 6 months)
   If negative - at least a statement should be made such as "O.E.Neg."
   "Phys exam Neg." If positive - positive physical findings to be recorded.

2. Medical history - family history, past illness, present complaint.

3. Doctor's awareness of the presence or absence of problems. (Record is not as important as the evidence that appropriate examination and enquiry has been done.)

6. Evidence of psychological support.

7. At least one follow-up visit in a month.

QUESTIONABLE - less than Adequate

OPTION II

5. Consultation, or referral to a psychiatrist

GRADE II - Depression with impairment of function (social, vocational or physical) which has been recognized by one of the following:

   a) the patient
   b) a concerned person or relative
   c) the physician

OPTION I

ADEQUATE

1. A general physical examination (done within 6 months)
   If negative - at least a statement should be made such as "O.E.Neg."
   "Phys. exam Neg." If positive - positive physical findings to be recorded.

2. Medical history - family history, past illness, present complaint.
3. Doctor's awareness of the presence or absence of problems. (Record is not as important as the evidence that appropriate examination and enquiry has been done)

4. Evidence of enquiry concerning drugs, either prescribed or self-administered

8. Treatment by family physician up to one month if there is
   a) evidence of structured therapy
   b) no deterioration

9. Treatment by family physician up to three months if there is evidence of improvement.

QUESTIONABLE - Less than Adequate

OPTION II

5. Consultation or referral (recommended and/or carried out)

GRADE III - Patient is suicidal, psychotic or non-functional as determined by one of the following:
   a) patient
   b) significant other
   c) the physician

OPTION I

ADEQUATE

1. A general physical examination (done within 6 months)
   If negative - at least a statement should be made such as "O.E. Neg".
   "Phys exam Neg." If positive - positive physical findings to be recorded.

2. Medical history - family history, past illness, present complaint.

3. Clear indication of psycho-social enquiry. (Record is not as important as the evidence that appropriate examination and enquiry has been done.)

4. Evidence of enquiry concerning drugs, either prescribed or self-administered

8. Treatment by family physician up to one month if there is
   a) evidence of structured therapy
   b) no deterioration

11. Treatment by family physician LONGER than one month if there is evidence of improvement to Grade II level.

OPTION II

5. Consultation or referral to a psychiatrist (immediate if evidence of suicide).

OPTION III

10. Hospitalization (immediate if evidence of suicide)
ELIGIBILITY - An adult patient 22 years of age and over presenting with three or more of the following symptoms or stated diagnosis of depression - feeling of depression - fatigue - sleep disturbance - apathy - "turned off" - stated nervousness - constipation - loss of libido - loss of appetite - irritability - muscularkeletal discomfort - chronic recurring headaches

Includes patients with pre-existing and continuing depression.

Grade I (0601) - depression without evidence of impaired function or complication

Grade II (0602) - depression with impairment of function (social, vocational or physical)

Grade III (0603) - patient suicidal, psychotic or non-functional.

EPISODE code at the conclusion of the study period or the last recorded visit for depression.

1 - YES  I.D.
2 - NO

R.T.

STUDY CODE

CATEGORIES OF INTEGRATION

- General physical examination (within 6 months)
- Doctor's awareness of the presence or absence of problems
- Family history
DEPRESSION (Con't)

- Past history

- Present complaint

- Enquiry re drugs (prescribed or self administered)

- Psychological support (family physician)

- At least one follow-up visit a month (family physician)

- Treatment by family physician up to one month

- Treatment by family physician longer than one month

- Treatment by family physician up to three months

- Evidence of improvement

- Evidence of structured therapy

- Deterioration of condition

- Improvement to grade two level

- Consultation - psychiatrist (immediate if evidence of suicide)

- Hospitalization (immediate if evidence of suicide)

* When reviewing charts, if prescription medications are recorded, accept this as evidence that the physician is aware of medications taken by the patient. If there is no evidence in the records that prescription medications are recorded, then there must be evidence that the physician has made enquiries as to the medications taken by the patient.
DEFINITION OF AN EPISODE - URINARY TRACT INFECTION

For persons meeting indicator condition criteria, the first visit in which this diagnosis is recorded or necessary symptoms recorded within the period of study. It ends at the conclusion of the study period or the last visit concerning this indicator condition, whichever comes later.

DEFINITION OF TERMINOLOGY

1. Acute - a urinary tract infection with no preceding episode within the past year.
2. Recurrent - this is self-evident; recurrent urinary tract infections within one year; second episode within the year.
3. Minor - symptoms are localized to the bladder or urethral area. There are no secondary symptoms such as fever, chills, rigor, loin pain, general malaise, etc.
4. Major - symptoms extending beyond the bladder, such as pain in the upper abdomen or loin, chills, fever. Haematuria could be considered in the minor group since this would be an episode of acute haemorrhagic cystitis.

N.B. Haematuria with symptoms of cystitis would be approached like any other cystitis. An asymptomatic haematuria would be an entirely different indicator condition.

For purposes of study, those patients who may previously have had surgical management and investigation of urethral vesicle reflux problems are excluded.

Symptoms

Symptoms acceptable under the definition of symptomatic infections include: frequency, dysuria, haematuria, suprapubic pain, loin or loin pain, chills, fever, general malaise.

CLASSIFICATION FOR PURPOSES OF THIS STUDY

1. Acute Minor or equivalent - equivalents acceptable are acute cystitis, cystitis, lower G.U. infection, urethritis, bladder infection, trigonitis.
2. Acute Major - equivalents are pyelitis, pyelonephritis, peri-renal abscess, ureteritis.
3. Recurrent Minor - equivalents acceptable are chronic cystitis, recurring cystitis, recurring bladder infection, recurring lower G.U. infection, chronic or recurring urethritis, etc.
4. Recurrent Major - equivalents acceptable are chronic pyelitis, recurring pyelitis, chronic or recurring pyelonephritis, chronic or recurring ureteritis.
CATEGORIES OF INTERVENTION

A Examination

1. Abdominal examination, including an examination for costovertebral angle tenderness.
2. Pelvic examination

B Laboratory and Diagnostic Procedures

3. Office urinalysis, for albumin, glucose and microscopic
4. KSU for urinalysis, culture and sensitivity
5. Repeat KSU after cessation of antibiotic therapy
6. Gc. Smear
7. I. V. P.
8. Examination for acid-fast tubercle

C Therapy

9. Appropriate antibiotic (inappropriate antibiotic would include Streptomycin, Lincomycin, Furadantin, etc.) not less than ONE week.
10. Appropriate antibiotic as above for duration of FOUR weeks.
11. Selective antibiotic after culture and sensitivity have been reported - (NOT LESS THAN ONE WEEK)
12. Selective antibiotics as above - duration - FOUR weeks
13. Follow-up visit with repeat urinalysis (office or lab)

D Consultation

SCORING

Acute Minor

ADEQUATE

OPTION 1

1. Office urinalysis, for albumin, glucose and microscopic
9. Appropriate antibiotic (inappropriate antibiotic would include Streptomycin, Lincomycin, Furadantin, etc.) not less than ONE week.
11. Follow-up visit with repeat urinalysis (office or lab.)

OPTION 2

14. Consultation

INADEQUATE

Less than adequate
Acute Minor

SUPERIOR

3. Office urinalysis, for albumin, glucose and microscopic.
9. Appropriate antibiotic (inappropriate antibiotic would include Streptomycin, Lincomycin, Furadantin, etc.) not less than ONE week.
13. Follow-up visit with repeat urinalysis (office or lab.)

ONE OF THE FOLLOWING

4. MSU for urinalysis, culture and sensitivity.
5. Repeat MSU after cessation of antibiotic therapy.

PLUS ONE OF THE FOLLOWING:

1. Abdominal examination, including an examination for costovertebral angle tenderness.
6. Gc. Smear
7. I. V. P.
12. Selective antibiotics as above - duration - FOUR weeks.

Acute Major

ADEQUATE

OPTION 1

1. Abdominal examination, including an examination for costovertebral angle tenderness.
3. Office urinalysis, for albumin, glucose and microscopic.
4. MSU for urinalysis, culture and sensitivity.
7. I. V. P.
12. Selective antibiotics as above - duration - FOUR weeks.
13. Follow-up visit with repeat urinalysis (office or lab.)
5. Repeat MSU after cessation of antibiotic therapy.

OPTION 2

14. Consultation

INADEQUATE

Less than adequate.
Acute Major

**SUPERIOR**

**OPTION 1**

1. Abdominal examination, including an examination for costo­vertebral angle tenderness.
2. Pelvic examination
3. Office urinalysis for albumin, glucose, and microscopic.
4. MSU for urinalysis, culture and sensitivity.
5. Repeat MSU after cessation of antibiotic therapy.
6. I. V. P.
12. Selective antibiotics as above - duration - FOUR weeks.
13. Follow-up visit with repeat urinalysis (office or lab.)

**OPTION 2**

14. Consultation

PLUS ANY ONE OF THE FOLLOWING

2. Pelvic examination
6. Gc. Smear
8. Examination for acid-fast tubercle

Recurrent Minor

**ADEQUATE**

**OPTION 1**

1. Abdominal examination, including an examination for costo­vertebral angle tenderness.
2. Pelvic examination
3. Office urinalysis, for albumin, glucose and microscopic
4. MSU for urinalysis, culture and sensitivity
7. I. V. P.
12. Selective antibiotics as above - duration - FOUR weeks.
13. Follow-up visit with repeat urinalysis (office or lab.)
5. Repeat MSU after cessation of antibiotic therapy

**OPTION 2**

14. Consultation

**INADEQUATE**

Less than adequate
Recurrent Minor

SUPERIOR

Adequate PLUS

6. Gc. Smear OR

8. Examination for acid-fast tubercle

Recurrent Major

ADEQUATE

1. Consultation (MANDATORY)

INADEQUATE

Less than adequate

SUPERIOR Adequate PLUS

13. Follow-up visit with repeat urinalysis (office or lab.) performed by the family physician in hospital or in the office.

5. Repeat MSU after cessation of antibiotic therapy.
- Begins - with a diagnosis or symptoms recorded within the study period.
  (frequency, dysuria, haematuria, suprapubic pain, flank or loin pain, chills, fever, general malaise)
- Ends - at the conclusion of the study period or the last visit concerning the condition.

**Local Mictur**
0701
- first episode within the year.
  Symptoms - localized to bladder or urethral area.
  (cystitis, lower G.U. infection, urethritis, bladder infection, trigonitis)

**Recurrent Mictur**
0702
- Recurring within the year.
  Symptoms - localized to bladder or urethral area.
  (recurring or chronic cystitis, bladder infection, lower G.U. infection, urethritis)

**Acute Mictur**
0703
- Failure to respond to initial therapy; first episode within the year.
  Symptoms - pain in upper abdomen or loin, chills, fever.
  (pyelitis, pyelonephritis, peri-renal abscess, urethritis)

**Recurrent Mictur**
0704
- Recurring within the year.
  Symptoms - pain in upper abdomen or loin, chills, fever.
  (chronic pyelitis)

**Asymptomatic**
- haematuria with symptoms of cystitis.

**Patients**
- Asymptomatic haematuria
- patients with previous surgical management and investigation of urethral vesicle reflux
- chronic problem of B.U.T.
  (paraplegics, quadraplegics, multiple sclerosis)

<table>
<thead>
<tr>
<th>1 = YES</th>
<th>2 = NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. O.</td>
<td>1</td>
</tr>
<tr>
<td>R. T.</td>
<td>2</td>
</tr>
<tr>
<td>STUDY CODE</td>
<td>3</td>
</tr>
</tbody>
</table>

- Abdominal examination & costovertebral angle tenderness
- Pelvic examination
- Urinalysis
- Microscopic
- M S U - culture & sensitivity
- Repeat M S U - post antibiotic therapy
- G C Sear
- I.V.P.
- Acid-fast tubercle
- Appropriate antibiotic (not less than one week) (inappropriate - strep; lincomycin)
- Appropriate antibiotic - four weeks
- Selective antibiotic - not less than one week (after culture & sensitivity)
- Selective antibiotic - four weeks
- Withhold antibiotics when no growth reported
- Follow-up visit & repeat urinalysis
- Consultation
Appendix III - Reliability Check

<table>
<thead>
<tr>
<th>non-physician</th>
<th>inadequate</th>
<th>adequate or superior</th>
<th>TOTALS</th>
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<td></td>
<td>34</td>
</tr>
</tbody>
</table>

Kappa = \( \frac{P_{\text{observed}} - P_{\text{chance}}}{1 - P_{\text{chance}}} \)

\[
P_o = \frac{8 + 21}{34} = 0.85
\]

\[
P_c = \frac{13 \times 8 + 21 \times 26}{34} = \frac{3 \times 1 + 16.1}{34} = 0.56
\]

\[
K = \frac{0.85 - 0.56}{1 - 0.56} = \frac{0.29}{0.44} = 0.66
\]