

PROCESS MEASURES OF QUALITY OF CARE: A STRATEGY FOR
VALIDATION AGAINST OUTCOMES

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ABSTRACT

Quality of care evaluation strategies are needed for meaningful assessment of health care delivery for research, quality assurance and educational purposes.

For the purpose of improving strategies for measuring quality of care, this thesis first reviews methodologic features of available measurement strategies as reported in the current scientific literature. Secondly it proceeds with the development of a descriptive research design to evaluate the criterion validity of a strategy for evaluating process items by comparison with comprehensive outcome measures including physical, emotional and social function. Thirdly, the development of a new strategy for measurement of interpersonal skills, which is incorporated into the process evaluation, is described.

The objective of the study is to study patients with acute myocardial infarction in order to determine whether measurable differences in the care administered to and received by these patients result in clinically significant differences in these patient's health status six months later. Acute myocardial infarction has been chosen as a disease appropriate for the testing of this strategy because of its high incidence, its functional impact upon the patient, the variation in process management items performed by different physicians, the different clinical settings involved, the relative ease of diagnosis and availability of an inception cohort. A community

hospital setting has been selected for the reason that, compared with a teaching hospital setting, the generalisability of the study to the practice of other physicians will be greater since the majority of physicians involved in the care of patients with acute myocardial infarction work in community hospital settings.

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1. INTRODUCTION

"The core of quality of medical care is the extent to which scientifically proven effective methods of treatment are properly applied to patients who can benefit from them", (Cochrane) (23).

Quality of care evaluation strategies are needed for meaningful assessment of health care delivery to specified populations for research and ongoing quality assurance purposes; in addition they are likely to be useful as an educational feedback measure based on the performance of the health professional.

Increasing pressure is being applied to the medical profession in North America to provide evidence that optimal health care is being provided. In Canada consumer interest in the health services has increased since the introduction of health insurance schemes financed by taxes. The Hall Commission (111), an influential report laying the groundwork for National Health Insurance, discussed the quality implications of its recommendations and defined the goal of a health care system as achievement of the 'highest possible health for our people'. Soon after the introduction of National Health Insurance, the Federal and Provincial governments began placing emphasis on investigations to help provide answers to the difficult issue of balancing economy and quality (135). Governmental intervention in the regulation of the medical profession in Canada is increasing due to the fact that the government rather than the medical profession has a responsibility for the expenditure of public taxes. A measure designed to ensure quality for the consumer is the policy in Ontario which restricts

the role of the provincial regulatory body, The College of Physicians and Surgeons of Ontario, to protecting the public as opposed to the medical profession (49). The Health Disciplines Act of 1975 further underlines the obligations for public accountability by increasing lay representation on all the professional regulatory bodies, and by the creation of an exclusively lay body called a Health Disciplines Board, whose responsibility is to supervise the professional regulatory bodies (54).

Since January 1977 quality appraisal has become mandatory for hospital accreditation in Canada (50) and a similar mechanism was recommended in 1976 for primary care in Ontario (41).

In the United States the Professional Standards Review Organizations were set up by Congress as one of the provisions of the Social Security Amendments of 1972 (139) with the aim of effectively diminishing unnecessary hospital care for Medicare and Medicaid patients by employing utilisation review methods that had been developed by foundations for medical care (35, 147). It was widely feared that the safeguarding of quality was not guaranteed by such legislation, and in fact might deteriorate if governmental peer review was devoted entirely to cost control (120). In view of this, increasing effort by the medical profession has been directed at developing models for quality assessment and assurance (121) and quality assurance has subsequently been increasingly emphasized in the interpretations of the PSRO legislation (138).

Approaches to measurement of quality of care

Quality of care encompasses a complex set of interactions including provider behaviours, patient behaviours and provider-patient interactions. Approaches to the evaluation of quality of care are commonly classified into one of three categories, structure, process or outcome (32). Assessment of

structure encompasses the numbers and qualifications of health professionals as well as the characteristics of the administrative organisation and the physical facilities. Process assessment refers to the evaluation of the actions of health professionals in the management of patients; it can be subdivided into technical process (e.g. investigations, physiologic monitoring and drugs prescribed) and interpersonal process (e.g. patient education). Assessment of outcome refers to the end results of health care in terms of the effect it has upon the patient's health.

Health implies a positive state of bodily function. The World Health Organisation has defined it as follows: 'Health is a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity' (153) which has subsequently been interpreted by a World Health Organisation technical study group as a condition or quality of the human organism which expresses adequate functioning under given genetic and environmental conditions (154). If this is accepted then the functional status should be the definitive measure of quality of care; this corresponds to 'outcome' as defined above.

There are important implications if the outcome health status is used as the definitive measure of quality of medical care. It means that process and structure measures are only acceptable as indicators of quality where they have been demonstrated to predict the outcome of interest.

Although licensure of professionals and accreditation of institutions are largely based on structural characteristics, the effect of the latter upon outcomes is indirect. Their use was justified when other measures were

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unavailable, but since there are now strategies that are likely to detect variations in outcome health status, structural assessment will not be considered further.

Over the past 20 years emphasis has increasingly focussed on process evaluation and considerable experience has accumulated in the use of these strategies (13,43,74,81,92,104,125,127). They have been shown to be feasible and potentially useful for both research and ongoing quality assurance purposes, although the scope of the instruments is limited. However, limitations in process evaluation exist. First, the standards against which the performance is judged is usually based not on clinical outcome but upon what is considered to be good practice by the leaders of the profession. Second, validation of such process strategies against outcome has had to await the development of feasible and valid outcome measures. Thirdly, the cost of both the implementation of the process strategies and of rectifying the deficiencies identified is considerable (see page 18). Finally, current process strategies fail to include assessment of important dimensions of care such as patient education.

The current situation clearly points to the necessity for validation of these process strategies by comparison with outcome. Fortunately over the past few years there has been substantial progress in developing instruments for assessing health status in terms of physical, emotional and social function (8,119).

On reviewing the current situation this author became interested in developing process measures that include the interpersonal dimension, and then

developing and applying a model for assessment of their correlation with the health outcomes of the patient. In this thesis methodologic issues involved in the development of a comprehensive and valid process evaluation strategy are discussed in the content of the current literature, and a research design is presented for evaluating the productive validity of these measures by comparison with clinical outcomes.

2. A REVIEW OF THE LITERATURE ON PROCESS MEASURES OF QUALITY OF CARE.

The review of the literature will be based upon the following methodologic features which relate to the credibility and utility of any evaluation strategy (modified from Sackett et al (119)).

1. Feasibility: The strategy should be capable of use in a variety of health settings.
2. Comprehensiveness: The strategy should encompass all major dimensions of quality of care.
3. Sensitivity: The strategy should detect clinically significant differences in quality of care.
4. Cost: The cost should be appropriate to the objectives.
5. Precision and Minimisation of Error: Error should be minimised and the reproducibility of the measures should be at an acceptable level.
6. Analysis: The measurements should be in the form of numerical scores to which statistical analysis can be applied.
7. Validity: The strategy should be validated against a criterion measure; in this instance the criterion measure should be physical, emotional, social and physiologic function.

2.1. FEASIBILITY

An evaluative strategy should be sufficiently simple and acceptable for it to be useful in all health settings. Models that have been used include record review, direct observation and questionnaires.

Record Review: This is the most common strategy for process evaluation in most settings. There are two principal approaches to its use depending on whether the implicit judgement of the evaluator is relied upon or alternatively whether prior explicit and formal specification of the criteria by which the record will be judged are utilised.

Studies that have utilised the implicit judgement approach include extensive investigations carried out by Columbia University for The Teamsters Union (91) and some of those of the Health Insurance Plan of New York (92); these included studies of both hospital and ambulatory care. For example a random sample was obtained of hospital records of 292 patients who had a claim paid by Blue Cross in May, 1962 for hospitalisation in hospitals in New York City. These were reviewed by thirteen clinicians with 'recognised professional standing in their specialties'. Many problems relating to quality medical care were identified (91). This approach has the advantage that there is no limit to the number of conditions that can be assessed, but has problems in terms of reliability and is limited by the necessity for an expert physician's time. Nonetheless this approach is still used for undergraduate and postgraduate internal educational purposes as an unstandardised component of bedside teaching, although some have formalised this for evaluation of educational progress (87,96,97).

The explicit approach has been widely applied in hospital (43,81,105, 127), ambulatory care (60,74,102,125) and emergency rooms (13,48). Lembcke (81)

was one of the first to utilise criteria in hospitals; he developed them as guides for his own use in external audits which he performed at the invitation of hospitals, and demonstrated their application in 15 areas of medicine and surgery. Payne et al (105) developed and applied this approach to over 50 conditions, again primarily in hospitals. This same approach has been incorporated into the PAS-MAP computerised system of the Commission of Hospital and Physician Activities which is presently used to evaluate 42% of the short-term hospital discharges in the United States, and 28% of those in Canada; this has been recently extended to include emergency room care (127). Ambulatory care studies initially received little emphasis, but Kessner in 1969-70 developed the disease specific tracer condition approach and demonstrated its feasibility in a study that evaluated the care of children received from a prepaid group practice and a neighbourhood health center (74). Sibley et al (125) extended the tracer disease concept to presenting complaints, commonly used drugs and specialist referrals in a study to measure the quality of care provided by physicians and nurse practitioners in the primary care setting in Canada. They found that the quality of care provided by nurse practitioners was not statistically significantly different from conventional care by a family physician. Greenfield et al have developed a sophisticated system for inpatient and ambulatory assessment of quality of care, utilising branching criteria to reflect sequential judgements which allows for the assessment of only those criteria relevant to the patient. They have formulated protocols for 20 conditions and have carried out some validation studies on patients with urinary tract infection and chest pain by comparison with other process techniques and with outcome (6,46,47,48).

Although feasibility has been demonstrated, record review has problems with completeness of documentation and comprehensiveness, which will be discussed later.

Direct Observation and Tape Recording

Taylor (136) was one of the first to describe the use of the direct observation method; an observer assessed the interactions between 94 physicians and their patients, but described these encounters in a subjective anecdotal fashion so that it is difficult to obtain objective evidence on the quality of care using such an approach. Peterson et al (108) used direct observation, without attempting documentation of details, to assess technical care given by 88 physicians in their offices in North Carolina, and utilised a weighted scoring procedure for comparisons. The performance of 66 of these physicians was found to be less than optimal. Commenting on the possibility that physicians might change their behaviour when observed, the authors claim that this did not occur since the physicians were not informed that assessment of the level of performance was one of the objectives of the study. However, it seems improbable that this was the case. Subsequently the same technique was utilised in Canada by Clute (22) and in Australia by Jungfer and Last (67) with similar results. The following studies from the literature on doctor-patient communication and medication compliance are relevant. Pratt et al (110) observed and recorded encounters of 55 new patients in a hospital general medical clinic in New Jersey as part of a study to determine physicians attitudes and beliefs about patient's knowledge, in which they demonstrated that physicians tend to underestimate the medical knowledge of patients. Svarstad (134) observed and manually recorded all verbal communication that took place in 153 encounters between patients and physicians in a neighbourhood

health center, to isolate dimensions of physician communication that might relate to the patient's subsequent compliance behaviour. Tape recording alone has been used: Korsch et al (78) recorded the verbal communication that took place in 587 encounters between physicians and children with their mothers in a paediatric clinic, in order to compare it with subsequent patient satisfaction and compliance. Zuckerman et al (157) recorded 51 patient-physician encounters in a paediatric ambulatory clinic and compared the data with information written in the medical record.

These techniques have not found wide acceptance mainly because of the large amount of professional time in observation and interpretation, and the likelihood that the practice of the physician is probably altered by this obtrusive measurement (33).

Questionnaires: Physician questionnaires have been used in a few studies. Kark et al (71) in a study of continuity of medical care after discharge from hospital interviewed the physician looking after the patient to find out about instructions given to the patient. Hulka et al (60) used a list of instructions on which the physician ~~marked off~~ those that took place in a study of quality of care in a primary care setting in Indiana. Inui et al (64) in a study of quality of care on hypertension used a questionnaire to assess physician's estimates of the proportion of clinic time spent on different areas of management. A major problem with physician questionnaires is the fact that the physician quickly learns which attributes the investigators are interested in, and this may alter their usual behaviour.

Patient questionnaires have not been used as a data source for quality of care assessment, although evidence from studies on doctor-patient communication and compliance with medications suggests that information on process,

TABLE 1 : Weighting of Feasibility of Different Strategies
for Measurement of Quality of Care.

STRATEGY	FEASIBILITY IN DIFFERENT SETTINGS	
	In-Patient	Ambulatory
Record Review		
Implicit Judgement	1	2
Explicit Judgement	4	4
Direct Observation or Tape Recording	1	1
Physician Questionnaire	2	2
Patient Questionnaire	3	3

4 = Highly Feasible

0 = Not Feasible

especially issues relating to patient education, may be obtained. Kane and Deuschle (68) compared the results of a questionnaire with the patient's record in 99 patients from a rural population in Kentucky, and found that several months later, although only 28% could name at least one other drug, the majority remembered one of their diagnoses, 95% knew the purpose of at least one of their drugs, 74% knew the duration of some of their medicines; for those patients prescribed a diet 26 out of 27 could describe the diet; over 50% of patients assigned to a special activity could recall what activity had been advised. In a study of patients with Diabetes Mellitus, Hulka et al (59) compared the results of a checklist completed by physicians with the results of a questionnaire (administered about two weeks later) that assessed patient knowledge of the instructions given by the physician concerning management and self-care. Two-thirds of the information imparted was remembered; considering that these were follow-up visits in a primary care practice and that the number of items of instruction ranged from 4 - 21 with a median of 12, patient memory seems relatively efficient. Korsch et al (78) compared a tape recording of 587 clinic visits with an interview 7 - 14 days after the visit, and noted that only 'a few cases of noncompliant behaviour appeared to be explicable on the basis of failure to perceive the instructions, and others on the basis of failure to understand the rationale of treatment'.

On the basis of this literature review it can be seen that the feasibility of the different methods varies; table 1 summarises the author's opinion of the relative feasibility of the different strategies in both in-patient and ambulatory settings.

2.2. COMPREHENSIVENESS

Evaluative strategies should assess all the areas of interest; in the case of process evaluation the dimensions of management and the range of diseases sampled are relevant.

The range of dimensions of management included in various studies varies considerably as can be seen in Table 2 . Some have confined themselves to a few dimensions of care. Huntley et al (61) assessed outpatient care from the medical record using two criteria, the completeness of the data base and the percent of abnormalities found but not followed up. Williamson et al (150) also confined themselves to assessing the abnormalities found on routine laboratory test results. The Commission on Professional and Hospital Activities recommends a multi-dimensional approach including assessment of history, physical examination, physiological measures, anthropological parameters, laboratory and neurological investigations, consultations with other health professionals, use of drugs, detection and management of complications, disposition of the patient and length of hospital stay (142). Kessner (73) claimed that an efficient way to obtain data relating to wide range of process dimensions was to utilise different conditions, each of which represent different aspects of management.

A major omission from the majority of quality of care strategies is the dimension of patient education, with the notable exception of Hulka (61) and Inui (64). However, studies on doctor-patient communication and compliance with medication discussed in the section on feasibility, suggest that direct observation or patient questionnaires might be used for this purpose.

The measurement of only a few aspects of management is likely to produce misleading results (since an incomplete picture of the process of care is obtained) unless high correlations are demonstrated between the different dimensions of care; this has been studied with conflicting results in investigations using implicit approaches (91,108) which may be due to the limitations of this approach, but there are no data using the explicit criteria approach.

Similar concerns apply to the range of conditions looked after by a

TABLE 2: Examples of Variation in the Range of Management Dimensions in Quality of Care Studies.

	Prevention	History	Physical Examination	Laboratory Results	Therapy	Patient Education	Consultations	Follow - Up	Style of Record	No. of Dimensions
Williamson (150)				+						1
Huntley (61)				+					+	2
Brook (14)				+	+			+		3
Starfield (131)				+	+			+		3
Wu (64)		+	+		+	+				4
Lindsay (83)		+	+	+	+			+		5
Clute (22)	+	+	+	+	+				+	6
CPHA (142)		+	+	+	+		+	+		6
Hulka (60)	+		+	+	+	+		+		6
terson (108)	+	+	+	+	+				+	6
ssner (73)	+	+	+	+	+	(+)	+	+		8
Sibley (125)	+	+	+	+	+	(+)	+	+		8

(+) = Only required in a minority of instances.

physician or group of physicians. In the absence of data showing correlations between the quality of care in different conditions it will be necessary to evaluate all conditions about which information is desired. However, a major proportion of the patients seen by primary care physicians are represented by relatively few health problems (149); so that by focussing on these a more representative picture may be obtained. In a study of the office practice of internists in Ohio and Connecticut (52) criteria were developed for eight conditions or problems which covered 20% of the patient visits. As discussed above, the PAS-MAP system has developed standards for over 40 diagnoses and Greenfield's group have over 20 protocols which demonstrates that a comprehensive range of conditions can be assessed.

Incompleteness of Recording: A major limitation of comprehensiveness in strategies utilising the medical record is the inconsistency with which physicians record all aspects of management. This makes it difficult to distinguish between actions not performed and actions performed but not recorded. Several medical record studies have found it difficult to assess the process of quality of care for this reason (42,80,102,106,108). Osborne and Thompson (102) found that although over 85% of physicians in one study agreed to the importance of 145 explicit criteria for 7 conditions in children, documentation of criteria was approximately 50%; half of the physicians involved felt that the results did not accurately portray their performance, since they claimed that they were performing but not recording a large number of the procedures and actions being assessed. Morehead (91) studied several neighbourhood health centers and found that documentation of care for paediatric patients was less than that for adult patients. In contrast, Kroeger (79) studied the office practice of a sample of members of the New York Society of Internal Medicine and concluded that their

records were adequate to obtain reproducible judgements. Zuckerman (157) compared medical records with information obtained from a tape recording of the interview and found that diagnoses, chief complaints, scheduled appointments, diagnostic studies, non-drug therapy and names of medications were well recorded. Sibley et al (125) found sufficient information to satisfy explicit criteria in over 60% of 168 episodes of care in a community primary care setting; this high level may have resulted from the fact that they addressed this problem of incompleteness by only choosing criteria considered significant enough to be recorded in the opinion of a peer group of primary care physicians, and also by careful training nurse abstractors.

Another strategy to improve the documentation has been active encouragement to do so where the physicians are voluntarily participating in an educational program based upon the results of the evaluation (52). Morehead (91) supplemented the record with physician interviews but did not find this useful as the interviewee tended to become defensive, and on occasion contradicted what was written on the record. Lembcke (80) utilised the notes written by other health personnel especially nurses, to extend the available information. Hulka (60) provided the family physicians with a checklist for them to document items of instruction given to patients. Rosenfeld (115) took the approach that validity of records could be improved if the deficiencies are separated into those that may be due to documentation ('presumptive' items), and those unrelated to documentation ('substantive' items) such as prescription of contraindicated drugs.

2.3 SENSITIVITY

An evaluation strategy should be able to detect important changes in the attribute of interest; in the case of process evaluation it should detect

clinically significant differences in the quality of care.

The majority of process studies of quality of care have identified considerable deficiencies as compared with standards set by experts, and these have been demonstrated in a wide range of conditions. A number of hospital studies have demonstrated deficiencies (43,81,92,104,126). In a study of perinatal mortality in New York (76) 42% of deaths in mature infants were judged to have been preventable. Surgical data includes studies such as that of the Commission on Professional and Hospital Activities (126), which demonstrated that up to 37% of operations were not justifiable in 5 general hospitals. Using explicit criteria Brook (13) reported that 98% of medical records of patients with three common conditions in a teaching hospital ambulatory clinic were deficient. Abnormalities found on screening both inpatients and clinic patients in hospital were ignored in 85% and 25% respectively (62,150). In the primary care setting deficiencies were noted in over 30% of the identified tracer conditions in three family practices in Ontario (125).

The ability to detect not only differences but change is relevant to sensitivity. In quality assurance systems, changes considered clinically significant by the professional groups involved have been demonstrated following various strategies to correct the deficiencies (37,40,43,55,64,80,103,126,150). For example Fleisher (43) reported the problems and results of attempting to set up an ongoing system of patient care quality assurance incorporating continuing educational methods of rectifying identified deficiencies. In five hospitals out of ten the system was successfully implemented. In eleven out of thirteen conditions evaluated in these five fully participating hospitals, improvements were found a year after instituting this quality assurance strategy.

The most powerful evidence for adequate sensitivity is the demonstration that changes in the process evaluation predict changes in outcome. There are no controlled trials documenting this. A few descriptive studies (14,48,83,113,131) suggest that deficiencies in process are associated with deficiencies in some limited outcome measures, such as an association between deficient management of chest pain in the Emergency Department with subsequent morbidity (see page 31) (48).

2.4 COST

Little attention has been paid to the cost of instituting ongoing quality assurance strategies. In a study of 430 medical records of admissions to New York hospitals in 1962-63, the cost of reviewing an admission was about \$140 including the abstraction, computer time and analysis of results (91). More recently Holloway et al (57) estimated that by utilising the PAS-MAP computerised system the records of 7,200 discharges in a community hospital in California could be evaluated at a cost of \$2.10 per record (at 1972 costs); this includes the cost of abstraction of the chart by the hospital and the subscription cost for the computerised data collation and analysis. They compared this with manual procedures and showed that the manual procedure costs varied considerably in proportion to the number of cases evaluated, the computer becoming cheaper as the numbers increase. McSherry (88) showed that process evaluation can be very expensive, and evaluation of 690 records in a New York teaching hospital cost \$104 per record, including the salaries of non-professionals, capital purchases and office supplies, but excluding physician time.

A factor in increasing cost is that as more sensitive strategies for measuring quality of care are developed they tend to be more complex and expensive. It has been suggested that 1% - 2% of the health costs would be an

appropriate maximum (38,116). Physician time is one of the most expensive items and the increasing use of non-physicians to perform process evaluation (74,102, 125,127) may restrict costs.

In another dimension the cost of correcting the process deficiencies identified in these studies is startling. Brook (15) suggests that if published studies are representative of the deficiencies in medical practice throughout the United States, the number of process items carried out would have to be increased by about 40% for inpatient hospital care and by 100% for ambulatory care in order to meet existing criteria. This would increase health care expenditure in the United States by \$130 billion, nearly 1% of the Gross National Product.

Cost-effectiveness studies of instituting ongoing quality assurance strategies will have to await validation of the effectiveness of process strategies by comparison with outcome.

2.5 PRECISION AND MINIMISATION OF ERROR

The reproducibility of the process measurement should be at an acceptable level, and error should be minimised. The identification of explicit standards against which to evaluate the process generally has resulted in a degree of precision much greater than that of studies without defined standards (the 'implicit' approach). Morehead (91) used an implicit approach instructing the judges to "use as a yardstick in relation to the quality of care rendered, whether you would have treated this patient in this particular fashion during this specific hospital admission". She reported that there was disagreement in assigning care as either satisfactory or unsatisfactory in over 20% of cases, and she obtained an acceptable level of agreement (92%) only after the two judges discussed cases about which there was disagreement. Such a maneuver has

been criticised by Sheps (124) on the grounds that one judge may influence the other and that the final assessment is therefore not a consensus. Peterson et al (108) also used implicit criteria, although they specified the dimensions of care for their direct observation studies. They measured precision by having each of two observers visit and grade seven physicians previously graded by the other; and to measure within-observer variation each of two observers revisited four of their own previously visited physicians. They found considerable disagreement, and furthermore found that intraobserver variation was greater than interobserver variation in many instances. Brook (14) found that three physicians using implicit process criteria disagreed in over 30% of 296 patients with hypertension, urinary infection or peptic ulcerations, and intraobserver disagreement was found in 15% of 160 cases assessed on two occasions by the same physician. Zimmer (156) studied the effect of additional information upon reliability. Four physicians were asked to review the record of each patient while still in hospital to assess the need for hospitalisation; two of the judges were restricted to information on the patient's record, whereas the other two were permitted to interview the patient's physician and, to examine the patient if they wished. Agreement between the two judges using the records only was 85% and in the two judges who had extra information was 89%, a statistically non-significant difference.

The use of explicit criteria allows acceptable precision to be attained even when the record abstraction is carried out by non-physicians; inter-observer reproducibility by comparison with physicians in excess of 90% has been demonstrated by record librarians and nurse abstractors both in hospitals (42,46) and in primary care (125).

A problem in assessing reproducibility by different groups in different settings is the fact that few investigators publish details of the criteria used in their process strategies.

2.6 ANALYSIS

The execution of a quality of care strategy should result in numbers to which statistical analysis can be applied. Furthermore, the scoring should be appropriate for the objective. The ability to discriminate between different levels of quality of care depends upon the number of intervals in the scale - studies using implicit criteria often use a simple categorical scale and the discrimination is achieved by comparing the percent of scores within each category. Morehead (91) used two categories optimal and less than optimal; Peterson (108) initially used three, good, fair and poor, of which the middle one was acknowledged to be indeterminate.

The advantage of such a scale is that it reflects the all or none aspect of medical care; care that is good in most parts but disastrously inadequate due to one vital error in one component will be rated unsatisfactory. The disadvantage of this type of scale with few divisions is the possible loss of information and lower ability to discriminate.

Numerical sub-scores have been widely used; these have the advantage that they are likely to be more sensitive and can give information on each of these contributory components. A problem then arises in deciding whether the overall performance was satisfactory. Some studies have simply added up the sub-scores (42,98). Several investigators have arbitrarily assigned weights to different categories in an attempt to reflect differing importance of items as shown in Table 3. Peterson and co-workers (108) found a simple category system unsatisfactory and developed a weighted system reflecting their opinion

TABLE 3 : Examples of Weighting Protocols used in Quality
of Care Studies.

	Peterson (108)	Clute (22)	Morehead (91)
History	30	30)
Physical Examination	34	30)40
Laboratory Investigations	26	6)
Therapy	9	9)
Preventive Measures	6	6)30
Medical Records	<u>2</u>	<u>2</u>	<u>30</u>
Total	<u>107</u>	<u>83</u>	<u>100</u>

that the diagnosis was the most important item. Clute (22) used the same approach as Peterson but altered the weighting giving equal weights to history taking and physical examination, and laboratory work received less weight. Morehead gave greater weight to the medical record (91). Payne and Lyons(106) developed a Physician Performance Index for which panels of physicians decided on the weights of the different component criteria for individual conditions; the resulting index is the sum of observed item weights divided by the sum of maximum possible weights for that case. Rimoldi (112) used the frequency with which specified items of information were used in the solution of a test problem as a measure of that items' value. This approach does not ensure that critical items are included for an acceptable result. Sibley et al(125) overcame this by insisting that all of specified minimal criteria have to be present for the case to be acceptable. Morehead (91) proposed that interlocking scores could be used whereby if the diagnostic score failed to reach an acceptable level, then the score for treatment could not exceed a certain maximum level.

If clinical outcome is the definitive measure for quality of care, then weighting of process criteria on the basis of their relation to outcome by a statistical technique such as discriminant function analysis, would not only enhance the validity of weighting but this weighting would be more likely to discriminate between groups receiving different levels of care.

2.7 VALIDITY

All process measures of quality of care should be validated against criterion outcome measures since the outcome health status is considered to be the definitive measure of quality of medical care (see page 3).

In the past this relationship has been assumed since valid outcome measures were not available so that standards were selected by other methods. Morehead (91) used the implicit clinical judgements of the physician selected to carry out the evaluation. Criteria set by expert panels or derived from text books and standard publications have been commonly used (40,46,80,102,105). An alternative approach is to obtain standards from actual practice, either that of a criterion institution or of a general community, which have the advantage that they are seen to be realistic objectives that have shown to be feasible elsewhere. The PAS-MAP system (127) operates against standards derived from over 1,000 hospitals and results of the institution being evaluated are compared against the mean of all the hospitals. Furstenburg (44) used patterns of prescribing in teaching hospital clinics as the standard to judge prescribing in private practice.

Over the past few years attempts have been made to study the inter-relationship between process and outcome. Three major issues need to be considered in relation to these studies. Before a relationship is likely to be demonstrated, all three, where applicable, need to be fulfilled:

1. The efficacy of the process item; whether execution of the process item by the physician has any effect upon outcome assuming that compliance is satisfactory.

TABLE 4 : Methodologic Issues in Studies Comparing Process with Outcome.

	Fessel (42)		Brook (14)		
	Appendicitis	Myocardial Infarction	Urinary Infection	Hypertension	Pepti Ulcer
(1) Small sample size for differences in rate of outcome					
(2) Possible Neyman bias		+			
(3) Insensitive or inappropriate process measures		+		+	
(4) Inappropriate index formation for process	+	+			
(5) Possible bias due to incomplete recording	+	+			
(6) Compliance issues possibly influencing results				+	
(7) Possible Contamination				+	
(8) Failure to standardise appropriately for external non-study variables	+	+	+	+	+

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es in Studies Comparing

ome.

Brook (14)				Starfield (131)	Lindsay (82,83)	Romn (113)	Nobrega (98)	Green (48)	
Cardiac Infarction	Urinary Infection	Hypertension	Peptic Ulcer	Anemia	Urinary Infection	Myocardial Infarction	Cardiac Failure	Hypertension	Chest
					+	+		+	
+								+	
+		+					+	+	
+						+	+	+	
+				+					
		+		+		+	+	+	
		+				+	+		
+	+	+	+	+	+	+	+	+	+

2. Compliance: whether the patient has followed through and complied with the process item, where process items involve the patients (such as taking drugs) since effectiveness of process will only be demonstrated when the maneuver is completed by both physician and patient.
3. Data collection: whether the physician has recorded the process actions executed, since most current strategies utilise the medical record.

Additional methodologic issues arising out of the review of studies of the relationship between process and outcome are summarised in Table 4.

Codman (24) is credited as the pioneer in this field; in 1916 he reported his experience with his routine practice of recalling all his surgical patients one year later to determine whether the operation had been successful and where it was unsuccessful, described how he reassessed the case to see whether this was due to the wrong diagnosis, improper operative technique or to the natural history of the disease.

Fessel and Van Brunt (42) studied the relationship between process and outcome in patients with acute appendicitis and myocardial infarction, and found no relationship. For appendicitis diagnostic process was measured using the medical record and the outcome was defined as histologically proved inflamed appendices. For the myocardial infarction audit the medical record was again used for process, and in addition the outcomes were also obtained from the outpatient follow-up charts, these being time lost from work, angina, congestive heart failure, myocardial reinfarction and death. They compared the differences between the mean number of process items for the condition between hospitals with the outcomes of interest and found no correlation. They also compared the audit scores of.

50 patients who survived acute complicated myocardial infarction with those of 50 patients who died from it in the hospital, and showed no relation of process to outcome. Methodologic issues arising from this paper are (see Table 4): (a) Process criteria were selected from a hospital with a full complement of house staff and compared with other hospitals where it is implied this was not the case. This has probably introduced a definite bias whereby this method of choosing the process criteria is likely to result in inequalities more related to extent of documentation rather than performance; (b) the sensitivity of the process measure is likely to be fairly low since only four out of twenty six items incorporated into the overall index score relate to management, and there is little variation in the extent to which these items were fulfilled. It would seem unlikely that items such as family history and performance of VDRL will have a causal relationship with outcome. Inclusion of these not only reduces the sensitivity but are also of dubious validity; (c) there is not appropriate adjustment for external factors such as disease severity. Other work on disease severity is referred to but incorrectly applied; Hughes showed that specified findings when recorded as present predicted the outcome, but Fessel and Brunt computed whether these items were recorded at all, irrespective of whether they were present or absent, and found no relation to this predicted outcome. Common to all these studies is the possibility of significant process correlations with outcome being masked by external factors such as disease severity which can be allowed for by special statistical methods (see page 67); (d) it is unclear whether any action was taken to avoid a 'Neyman' bias. Because the outcome was assessed from the records alone, if the patient dropped out, had symptoms or died without being readmitted these outcomes would be missed.

Brook (14) compared process with outcome in patients with hypertension, urinary tract infection and peptic ulceration, using both implicit and explicit techniques. Outcomes were assessed on the basis of mortality and follow-up interview at five months for uncontrolled hypertension, positive urine cultures and persisting peptic ulcer symptoms in addition to activity and mortality. The implicit process judgement was compared with the actual outcome measured in contingency tables and a few significant correlations were found between the process judgement and the results of the five month urine culture in patients with urinary tract infection and with the follow-up blood pressure control in the hypertensive patients. Comparing the explicit process criteria with outcome produced the following significant correlations: (i) In patients with urinary infection, a negative correlation between follow-up urine analysis and activity at five months; (ii) In patients with hypertension a positive correlation between ordering of a salt restricted diet and blood pressure control; (iii) In patients with peptic ulcer a positive correlation of control of ulcer symptoms with prescription of antacids, provision of information to the patient's private physician and seeing the physician at least monthly. The methodologic issues of efficacy and compliance are discussed. However, no adjustment for external factors such as disease severity is made and the outcome measure of persistent symptoms and decreased activity are inappropriate for the condition of hypertension, (see Table 4).

Starfield and Scheff (131) compared process with outcome in the quality of care given to children with iron deficiency anemia; for those patients given appropriate drug regimens and follow-up, the outcome haemoglobin level was statistically significantly higher than those of patients who did not

satisfy these process criteria. It would be interesting to learn whether the physical, emotional or social outcomes were related to this process. The methodologic issues raised in this study are (see Table 4); (a) on the issue of efficacy, although giving iron raised the haemoglobin it cannot be assumed that this therapy had any effect upon the symptomatic status of the patients. A controlled study failed to show that raising the haemoglobin in anemic patients is responsible for relief of symptoms (23). This emphasises the need to include functional outcomes of patients as well as physiological ones in studies comparing process with outcome; (b) compliance with taking iron is described, but it is surprising that 3 out of 9 patients who were described as taking it inadequately had a satisfactory outcome haemoglobin level; (c) recording differences may have introduced bias since the process criteria were satisfied more often in the clinic with more paramedical personnel where the physician was a Fellow as compared with clinic with a lower rate of satisfied process criteria staffed by fewer personnel and where the physicians were housestaff; (d) external factors such as co-existent disease were not considered.

Lindsay et al (82) have studied the relationship between process and outcome in acute bacterial cystitis in women. Forty-two cases were reviewed by analysis of patients records for process items; outcome measures included a positive urine culture six months later (2 patients), and recurrent urinary symptoms (15 patients) obtained by a follow-up questionnaire. No correlation was found. As the authors state, this study is unlikely to have shown a relationship due to the infrequency of adverse outcomes with a sample this small. In a second study Lindsay et al (83) used the same approach with out-patient medical care of patients following hospital discharge after myocardial infarction, in which process was weighted and combined into an index and

compared with mortality. A significant association between ten process items (inquiry about cardiovascular symptoms, inquiry about smoking, inquiry about activity status, blood pressure recorded, weight recorded, notation of examination of heart and lungs, fasting blood sugar, serum cholesterol, serum triglycerides, pharmacologic treatment if hypertensive) performed at the first post hospital visit and mortality at two years was found but later process did not show a correlation. Points of methodologic concern with this study include: (a) the insensitivity of mortality as an outcome with this sample size when the bulk of mortality occurs before and during hospitalisation; (b) the fact that weighting was arbitrary when it could have been used to discriminate by using discriminant function analysis; (c) the absence of a baseline measure to avoid the contaminating effect of the differing process interventions such as patient education and medications that took place during hospitalisation; (d) Compliance may be important when assessing the association of process items such as anti-arrhythmic drugs with the outcomes.

Romm et al (113) studied patients with heart failure for correlations of process with the outcomes of activity and symptoms after six months; a significant association between physician awareness of patient concerns and the outcome of symptomatic cardiac failure was only found in a group of patients who were minimally symptomatic initially. Methodologic concerns here include: (a) the possibility of significant process correlations with outcome being masked by initial disease severity is quite likely in view of the finding that disease severity was the strongest association with outcome; (b) the insensitivity of the management process criteria, and the index construction chosen; (c) the use of a checklist for instructions which will tend to change physicians' behaviour and encourage uniformity when the objective is to analyse

differences for correlation with outcome; (d) compliance may be important for such process items as instructions on diet.

Nobrega et al (98) studied patients with hypertension in which process variables were compared to physiologic outcome of control of blood pressure, and no association was shown. Methodologic concerns with this study include: (a) the possibility of 'Neyman' bias since it is unclear how the sample was identified, as the description implies that a record analyst identified those who were still resident in Rochester at the time of the intended follow-up from the medical record; (b) the sampling also suggests that an inception cohort was not used since the patients studied were continuing to attend at the clinic, and this may explain the small variation in the range of the outcome blood pressure; (c) in view of the small variation a larger sample size is needed to achieve a reasonable beta level; (d) Compliance was assessed but details of its relationship to the control of hypertension are not given; (e) the inappropriate process criteria chosen, such as family history and flank pain, which may mask a significant relationship of other more relevant process items; (f) the failure to remove the effect of other confounding variables that may mask the effect of the process variables upon outcome.

Greenfield et al (48) studied the management of patient's presenting with chest pain in an emergency department who were not admitted and assessed the process as it related to death or subsequent hospitalisation for a condition related to chest pain. A sensitive method assessing process from the medical record was used; this utilises branching criteria to reflect sequential judgements which allows for assessment of only those criteria relevant to the patient. One hundred and eleven patient charts fulfilled the process criteria

and none of these had a poor outcome; 26 patient charts failed to fulfil the criteria, 3 of whom died within three weeks from cardiac causes.

Although the relationship between process and outcome is statistically significant one cannot generalize from such small numbers and the outcomes were limited in scope. However, it is probable that this method has advantages over the inflexible list of process criteria used in most studies.

To summarise, this section on validity has demonstrated that outcome studies are feasible and some reasons have been presented that might be responsible for the failure of some of these studies to demonstrate an association between process and outcome. Features present in many of these studies that limit the usefulness of their results, include: (a) the absence of comprehensive outcome measures encompassing physical, emotional and social function; (b) the failure to consider type II errors in deciding on sample size; (c) failure to make appropriate adjustments for confounding factors not influenced by quality of care.

Conclusion:

The evidence discussed above demonstrates the potential of process measures of Quality of Care as a useful evaluation measure that warrants further development and methodologic validation. This will be the subject of subsequent chapters.

3. RESEARCH DESIGN

3.1 INTRODUCTION

The results of the studies cited in the previous sections suggest that clinical process measures are feasible, appear to be sensitive to differences in quality of care, can be used for the majority of diseases in both hospital and ambulatory settings; their data can be abstracted with precision and is amenable to statistical analysis. An essential criterion for credibility of the strategy remains unfulfilled - validation against clinical outcomes.

The remainder of this thesis will be devoted to developing and testing a strategy for criterion validation of clinical process against clinical outcome; in addition a measure to extend the dimensions of process assessment to include patient education will be developed and integrated into the strategy. These will be designed in the context of the management of acute myocardial infarction.

Acute myocardial infarction has been selected for the following reasons:-

1. It is common and a threat to life. Ischemic heart disease is the most common cause of death in Canada - it accounted for 51,817 deaths in 1974(132); likewise coronary artery disease is the most common cause of death in the United States (5). Acute myocardial infarction is one of the most frequent causes of admission to hospital(132,140). For example 768 patients were admitted to hospitals in the City of Hamilton in the twelve months July 1st, 1974 to June 30th, 1975 (65). The prevalence of coronary artery disease in the United States general population based on reports

from the 1972 National Survey has been estimated at 16.2 per 1000 persons (141). The high incidence and prevalence means that the potential for studying sufficient patients with acute myocardial infarction to allow meaningful inferences from quality of care studies is enhanced.

2. Myocardial infarction has a major impact upon the physical, emotional and social function of patients who survive (62); this provides a suitable model for combining evaluation of the impact of medical intervention upon a comprehensive range of functional outcomes.
3. There is considerable variation in the current management of patients with this condition which allows comparisons to be made that are not unethical in that patients are not being denied management that is universally applied.
4. Evaluating the process of care in acute myocardial infarction involves a variety of settings, including an intensive care unit, a general hospital ward and ambulatory clinics. This extends the generalisability of any strategy that can be used to compare process with outcome in such patients.
5. An inception cohort can be identified comparatively easily since almost all patients with this condition are admitted to coronary care units if they survive for long enough.
6. Sufficient data are usually available from the medical record to allow reasonably rigorous entry criteria to be specified without the expense of requiring independent assessors that many outcome strategies require (151).

7. The effects upon outcome of underlying disease severity not influenced by the quality of care, have been evaluated by several investigators (page 67). These confounding variables could either bias the results or mask the effect of clinical process upon clinical outcome, if not compensated for by appropriate statistical techniques. That such factors have been identified increases the chance that the unbiased effect of process upon outcome will be measurable.
8. The costs of medical care for these patients is considerable in view of the technology and high levels of staffing needed in coronary care units (11), so it seems appropriate to assess the effectiveness of this management in order to evaluate the justification for this expense.

3.2 RESEARCH OBJECTIVE

To determine whether measurable differences in the care administered to and received by patients with acute myocardial infarction results in clinically significant differences in these patients' health status six months later.

3.3 DESIGN - OVERVIEW AND JUSTIFICATION

The study will be a compound descriptive study. The care given or prescribed by physicians and received by patients during the patient's hospitalisation and at follow-up visits will be assessed and analysed for correlations with clinical outcomes and with the physical, emotional and social functional status of the patient six months after their admission for myocardial infarction.

Physician actions will be measured by chart review and questionnaires completed by the patient, his/her family and the physician. The outcomes will be measured by questionnaires, chart review, physical examination and exercise testing.

It is expected that this descriptive study will form the basis for a subsequent controlled trial in which the effects of a therapeutic package containing the items identified during this study as possibly contributing to improved outcome will be compared with a control group of patients not receiving these interventions*. Details of this experimental study's design must await the results of the descriptive study and this thesis will be confined to the design of the former.

Justification of Design

1. An explanatory descriptive study will allow the usual practice of physicians to be evaluated in order to assess which and what proportion of the process items of interest are being performed, and how much variation in performance is present. It is expected that the proposed criteria for physician inclusion will produce significant variation in this process of care.
2. The differences found will be analysed for correlations with outcomes; those found to be correlated can then be formally tested using an experimental design.
3. The descriptive study will also identify the 'baseline' management strategies to which the experimental manoeuvre can be added.
4. Furthermore, this descriptive study will form the basis for stratification for the confounding effects of differences in biological indexes of disease severity and for the different styles of practice.

* Some components of the experimental package, such as resuscitation and certain drugs, cannot of course be denied the control group.

3.4 DETAILS OF THE DESIGN

3.4.1 SAMPLE

The sample will consist of consecutive patients fulfilling the diagnostic criteria admitted alive to the specified hospital(s) under the care of physicians who have agreed to participate in this study.

Patients -

Inclusion Criteria: The presence of two out of three of the following -

- i) Anterior chest pain lasting for more than thirty minutes which is severe enough to cause the patient to alter his activity and which is not relieved by rest. A protocol will be used for definition of the history to avoid labelling variation bias (which is defined as variation in the identification of eligible study subjects leading to bias in the inclusion and exclusion of study subjects).
- ii) A rise in enzymes (SGOT, CPK, HBD, LDH) to levels one and a half times above the upper limit of normal, with subsequent return to normal within an appropriate time (depending upon the enzyme) among survivors.
- iii) ECG changes indicating the evolution of an infarction as specified by Kannel and Gordon (69).

Exclusion Criteria:

1. Patients with a history of previous infarction within six months of admission will be excluded to avoid contamination of process maneuvers from previous instructions.
2. Any patient who is disoriented to time, person or place or who has a memory defect, since this would invalidate the outcome and process questionnaire.

3. Any patient who is cared for by more than two physicians since this will be likely to introduce errors in ascertaining details of the patient-physician interaction by patient questionnaire.
4. Any patient on whom aorto-coronary bypass is performed during the study period since this will complicate assessment of the relation of other process measures upon outcome, and will involve interaction with physicians not included in the study.
5. Any patient with metastatic neoplastic disease, since the neoplasia is likely to affect the outcome measures independently of the myocardial infarction.

Site -

It is intended to carry out the study in a coronary care unit equipped community hospital setting where the care of the patients in the intensive care unit is managed by internists, but the subsequent management (when the patient is transferred to the general wards and after discharge) is carried out by the patient's family physician. It is expected that the majority of patients will be admitted to the intensive care unit initially.

Physicians -

The hospital chosen will be staffed by family physicians with the following characteristics:

- i) They will be primary care physicians.
- ii) They will have been responsible for the care of patients with myocardial infarction in the hospital selected during the year prior to the study.
- iii) Less than 50% of the physicians will have passed the certification exams of the College of Family Practice.

- iv) Less than 50% will have been in practice for ten years.
- v) Less than 50% will routinely advocate a formal rehabilitation program for patients with myocardial infarction. This information will be elicited from the physician.

The reason for these criteria is to ensure that the process items of interest are not routinely performed on all patients. The data in relation to these same criteria will be described for all non-participating physicians using the hospital in order to estimate how representative the physicians chosen are.

Sample Size Considerations -

If a clinically significant difference in clinical outcomes such as return to previous leisure activities is 25% with a baseline of 50% (as has been suggested by a group of experts (7)) and the type I error level acceptable is 0.05, and the type II error level acceptable is 0.15, then a sample size of 162 patients is required.

There are twenty-one hospitals in Ontario with over 200 patients discharged per year with a diagnosis of acute myocardial infarction; less than six of these are community hospitals, as most of them are teaching university-associated hospitals. There are sixty-two hospitals with over 100 patients discharged per year with this diagnosis (101) so that by selecting three hospitals sufficient patients can be expected to be obtained within an eighteen month period. The pretest (see page 49) will allow a more accurate estimation of the number of patients likely to fulfil the inclusion criteria with a time period.

3.4.2 PROCESS ATTRIBUTES AND OVERVIEW OF MEASUREMENT

The author in conjunction with another experienced internist, Dr. J. Sibley, identified management options available to physicians based on literature review and clinical experience.

These attributes are listed in Table 5. These options have been transformed into criteria that would indicate whether the particular action had taken place and the method most appropriate for its measurement selected. Strategies for measurement will consist of the following:-

- i) Medical Record - this will be the main source of data for utilisation data, history taking, physical examination, use of medications and results of laboratory tests. Details of the method are described later in this chapter.
- ii) Patient Questionnaire - this will be used to assess questions asked by the physician in the assessment of the patient and also instructions given to the patient by the physician. These are areas of process measurement that are unlikely to be recorded in the medical record but are likely to significantly affect the outcome of patients. Details of the method are described later in this chapter.
- iii) Family Questionnaire - this will be used to obtain data concerning items discussed by the physician with the family.
- iv) Physician Questionnaire - The physician will be requested to complete this at the end of the whole study using his records if he wishes. Items to be included are listed on Table 5. The questionnaire will not be completed earlier in the study in order to protect against cuing the physician into the items of interest, thus altering his behaviour.

3.4.3 MEDICAL RECORD ABSTRACTION

As shown in Table 5, the medical record will be used to assess several elements of the process of care both during the patient's hospital stay and during the follow-up ambulatory visits to the physician's office. Previous

TABLE 5 : Process Variables/Attributes

	SOURCE OF DATA		
	<u>Record</u>	<u>Questionnaire</u>	<u>M.D.</u>
1. <u>Length of Stay and Follow-Up Visits</u>			
Length of stay in I.C.C.U.	+		
Length of stay in hospital	+		
Follow-up within 3 weeks of discharge	+		
Follow-up within 7 weeks of discharge	+		
2. <u>Assessment and Therapy of Complications or Coexistent Disease</u>			
Arrhythmias	+		
Cardiac failure	+		
Dyspnoea at follow-up	+	+	
Angina	+		
Hypotension	+		
Hypertension	+		
Chest infection	+		
Urinary infection	+		
3. <u>Assessment of Drug Management and Side Effects</u>			
Correct Dosage	+		
Side Effects (e.g. Serum Potassium)	+	+	

Continued.....

TABLE 5 : continued -

	SOURCE OF DATA			
	<u>Record</u>	<u>Questionnaire</u>	<u>Family</u>	<u>M.D.</u>
4. <u>Assessment of Physical Capacity and Prescription of Exercise</u>				
Physical capability in home	+	+		
Exercise test	+	+		+
Stepped exercise prescription	+	+		
Formal exercise program	+	+		+
5. <u>Patient Education</u>				
a) <u>Adjustment to Hospitalisation</u>				
Coronary Care Unit - Information re purpose and reassurance				+
Mentor	-			+
I.V. Infusion	-			+
Oxygen	-			+
E.C.G.	-			+
Blood tests	-			+
X-rays	-			+
Transfer to general ward	-			+
Activity - Information and Advice	-			+
Diet	-			+
Social Problems caused by hospitalisation - Assess and Advise				+
(e.g. Care of children; work responsibilities)				+
Response to illness by patient - Assessment and Reassurance				+
(e.g. Anxiety and Depression)				+

Continued.....

TABLE 5 : continued -

	SOURCE OF DATA			
	<u>Record</u>	<u>Questionnaire</u>	<u>Family</u>	<u>M.D.</u>
5. continued...				
b) <u>Adjustment to Home Life</u>				
<u>Activity Advice - Activities of daily living</u>				
- Work	+	+	+	
- Recreation	+	+	+	
- Sex	+	+	+	
Medications - indication, name, dose	+	+	+	
Diet	+	+	+	
Smoking				
Symptoms which should be reported				+
Community Resources (e.g. V.O.N.)				
Clinic Appointments				
c) <u>Information about Disease</u>				
<u>Normal Anatomy and function of heart</u>				
Atherosclerotic Heart Disease		+	+	
Risk factors		+	+	
Healing		+	+	
Safety of prescribed activity		+	+	
Warning signs of heart attack		+	+	
Complications present		+	+	
Coexistent Disease		+	+	
d) <u>Educational Materials given to patient</u>				
Pamphlets		+	+	+
Slide Tape Shows		+	+	+

Continued.....

TABLE 5 : continued -

	SOURCE OF DATA				
	<u>Record</u>	<u>Questionnaire</u>	<u>Patient</u>	<u>Family</u>	<u>M. D.</u>
5. continued.....					
e) <u>Written Therapeutic Instructions</u>					
<u>Activity</u>		+			
<u>Medications</u>		+			
<u>Diet</u>		+			
6. <u>Psycho-Socially-Oriented Management</u>					
<u>Family Session</u>	+	+			+
<u>Family Therapy</u>	+	+		+	+
<u>Group Therapy</u>	+	+			+
<u>Psycho Therapy</u>	+	+			+

work has shown the medical record to be a sensitive instrument for detecting variations in the process of care both in hospital (81,92,104,126,150) and for ambulatory visits to family physicians (125). It is proposed to use the strategy developed by Greenfield et al (46) in the development and application of criteria; this increases the sensitivity of the measurement by utilising branching criteria to reflect sequential judgements. This allows for assessment only of those criteria relevant to the patient. For example, in a patient with myocardial infarction complicated by angina a subset of criteria relating the assessment and management of the angina is relevant, whilst it is inappropriate to assess patients with myocardial infarction without angina by the same criteria.

An abstraction worksheet will be developed from the list of criteria to be assessed by chart review. The abstraction will be performed by a specially trained record librarian or nurse. Again, prior experience suggests that this strategy has high precision. The author has experience with chart reviews in a hospital audit of patients with myocardial infarction for which a record librarian was trained to abstract pertinent clinical information. Interobserver (compared with a physician assessing the charts independently) and intraobserver variation (with a year between assessments) was less than 10% on each of over 500 criteria. Specially trained nurses have also been shown to achieve high levels of agreement with physicians in the audit of ambulatory care records (125).

3.4.3.1 PRETEST OF MEDICAL RECORD ABSTRACTION

A pretest of the record abstraction will be carried out using the hospital and ambulatory records of 25 myocardial infarction patients in a pilot study. Observer variation on each item that is less than

10% will be accepted as adequate confirmation of the reliability of the instrument. If observer variation is greater than 10% on any item, the corresponding criteria and the worksheet will be modified and the abstractors further trained and retested until this level of agreement is achieved.

3.4.4 QUESTIONNAIRES FOR ASSESSMENT OF PROCESS -

As discussed in the section on the literature review, several of the attributes listed in Table 5 are not consistently recorded in the medical record (page 15). Local experience of the author from auditing in-hospital records of patients with acute myocardial infarction supports this opinion; for example, in less than a quarter of charts audited was there any mention of any advice given to the patient. Accordingly these processes will be measured by questionnaires administered to patients, their families and their physicians. No patient or family questionnaire to be completed by patients and their families has been developed to assess several of these items of interest, and this instrument will have to be developed in this study.

Whenever a new questionnaire is to be developed, several potential sources of inaccuracy (which includes systematic deviation from the true result (bias) and random variation (error)) must be recognised and avoided. These biases and plans for avoiding them, consist of the following:-

1. Inaccuracies associated with the method of data collection. Lack of motivation of the respondent, misunderstanding of questions and literacy problems can be responsible for considerable inaccuracies in the data collected (143). In order to minimise these, the questionnaire will be administered by personal interview which (compared with self-administered questionnaires) can be expected to achieve a higher response rate; allows clarification

of misunderstood questions and is not so dependent on the subjects' literacy. The training and pretesting of the interviewers will include attention to consistency. The interviewers will be recruited from the McMaster University Field Survey Unit which has demonstrated such consistency in past studies.

2. Inaccuracies due to time - It is unlikely that the respondent will recall all the details of all the interactions with his physician at the end of the six month period being studied. Estimates of patient recall suggest that two weeks may be the longest that reliable factual information may be obtained following discharge from hospital or after ambulatory visits (60, 77, 133). The significance to the respondent of the event being assessed is known to affect the response error due to memory (59, 133); a myocardial infarction is likely to be considered by the patient as a highly significant event and it may be found that the facts concerning interactions with the physician in these patients are accurately recalled for longer than two weeks. A bias also related to memory but working in the opposite direction is that of telescoping - overreporting the frequency of events (133, 143). This tends to occur where the event of interest did take place on one occasion at least, and the respondent reports that the event occurred on more occasions than it actually did - this will need to be assessed where more than one interaction with the physician is being enquired about.

Both of these types of memory bias will be measured during the pretest in order to select the optimal timing for minimisation of these biases (see page 50).

3. Inaccuracies due to Reactivity Bias - This refers to the effect of the questionnaire itself upon the subsequent behaviour of the patient. The questionnaire will probably be administered to the same respondent more than once if

the pretest demonstrates that memory decay is a major problem.

It then becomes important to attempt to avoid changing the respondent's behaviour by the questionnaire itself (123); two approaches will be used to minimise this. Firstly the questions of interest will be interspersed with questions that are not related to the concepts being studied but are equally credible. For example, a question might be asked about whether a specific drug had been prescribed or the number of children, neither of which are of interest for the investigation. Secondly, funnelling of questions starting with broad unstructured questions (143) avoids letting the respondent know exactly which specific features the interviewer is interested in: If the response to the first question is negative, thus avoiding undue emphasis on a topic not discussed by the respondent with his physician. The extent to which this bias is present will be evaluated in a pretest (see page 51).

4. Inaccuracies due to sensitive questions - Questions that relate to unpleasant or embarrassing topics are less likely to be answered truthfully. This is relevant to this study for questions such as those relating to sexual function. This will be minimised by the positioning of questions relating to sensitive topics such as sexual activities in the latter half of the interview to allow the interviewer to establish rapport with the respondent; attention will be paid to placing them in context and introducing the topic in the least threatening way (143). The extent to which the respondents are not giving accurate responses will be analysed in comparison with direct observation of the interaction between patient and physician during the pretest.

5. Inaccuracies due to Social Desirability Bias - This occurs when the respondent feels that it might be socially undesirable to give the accurate response - for instance the patient may give an answer that the respondent feels would please the physician, although they know it to be inaccurate due to such

4)

reasons as in case the physician finds out the details of the questionnaire or the respondent might feel the interviewer wants a certain response. This can be minimised by emphasising confidentiality and training the interviewer to show complete acceptance of any answer. The extent to which this occurs can be assessed by looking for incorrect answers to the masking question included to minimise reactivity as well as comparing the questionnaire responses with direct observation of the interaction between patient and physician in the pretest.

Physician Questionnaire - This will be developed using the same guidelines as those described for the patient and family questionnaires. Reactivity bias will not be a problem since the interview will not take place until the end of the study, but it is likely to be less accurate than the patient and family questionnaire in view of the length of time between the events of interest and the completion of the questionnaire. The reason for not attempting to develop a similar strategy for the physician questionnaire, by the use of masking questions and funnelling is that this is unlikely to be successful in avoiding giving away which aspects of patient care are being measured.

3.4.4.1 PATIENT QUESTIONNAIRE FOR MEASURING PROCESS - Pretesting

The process questionnaires described above will be validated in a pretest against data obtained from direct observation of the interactions between the physician and the patient (and family where appropriate). This validation pretest will allow the accuracy of the questionnaire to be determined, and several possible causes of inaccuracy to be measured. The patient and family questionnaires will be applied at specified time intervals during the six month period after the patient's myocardial infarction according to the schedule shown on next page. Pretest patients will be randomly allocated into four groups of

equal size. The interactions of all pretest patients and their physicians will be directly observed. Group I will then complete the questionnaire within two days of discharge and within two days of each ambulatory visit. The other groups will be interviewed about those same items, only progressively later in the six-month follow-up period.

PILOT STUDY FOR PRETESTING PATIENT QUESTIONNAIRE

Patient Group	HOSPITAL		AMBULATORY CARE	
	Transfer to Ward from C.C.U.	Hospital Discharge	1st Visit	2nd Visit
1	+	+	+	+
2		+	+	+
3			+	+
4				+

+ = Patient Questionnaire to be administered within 2 days of event.

This design will allow the following determinations to be made:-

- i) Inaccuracy due to time. Memory decay may be assessed by measuring differences in the accurate recall of encounters between the groups interviewed at different intervals after these encounters, using the data from direct observation as the criterion - e.g. The post-discharge interview of group 1 is compared with the first interview in groups 2, 3 and 4; if less information is recalled in the latter groups and there is a progressive gradient the longer away from the event of interest that the patient is questioned, this would suggest that this difference may be due to memory decay. Telescoping will be

assessed in a similar fashion.

ii) Inaccuracies due to Reactivity Bias. Bias due to reactivity will be assessed by directly observing patient behaviour in subsequent encounters; e.g. the number of questions asked by the patient at a later visit that are connected with concepts asked about in a previous interview. For instance, if there is a difference in the number of relevant questions enquired about in the interviews after the first ambulatory visit in groups 1 and 2, after the second ambulatory visit in groups 1, 2 and 3, after the third interview in all groups and the difference increased with the number of preceding questionnaires then reactive effects are likely to be affecting the patient's behaviour. If there is a significant reactive effect then the questionnaire will need to be redesigned, unless the timing of the questionnaire in one of groups 2, 3 or 4 allows the reactive effect to be minimised without unacceptable memory decay.

iii) Inaccuracies due to Sensitive or Threatening Questions. The differences between the direct observation data and the questionnaire results will be determined for those questions considered sensitive or threatening (e.g. discussions of sexual function or fear of dying).

iv) Inaccuracies due to Social Desirability Bias. This will also be assessed by comparison of direct observation with the questionnaire for questions such as those concerning whether they were told why they had been prescribed any medications. The patient might feel that the interviewer would expect that people should know such information. In addition this will be assessed by the masking questions as already discussed.

Sample and Site for Pretesting the Patient Questionnaire

The pretest sample will consist of patients who fulfil the criteria for inclusion in the main study. The site will be a community hospital and the associated physicians' offices, plus the ward to which myocardial infarction patients are transferred from the intensive care unit should preferably be

adjacent to the coronary care unit (so that fewer observers will be needed). The qualification and certification criteria for entry of family physicians into the main study will be applied. To reduce the effects of individual idiosyncrosy, at least three family physicians will be evaluated during this pretest.

Allocation into Groups.

Pretest patients will be randomly allocated to the four interview groups using tables of random numbers balanced in sets of four.

Direct Observational Methods for the Pretest.

A check off list will be developed, describing the same items that are included in the patient questionnaire. This will itself be pretested by taping a series of simulated encounters which include known varying amounts of the information of interest. The observers will be mature adults with a nursing or social science background, trained specifically for the project; these qualities are expected to be useful in obtaining the physician's and patient's co-operation and trust such that they will be prepared to discuss sensitive issues in the presence of the observer. The observer will sit in on one or more encounters of participating physicians before the study begins to accustom the physician to their presence.

Justification of Direct Observation.

Direct observation is expensive but does provide the most accurate data as a criterion measure for validating the patient (and family and physician) process questionnaires. Alternatives considered included:-

1. A tape recorder without an observer; this was felt likely to present practical difficulties in ensuring that the encounters are taped consistently, and discussions with other clinicians indicate that it would be less acceptable to physician and patient than direct observation.

2. A check off list for the physician to complete at the time of the encounter was also considered but, of course, the physicians are likely to change their behaviour to comply with the check off list. Furthermore, the physician may not complete the check list consistently or reproducibly.

Analysis of Pretest

The results of direct observation will be compared with the patient questionnaire and the negative and positive predictive values calculated. Positive and negative predictive values of 70% or more will be deemed acceptable for utilisation of the patient questionnaire in the main study. The time intervals for the main study will be selected on the basis of maximum predictive values, accompanied by minimal reactive and memory loss effects (present for less than 20% of the process items).

Sample Site for Pretest

Forty patients will be included in the pretest since a minimum of eight patients in each group is required for statistical analysis of the predictive values obtained to evaluate the null hypothesis that the results could have occurred by chance (21).

3.4.5 OUTCOMES

ATTRIBUTES

The outcome attributes are shown in Table 6. The outcomes of primary interest are the occupational, physical, emotional and social health status of the patient. In addition, survival, the control of physiological abnormalities causing symptoms (e.g. angina) or patient behaviour that is likely to be harmful to overall health (e.g. dietary control for the obese) will be assessed. Finally, other items such as compliance or patient satisfaction, although not direct measures of functional outcome are related to the effectiveness of quality of

care, and will be measured. The reasons for selecting each of these outcomes are as follows:

1. Physical Function.

The 1972 United States National Health Survey (141) reported that of all persons with coronary heart disease 60.1% had some degree of activity limitation due to their condition. Hellastein and Friedman (56) have reported a significant reduction in sexual activity in patients six months after myocardial infarction compared with age matched controls. Weiss (144) and Tuttle (137) have reported that impotence developed in 10 - 33% of patients after an acute myocardial infarction although this was not confirmed by Hellastein and Friedman. A panel of experts (7) have suggested that the percent of patients who have returned to their previous leisure activities 3 - 4 months after an acute myocardial infarction will be 50% with average quality care and 75% with optimal care; and the percent of patients who have returned to their previous level of sexual function after 3 - 4 months will be 53% with average care and 67% with optimal care. Activities of daily living were not discussed by this group, but it seems possible that similar differences might be found with differing levels of care in view of the National Health Survey results discussed above. Thus, differences in quality of care can be expected to lead to differences in physical function.

2. Occupational Status

Between 15 - 20% of patients who were working prior to their myocardial infarction fail to return to work and unnecessary delay is common (8,14, 17). There is no evidence that prolonged convalescence improves the patient's physical state or prognosis, and it has been suggested that psychological harm may be done by this prolonged inactivity (12,18). In a study in Edinburgh (18) of 154 patients who were working on admission, 94 (69%) returned

TABLE 6: Outcome Attributes

Physical function

Occupational Status

Social function

Emotional function

Survival

Reduction in Cigarette Consumption

Control of Obesity

Control of Angina

Control of Cardiac Failure

Control of Hypertension

Patient Satisfaction

Patient Compliance

to work within four months and 102 (77%) within a year; Harpur (53) reported that 24% of 128 patients who were back at work at two years were not working at four months. Kellerman (72) reported that various rehabilitation centers had success rates of 80% of referrals successfully returning to work. These studies suggest that return to work is related to quality of care. An expert panel (7) has estimated that the percent of patients who have returned to their major daily activity 3 - 4 months after an acute myocardial infarction will be 58% with average quality care and 72% with optimal quality. Thus, this appears to be a good outcome measure which should be affected by the quality of care.

4. Social Function.

Social dysfunction following myocardial infarction has been increasingly recognised as due to problems relating to poor advice from health professionals, discouraging advice from the family, role changes in the family or associated emotional dysfunction (9,18,30,152,155). Bilodeau and Hackett (9) reported that the most commonly expressed issues included worries about acceptable by the family. Abnormal health perceptions have also been found to be associated with a failure to return to work (18). Results of a controlled trial suggest that group therapy can reduce social alienation, cynicism and competitiveness (63) and other studies suggest that group therapy can improve the psychosocial adaptation in patients and their wives (2,9,90). Despite the paucity of studies relating to social rehabilitation the data cited suggests that this is an important outcome that is likely to be affected by quality care.

5. Emotional Function.

Emotional dysfunction is recognised as an important late complication (60). Croog (29) reported that 50% of patients were depressed frequently or

occasionally one year after infarction. Using clinical assessment of anxiety and depression, Nagle et al (94) found that non-organic causes of invalidism were as common as physical ones in delaying return to work. Cay et al (18) studied 203 consecutive patients admitted to a coronary care unit and followed their psycho-social progress for a year; they found a significant degree of anxiety and depression unrelated to the severity of the myocardial infarction. Hackett and Cussem's Study (51) suggested that depression is the major problem in convalescence, and that exercise training is associated with a reduction of anxiety and depression scores on standard psychological testing. Others have suggested that early mobilisation, physical conditioning and patient education can reduce persistent depression (17, 62). Thus it appears that emotional status may vary with quality of care.

5. Survival

With the advent of coronary care units overall hospital case fatality for myocardial infarction has been reduced from about 30% to less than 20% (39, 66). A study conducted by the New York Health Insurance Plan in the 1960's showed that the case fatality rate one month following myocardial infarction was 17% for men hospitalised with their first myocardial infarction (446). In the Hamilton hospitals the mortality rate ranged from 11% to 26% between hospitals in 1975 (65).

It has been suggested (7) that case fatality rates can be used as a useful outcome indicator of quality of care after adjusting for sociodemographic and clinical variables that are not affected by quality of care (see page 67). A panel of experts have suggested that given optimal quality of care the mortality rate one month after acute myocardial infarction in patients who reach hospital should be less than 15%; given low quality care the mortality rate for the

same group of patients will be no greater than 25 - 30%. However, a sample size of 656 patients would be required to obtain an alpha level of 0.05 and a beta level of 0.15 to show a statistically significant difference for a case fatality rate of 15% versus 25%, and therefore, although included, is not considered an outcome of primary interest.

6. Reduction in Cigarette Consumption

Although there are conflicting study results concerning the association of cigarette smoking with subsequent reinfarction (89,146) it is considered harmful behaviour from other viewpoints such as its association with pulmonary disease. Croog (29) has suggested that physician guidance resulted in significant change in smoking habits based on data showing that 60% of patients (345 men) were not smoking a year after their first myocardial infarction, compared with 20% before the illness, although evidence was not described to show that physician guidance was the responsible agent for the change.

7. Reduction in Weight if Obese

Obesity is known to be associated with increased cardiac work, decreased myocardial compliance and contractility, and hypertension (3). The cardiac work and blood pressure have been shown to be reduced by weight reduction (4). Although obesity has not been demonstrated to be a major risk factor by itself, it would seem that reduction of weight in obese subjects with a compromised cardiac status from the myocardial infarction, is a suitable reflection of good quality care.

8. Angina

Data from the Framingham Study (70) showed that approximately half of

both men and women sustaining a myocardial infarction had angina afterwards. Dunkman et al (34) after reviewing the literature reported that less than 5% of patients with angina can be considered refractory to medical management; their review of response to Propranolol in several studies showed successful control in 77 - 100% of patients. Cay (18) reported that 48% of 101 patients reported mild or severe angina one year after infarction. This outcome can therefore, be expected to reflect the quality of care.

9. Cardiac Failure

Breathlessness and objective evidence of ventricular failure are present in up to 25% of patients after an acute myocardial infarction (10,18,129). Mild or severe breathlessness was reported in 51% of 101 patients one year after myocardial infarction in Edinburgh (18). Friedberg (45) states that many patients with cardiac failure requiring careful maintenance of Digitalisation and diuretic therapy can be controlled sufficiently for them to work. These data support the possibility of quality of care affecting the control of cardiac failure and justify its inclusion as an outcome measure.

10. Control of Hypertension

Although control of hypertension has not been shown to reduce the incidence of myocardial infarction, it reduces cardiac work which is appropriate for post myocardial infarction patients. Since control is achievable in most patients, the extent to which study patients are normotensive should reflect the quality of care they have received.

11. Patient Satisfaction

Patient satisfaction refers to a measure of the patients' attitudes towards his physician, the health care system and the medical care he receives. Although not a functional outcome this does relate to the general wellbeing of the patient. Although high levels of quality of care, especially in the area of education, might be expected to be reflected in better patient satisfaction,

studies of the effect of differing levels of quality of care upon patient satisfaction have had to await suitable methods for measuring satisfaction; these are now available (158) so that its inclusion as an outcome measure is justified.

12. Patient compliance

Several therapeutic maneuvers involved in the management of acute myocardial infarction patients are known to be efficacious (such as anti-hypertensive drugs, digoxin and diuretics for heart failure). However, the desired outcome will only be achieved if the patient complies with the physician's orders so that assessment of compliance provides information on an important intermediate step between process and outcome. Since the patient-physician interaction is also an important determinant of compliance, measurement of compliance as an indirect measure is justified.

3.4.6 OUTCOME MEASUREMENT STRATEGIES

The clinical outcomes will be assessed six months after the patient was admitted with the acute myocardial infarction. This time period was chosen on the basis that it allows the patient's physical, emotional and social function to be assessed using actual patient behaviours. The methods to be used are as follows:-

1. Survival

This will be assessed from the charts if it occurred during hospitalisation and from questioning of the physician or family if occurring later.

2. Physical Status

a) McMaster Index of Health (20). This questionnaire has been designed to reflect positive function as well as levels of disability. It has been found to be acceptable to interviewees, amenable to index construction, and can be administered by lay interviewers. It utilises a self evaluation method eliciting the respondent's views of his performance at doing certain activities.

Items of interest include activities of daily living such as walking, stair climbing and travel, self-care such as dressing, toiletry and feeding, and domestic duties such as participation in shopping, cleaning floors, cooking and clothes washing. The response categories to each question allow the performance of each activity to be graded from fully independent through increasing degrees of limitation to inability to perform the activity. The questionnaire refers to the week prior to its completion, to minimise recall errors. The 18 questions that best predicted a general practitioners judgement of physical function will be used. The methodologic features of this questionnaire are described in greater detail in the subsequent section on emotional status.

b) Questions will be developed to assess types of activity not explored in depth in the Index of Health, those of recreational, physical activity and sexual activity. The latter may be perceived by some respondents as threatening and the ways of minimising this, described on page 48, will be utilised. These questions will be developed along the lines used in the Index of Health and pretested.

c) A standard treadmill exercise test will be carried out six months after the infarction (95). This will provide objective evidence of the physical functional capacity of the patients which will be used as a basis for assessing whether reported limitations in activity have a physiological basis or whether it seems likely that these limitations might be attributable to such factors as poor emotional function or inappropriate advice from their physician.

A multi-level exercise test will be performed at the hospital where the patient was admitted under the supervision of a physician experienced in the procedure. Continuous electrocardiographic monitoring will be performed beginning before and continuing until after testing is completed. Facilities for management

of complications (including electrical defibrillation equipment) will be provided. The patient will be informed of the intent and details of the procedure, and will sign a consent form. Patients with abnormalities of rhythm or conduction on a resting electrocardiogram, gross cardiomegaly and overt cardiac symptoms at rest will be excluded. Criteria for stopping the test will be --

- a) attainment of maximum possible performance.
- b) symptoms suggestive of cardiac ischemia.
- c) diagnostic electrocardiographic change.

3. Occupational Status

A questionnaire will be developed to assess the patients level of functioning at work compared with his or her previous functional level. Job availability and other non-medical reasons for not working will also be assessed. In addition and with the patient's consent, information will be obtained from the patient's employer. Both of these instruments will need to be pretested.

4. Social Function

McMaster Index of Health - The index developed by Chambers (19) as part of the Index of Health Study will be used. Questions were selected from a number of existing questionnaires to fulfil the following two objectives; firstly to cover important life areas such as dwelling place, monetary situation, hobbies, organisational membership, friendships, marriage, feelings about religion and health perceptions. Secondly, questions were chosen to allow assessment of the extent of appropriate community activities, activities held appropriate by the individual and individual awareness of the social environment. The validation studies and pretesting will be described later in this chapter (see page 63).

It is proposed to use the 14 questions that best predicted a family practitioners judgements of the social function of his patients which have a sensitivity of 72% and a specificity of 77% for good social function. Validation issues are discussed in the following section on emotional function.

5: Emotional Status

The index developed by MacPherson (85) as part of the McMaster Index of Health Study will be used. Questions were chosen that related to Erikson's concepts of trust, autonomy, identity, initiative, intimacy and self esteem. The twenty-seven questions that best predicted a general practitioner's judgement of emotional function will be used which has a sensitivity of 60% and a specificity of 75% for good emotional function.

Previous validation studies of Indexes of Physical, Emotional and Social Function (20,119).

This questionnaire was pretested in various ways; firstly it was administered by a single interviewer to 70 patients in Hamilton, Ontario whilst they were in hospital in an acute medical ward, and 7 days or more after discharge. No major difficulties in interpretation of individual questions were encountered thus suggesting that the face validity is acceptable. Secondly, the ability of the questionnaire to detect changes in functional status is supported by the finding that there were significant changes in the social, emotional and physical function of these patients in acute medical wards between the interview in hospital and 7 or more days after discharge. Thirdly, criterion clinical validity was assessed by comparison of the results of the questionnaire with the assessment of an experienced family physician in 273 patients. Evaluation of the resulting indexes suggested that the questionnaire has criterion clinical validity; for example the fourteen questions that best predicted the clinical

assessment of social function had a sensitivity of 72% and a specificity of 77%. Fourthly, biologic validity was demonstrated in the same study; there was a strong relation between the questionnaire's assessment of physical function and age.

Further validation studies are indicated such as more precise evaluation of the ability of the questionnaire to detect clinically relevant changes in health, comparison with the assessment of other health professionals and short-term reproducibility. However, it has been successfully utilised in four health care studies including two randomised trials, and has sufficient credibility for it to be used in a study such as the one proposed in this thesis, providing that short-term reproducibility can be demonstrated (see page 66).

6. Reduction in cigarette consumption

This will be assessed by questions on number of cigarettes smoked a day and changes in smoking habits since the myocardial infarction. The questionnaire design will be based on the approach used by Doll and Hill (31) to assess changes in smoking habits.

7. Weight Reduction

Obesity will be ascertained from the patient's weight on admission to hospital (patients in overt cardiac failure on admission will be excluded) according to the standards described in the Actuaries Study (1). The outcome weight will be measured at the time the patient has the exercise test. The scales will be checked for accuracy on a regular basis.

8. Angina

This will be assessed by the Rose Questionnaire (114) and by an exercise test (95). Patients referred for aorto-coronary bypass although excluded (see page 38) will be asked to complete the Rose Questionnaire to evaluate whether

bias of results is likely due to differing indications for referral.

9. Congestive Cardiac Failure

This will be defined as the presence of one or more of the following - elevated jugular venous pressure, triple rhythm or gallop, edema of the ankles or sacrum, persistent basal crepitations on auscultation of the lungs, or radiological evidence of pulmonary congestion. The patient will be examined by an Internist and a radiograph taken at the time the patient attends the hospital for the exercise test.

10. Control of Hypertension

This will be considered present if the following systolic (first phase) and diastolic (fifth phase) blood pressures persisted on the lowest reading obtained with the patient sitting after at least ten minutes rest in a quiet room.

<u>Age Group</u>	<u>Systolic Blood Pressure</u>	<u>Diastolic Blood Pressure</u>
16 - 29	> 140	> 90
30 - 69	> 160	> 100
70 +	> 170	> 100

This will be measured when the patient attends the hospital for the exercise test. The sphygmomanometer will be checked for accuracy on a regular basis.

11. Patient Satisfaction

The questionnaire developed by Hulka et al (158) will be used to assess the level of patient satisfaction with respect to professional competence and personal qualities of the physician. This questionnaire has been extensively pretested; its split half reliability is in excess of 80% and the wide range of responses obtained suggest that it is a sensitive instrument. This will be further pretested for short-term reproducibility with the other outcome questionnaires.

12. Compliance

Questions will be included in the questionnaire concerning compliance with drugs, diet and exercise, utilising questions from the Standardised Compliance Questionnaire (118). This will be pretested.

3.4. 6.1 PRETESTING OF OUTCOME QUESTIONNAIRE

Short-term reproducibility of the questionnaire for outcome measure will be pretested six months after the myocardial infarction on the same patients as the process pretest study for validation of the patient questionnaire described on page 49. The outcome questionnaire will be administered to the forty patients in their homes on two successive occasions two weeks apart. (The first interview will be six months after the patient sustained the acute myocardial infarction). The reproducibility will be taken as acceptable if 10% or less of questions demonstrate disagreement. This pretest will also allow the newly developed questions to be tested for face validity to minimise any ambiguity in these new questions.

4. ANALYSIS

4.1 POTENTIALLY CONTAMINATING EXTERNAL VARIABLES

In order to make valid comparisons of outcomes it is necessary to control for other external variables that might affect the outcomes independently of the quality of care delivered so as to isolate the effect of the process items of interest. Such factors include the baseline level of the outcome of interest, other outcomes, sociodemographic and disease related factors that are not influenced by the quality of medical care, and compliance.

The citations listed in Table 7 refer to the effect of those external variables upon case fatality and there is little evidence relating them to other outcomes; an exception to this is an investigation by Schiller and Baker (122) who developed a productive rating scale for return to work.

Some of these factors may affect only a proportion of the outcomes, and since the number of factors that can be adjusted for is dependent on sample size, (the numbers in each 'cell' or category become too small for statistical analysis if too many factors are included) a peer group of epidemiologists and clinicians and statisticians will be asked to select the items they consider most likely to confound the results in a rank order.

4.2 STATISTICAL METHODS

The aim of the analysis is to identify those process variables that are significantly associated with outcome measures at the 0.05 level. Each outcome will be analysed for statistically significant associations with individual process items. Two approaches will be used, both based upon stepwise logistic

TABLE 7: EXTERNAL VARIABLES

	Method of Measurement	References for Association with Mortality (*Associated with return to work)
1. <u>Baseline Level of Outcome:</u> e.g. Previous work history - may affect return to work	As for outcome	122*
2. <u>Other Outcomes:</u> e.g. Angina and heart failure may affect return to work	As for outcome	18*
3. <u>Patient-Related Factors:</u> Age Sex Race Marital Status Educational Level	Chart Chart Chart Chart Questionnaire	58,99,107 86 86 122,* 145 122*
4. <u>Disease-Related Factors. -</u> <u>Admission or First Few Days:</u> Previous Infarction Low B.P. Systolic or Shock Enzyme Levels Site of Infarction Cardiomegaly or Cardiac Failure or Pulmonary Oedema Ventricular Arrhythmias Heart Block Previous Physical Inactivity Associated Disease or Diabetes	Questionnaire Chart Chart Chart Chart Chart Chart Questionnaire Chart	66,99,107,118,146 58,93,99,107 27,75,128 26,99 28,58,66,99,107,118,146 28,66,93 58,66,107 28,146

regression; firstly a simple chi-square analysis will be carried out to assess any statistically significant association between process and outcome. If such associations are found then a stepwise chi-square regression analysis will be used to assess whether this association between process and outcome may be also associated with confounding variables. Associations that remain significant at the 0.05 level after adjusting for the possible confounding variables will be included in the subsequent randomised trial. Second, a forced stepwise chi-square analysis with the confounding variables being forced into the regression analysis before the process item of interest will be employed. This is to reduce the possibility of missing significant process items of interest whose effect may be masked by the more powerful effects of confounding variables; by removing the effects of any such confounding variables before analysing the effect of the process item of interest, significant associations between process and outcome may be found that are not evident from a simple chi-square analysis.

This second approach can be demonstrated by the following example utilising stepwise chi-square analysis:

Let Y = the outcome of interest - return to work within 3 months of the occurrence of the myocardial infarction.

Let return to work = 1; no return to work = 0

Z = the process of interest - whether the physician advised the patient to return to work within 3 months after the myocardial infarction.

Let patients advised = 1; patients not advised = 0

X_j = Confounding variables designated as follows:-

X_1 = work status before illness	Working	Not working
X_2 = Shock	Present	Absent
X_3 = Pulmonary Oedema	Present	Absent
X_4 = Ventricular arrhythmia	Present	Absent
X_5 = Heart block	Present	Absent
X_6 = Post-infarction angina	Present	Absent
X_7 = Previous infarction	Present	Absent
X_8 = Site of infarction	Inferior	Other
X_9 = Age	≤ 50	> 50
X_{10} = Sex	M	F

The outcome is expected to be affected by both the process of care and the confounding variables and the relationship between these can be described as follows:

$$Y = F(Z, X_j), \text{ where } j = 1, 2, \dots, 10$$

where F - some specified function.

The confounding variables will be assessed in a stepwise fashion before assessing Z, the process of interest as follows:

- a) The individual confounding factors that are significantly associated at the 0.05 level with the outcome are identified by a series of ten 2 x 2 frequency tables analysed by chi-square. There will be ten of these tables.

		Y	
		1	0
X_j	1		
	0		

- b) Where there is more than one, significantly associated with outcome, the confounding variable most strongly associated with the outcome is identified - designated X_j' .

- c) The remaining nine confounding variables are each analysed together with the selected variable X_j in a series of nine 2×4 frequency tables again using a chi-square test.

		Y	
X_j'	X_j	1	0
1	1		
1	0		
0	1		
0	0		

- d) Where there is more than one confounding variable significantly associated with outcome (at the 0.05 level) when combined with X_j' , the most strongly associated variable is identified (X_j').
- e) This procedure is continued in this stepwise fashion increasing the number of combinations assessed until no significant associations are found with the remaining confounding variables. If there are no significantly associated confounding variables found in the initial step (a), the procedure stops there without assessing any of the combinations.
- f) The process item of interest (2) is then added to the combination identified above, and assessed in the same way by chi-square analysis.
 e.g. If no further confounding variables are significantly associated with outcome after step (d) then the process item of interest would be assessed by a chi-square using a 2×8 frequency table:

Y

X_j'	X_j''	1	0
1	1		
1	1		
1	0		
1	0		
0	1		
0	1		
0	0		
0	0		

g) The same level of significance (0.05) is used to decide whether the association with outcome is considered important.

5. CRITERIA FOR SUCCESS

The study will be considered a success if it fulfills the following criteria -

1. At least 15 process items are identified for which a variation in performance exists are identified. This will allow definition of the range of practice within which allocation would be acceptable and ethical in the subsequent controlled clinical trial.
2. At least 25 process items are identified that are significantly correlated with outcome, so that they may be formally tested in the subsequent controlled clinical trial.
3. Those biologic and sociodemographic indexes of severity that appear to be significant confounding variables are identified so that appropriate stratification may be incorporated into the allocation procedure in the subsequent controlled clinical trial.

6. ETHICAL CONSIDERATIONS

This study is not likely to meet with any major ethical problems, since it is not expected that there will be any constraints to freedom from assault. No excessive risk to the wellbeing of the patient will be involved since the procedures to be used consist of conventional investigations used in current practice. The quality of the care provided to the patient by the involved physicians will not be affected and indeed evaluation of current practice is the objective of the study. The benefits to the public of this study are considered to justify any minor inconvenience caused, since studies such as this are capable of playing an important role in decisions taken by those who decide on policy relating to quality of care assessment and peer review.

The purpose and plan of the study will be explained to the patients and physicians. Informed consent free from coercion will be obtained before patients enter the study. All patients will be free to withdraw at any time, and the patients will be assured that there will be no loss of medical care if they decide to withdraw. The confidentiality of the data obtained will be assured.

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