PERFORMANCE OF A PROCESS EVALUATION SYSTEM IN OUTPATIENT HOSPITAL-BASED CARDIAC REHABILITATION

by

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HNFE

(ABSTRACT)

This study retrospectively evaluated patient records from two cardiac rehabilitation (CR) service centers located in large urban hospitals using a Process Evaluation System (PES) recently developed through a collaborative project of the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), Madison, WI, and the Center for Clinical Quality Evaluation (CCQE), Washington, DC. The major aims were to: 1) evaluate the utility of the PES as an audit instrument for assessment of adherence to the 24 quality process criteria that comprised the PES; and 2) determine whether adherence to the PES criteria resulted in different patient outcomes for those cases where intervention need was documented at patient admission. Using the data abstraction manual and audit procedures developed by AACVPR/CCQE, a trained medical technician audited 150 CR records for consecutively treated outpatients who typically received 36 sessions of treatment in either Moses H. Cone Memorial Hospital, N.C. Heart Institute, Greensboro, NC, or Carolina's Medical Center, Charlotte, NC, covering a calendar period between 1995-97. The data were pooled from both sites for analyses and included patients with one or more of the following diagnoses: MI (37%), angina (14%), coronary revascularization (76%), and

other (18%). The cost of utilizing the PES was assessed by evaluating the technician time required to abstract a patient record and this was observed to improve over the course of the review period, i.e., mean abstraction time for initial versus final 20 records = 13.2 min. and 4.6 min., respectively. Experience with the PES suggested areas where instrument revision should be considered, e.g., the operational guidelines for extracting acceptable markers were not always clear enough or sufficiently flexible to allow determination of adherence of a record to the 24 quality process criteria. Adherence to the PES was determined, case by case, for each of the 24 criteria. In 129 cases (86% of the sample), complete adherence was found, i.e. 100% adherence to all 24 criteria that included indicators of key clinical steps for patient intake, treatment planning, and follow-up. The remaining 21 records (14%) showed adherence to at least 21 of the 24 criteria (87.5%). Given the uniformly high levels of adherence to the PES documented by these two program sites, the data could not resolve the question of whether patient outcome effects were different between cases of high versus low adherence to PES. Nonetheless, outcome data were examined to evaluate achievement levels in four different areas widely considered by clinicians as important to treatment success: blood cholesterol, smoking status, exercise tolerance, and body mass index (BMI). Of the study patients diagnosed with dyslipidemia 12 of 27 (44%) had levels < 200 mg/dl by exit. Seven of 14 documented smokers (50%) reported quitting at exit from treatment. Forty-nine patients of 117 (42%) who initially could only maintain treadmill walking for 10 min. at levels below 4 METs, were able to exceed this level by treatment end. Six of 104 (6%) with BMI values > 24.9 kg/m2 had a documented decrease in this indicator of overweight by treatment end. The threshold levels for outcome

criteria used here to describe achievement levels in this data set are somewhat arbitrary. However, the criteria are reflective of the standards typically suggested as meaningful for effective secondary risk reduction in CR programs (Franklin et al., 1996). The PES system was developed to audit the quality of CR process in treatment centers, as standardized by a consensus panel to reflect the content of the evidenced-based CR guideline recently published by the US Agency for Health Care Policy and Research (*Cardiac Rehabilitation as Secondary Prevention*: #17, 1995). The findings of this study suggest that the content markers of quality process in the PES are relevant and the instrument is efficient to administer. When field tested against two urban centers in North Carolina where state statutes require program certification for CR treatment centers, these centers demonstrated uniformly high adherence to the PES and a pattern of good achievement for several patient outcome measures accepted as relevant to evaluation of treatment success for individual patients.

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Chapter I

Introduction

Coronary heart disease (CHD), is the leading cause of death in the United States.   More than one in five persons in the United States has cardiovascular disease. With 485,000 deaths annually, amongst the 1.5 million people who have a myocardial infarction (MI), this is a most pressing health issue (Balady et al., 1994).   These numbers have improved since the 1960's, however, when CHD deaths and disabilities reached epidemic proportions at 50% of all deaths. Today through improved medical care and emphasis placed on control of smoking, high cholesterol, blood pressure and other risk factors the death rate resulting from heart disease has and continues, to decline. Exercise, and other aspects of cardiac rehabilitation have helped to aid in the decline of cardiovascular disease. There has been a documented 20% decrease in cardiac and overall mortality when followed over 2 - 3 years post-MI (Pashkow, 1996).   The estimated cost of CVD, associated with hospital stays, health care facilities, medical personnel and the almost 468,000 coronary revascularization procedures performed each year was an estimated 56 billion in 1994 (Balady et al., 1994). Today, with an even greater emphasis placed on rehabilitation as a secondary form of prevention, drugs, research, awareness and technology, we have been able to effectively lower costs in the areas of rehospitalization, loss of wages and mortality (Wenger, Froelicher, Smith, 1995).   Even as rates in mortality have decreased, the great numbers of people who contract this disease has not changed, and even more people who do have CHD are living longer. A study performed in 1996 revealed no statistically significant reductions in morbidity related to nonfatal reinfarction

in 15 randomized controlled studies (Pashkow, 1996). These statistics alone, warrant further attention. The population in general is aging, and as it does more and more significant numbers of people are living with this disease. Cardiac Rehabilitation (CR) is the recommended way to help these people manage their CVD risk factors and receive professional help.   A legislative mandate has been made to aid in improvements in health care delivery, measurement, and monitoring {Agency for Health Care Policy and Research (AHCPR, 1995a)}. Evidence from controlled clinical trials of cardiac rehabilitation has shown reductions of cardiac mortality of approximately 20%-25% (Balady et al., 1994).

The World Health Organization has defined Cardiac rehabilitation as

"...the sum of activities required to influence favourably the underlying cause of the disease, as well as to ensure the patients the best possible physical, mental and social conditions so that they may, by their own efforts, preserve, or resume when lost, as normal a place as possible in the life of the community. Rehabilitation cannot be regarded as an isolated form of therapy, but must be integrated with the whole treatment of which it forms only one facet..."(p.5)

Cardiac rehabilitation has five major components: exercise training, risk factor modification, educational counseling, vocational guidance and stress management training. It is a multi-disciplinary part of routine medical care and should be considered an integral part of comprehensive cardiac care (Thompson, 1994).

Much emphasis has been placed on the *outcomes* of care, in particular quality related outcomes such as: *functional* - physical and mental health, *clinical* - morbidity and mortality, *satisfaction* - patient and family, and *cost*-direct medical and indirect social. In volume one (*Issues*), of the Using Clinical

Guidelines To Evaluate Quality of Care, authors state that "The measurement and evaluation of outcomes provided the basis for assessing the benefits of any intervention" (1995). With this in mind, the present focus of care has expanded to include the *process* of care. Process of care incorporates preventative measures such as: diagnostic testing, procedures and treatments and other aspects of patient care (AHCPR, 1995c). By focusing on process measurements clinicians may help monitor and improve delivery of care and thus affect, in a positive way patient outcomes and cost of care (Batalden, Mohr, Nelson, & Plume, 1996).

The Agency for Health Care Policy and Research has examined, and recently funded, ways to evaluate quality of care using clinical practice guidelines. Health care can best be evaluated using an instrument that has been developed according to clear and understood methodology (AHCPR, 1995c). Judgments can then be passed about the deliverance of healthcare in accordance with recommendations based on clinical practice guidelines. The basic tools for improvements in health care include medical review criteria, performance measures and standards of quality. Medical review criteria, for example, is derived from guideline recommendations such as the presence or absence of high cholesterol levels. Performance levels are applied, as to which actions should be taken, according to the cholesterol values being ranked as high, moderately high etc. Outcomes are then achieved and standards of quality are decided. By using quality criteria, and the Performance Evaluation System (PES), the degree to which care has followed specific process and achievement of aspired outcomes can be determined. With this in mind,

guideline derived evaluation tools, or the functional form, can be used as one component of an overall effort in quality improvement (AHCPR, 1995b).

The production of an instrument, or PES, that allows easy collection of data with which to evaluate quality of care and ensure positive patient outcomes has been developed by AACVPR/CCQE.   The PES encompasses recently developed guidelines that include the process of care. The instrument is expected to have a positive affect on the outcome of care and therefore attainment of the much sought after goal, quality of care and patient satisfaction. It is through high quality healthcare that services or clinical care processes achieve the health outcomes desired by patients (AHCPR, 1995b).

Statement of the Problem

Variation in quality is a concern in all areas of healthcare.   Particularly in specialty areas that are new or rapidly developing.   There are numerous ways to reduce variations in quality and to raise the overall level of services. These include, but are not limited to, practice audits by practitioners groups, evaluation of treatment outcomes, and examination of the process by which care is delivered. In CR the AHCPR has recently funded a project to develop quality review criteria and performance measures based upon the Clinical Practice Guideline (AHCPR, 1995a).   The goal was to convert guideline recommendations into a tool for measuring process of care (AACVPR/CCQE Final Report, 1995). These efforts resulted in the CR Performance Evaluation System, (PES). It is with this instrument that specific data related to delivery of care can be extracted from patient medical records. Delivery and process of care can then be linked to resulting patient outcomes. Variations throughout

the field of CR can be examined, and reduced to raise the overall level of services.

Significance of the Study

Essential components of cardiac rehabilitation include: exercise, education, intervention and counseling. The criteria in this new approach, the Performance Measurement System (PES), are reflective of these. The quality review criteria and performance measures were developed based upon the *Using Clinical Guidelines to Evaluate Quality of Care*: volume 2 (Methods) (1995). This PES is the newest tool available for measuring quality of care and as of yet, no research has been done to determine the adequacy of the instrument or the types of information that it may produce when used to audit patient records from CR programs. Performance measurements will be appropriate for use in evaluation of community based facilities and hospital based facilities and it will be possible to review large numbers of cases. All necessary data can be obtained easily from the medical records of the Cardiac Rehabilitation patients. It is suggested that quality of care and patient outcomes can be determined by the amount of cases that demonstrate care conforming to a defined set of quality process criteria derived from an expert panels' judgment on the key features of the AHCPR / AACVPR Cardiac Rehabilitation Guidelines.

Research Questions

1. Does an audit of cardiac rehabilitation patient records with the PES in the early outpatient hospital-based setting yield an adequate data set for

evaluation of adherence to the 24 "quality" treatment process criteria specified by the instrument?

2. Is the PES an efficient instrument for extracting information from patient medical records in the setting of the early outpatient hospital-based cardiac rehabilitation program?

3. Do the records used for this evaluation of the PES contain information by which to evaluate the outcomes achieved for these patients at their exit from treatment, i.e., changes in cholesterol, weight, fitness level and smoking status?

4. For those records in which the audit identifies specific application of one or more of the PES "quality" process criteria, is there relatively greater success among those patients for achieving their outcome compared to patients not documented by the PES as needing that treatment component?

Delimitations

The following delimitations were imposed by the investigator:

1) This review will be restricted to early outpatient hospital-based program records, of 150 consecutive patients who were treated during the period December 1995- December 1996.

2) This review will be restricted to two early outpatient hospital-based cardiac rehabilitation programs that are located in large urban North Carolina hospitals, Carolina's Medical System in Charlotte and Moses H. Cone Memorial Hospital, N.C. Heart Institute, in Greensboro.

3) This review will consider patient outcomes(cholesterol, body mass index, smoking status, and exercise capacity) associated with selected measures for evaluation in this review. Subjects consisted of both men and women in two early outpatient hospital-based Cardiac Rehabilitation programs.

4) Adherence will be considered 85% of 24 criteria were either met or justified by documentation of an acceptable alternative.

Limitations

The following limitations affect the generalizability of the findings and interpretation of the data:

1) Applications of results were generalizable only to the two programs that were reviewed in this study. The programs were large urban North Carolina hospitals, located in the Southeastern region of the United States.

2) The possibility that some inconsistency occurred with respect to recording of data into patient medical records by various technicians and physicians at the different centers.

3)   The chance that inconsistency could also have occurred on the part of

the investigator/data abstractor due to personal knowledge or

experience.

Basic Assumptions

The following assumptions were made by the investigator:

1)   The 24 criteria to be evaluated reflect the necessary key components of

cardiac rehabilitation and behavioral interventions and meet the

necessary process criteria that represent recommended care.

2)   That all data necessary to fulfill the 24 criteria are available from

patient records for the data abstractor to extract (n=150).

3)   Values used were measured and recorded accurately in the patient

records.

Definition of Terms

AHCPR-
    Agency for Health care Policy and Research and was established by the
    Omnibus Budget Reconciliation Act (OBRA) as successor to the
    National Center for Health Services Research and Health Care
    technology Assessment.   It is a component of the Public Health
    Service.

Benchmark-
    Level of care set as a goal to be attained.

Clinical Practice Guidelines-
Systematically developed statements to assist practitioners' and patients' decisions about health care to be provided for specific clinical circumstances (AHCPR, 1995b, p. 35)

Criteria-
Standards by which something is evaluated or judged (AHCPR, 1995b, p. 36).

Coronary Heart Disease (CHD)-
Damage to or malfunction of the heart caused by narrowing or blockage of the coronary arteries, that supply the heart muscle. This disease can result in chest pain, angina and or acute myocardial infarction (AMI).

Data Abstraction Manual-
Contains everything necessary ,in step by step format, for extraction of data from the medical records related to 24 criteria to be examined. Provided in the Cardiac Rehabilitation Criteria Project Final Report.

Data Abstraction Worksheet-
Worksheet provided in the Cardiac Rehabilitation Criteria Project Final Report that allow easy recording of findings based on the 24 criteria from each record.

Early Outpatient Cardiac Rehabilitation-
Early outpatient hospital-based rehabilitation immediately following Phase I, focuses on individual exercise prescription with an emphasis on aerobic activity and also including flexibility and some muscle strengthening. Monitoring on individual basis and focus on comprehensive risk factor modification.

Efficiency-
When health care of desired quality is produced at the lowest cost, or when health care produced at a fixed cost is of the highest quality.

Health care Guidelines-
Guideline related to any aspect of medicine, including heatlthcare process, policy, regulation, financing, administration education and clinical practice (Ritchie, Forrester,& Fye, 1997).

Medical Review Criteria-
Systematically developed statements that can be used to assess specific health care decisions, services, and outcomes. Each criterion derived from a guideline recommendation is used to determine whether the case being reviewed conforms to a particular recommendation in the guideline. A status is assigned to each criterion to reflect the care given (AHCPR, 1995b, p.37).

MET-

Rate of energy expenditure at rest; approximately equal to $(3.5\text{ml})(\text{kg}^{-1})(\text{min}^{-1})$, or $1\text{ kcal}(\text{kg}^{-1})(\text{hr}^{-1})$

Performance Evaluation System(PES)-

Consists of Data Abstraction Manual and Worksheet from the Final Report, AACVPR/CCQE Cardiac Rehabilitation Criteria Project.

Performance Measures-

Methods or instruments to estimate or monitor the extent to which the actions of a health care practitioner or provider conform to the clinical practice guideline (AHCPR,1995b, p.37).

Patient Outcomes-

(*Inadequate)exercise capacity*: Initial exercise training METs vs final exercise training METs while in rehabilitation. Was this an adequate increase? i.e. Greater that 5 MET increase in exercise training?
If intervention for dislipidemia: If checked, what were the exit value, i.e. mean change and is it less than or equal to 200 mg/dl
Smoking: If appropriate. Was cessation of smoking achieved? Rates of quitting smoking.
If intervention for obesity/weight control: If checked, what were the exit values .i.e. mean change in BMI and are the values less than or equal to 24.9 kg/m^2.

Relevant -

Those identified by PES as having abnormality and / or need for intervention and were provided a targeted service, and were checked at follow-up.

Standards of Care-

Standards for facilities are commonly expressed in terms of a minimal level of policy, equipment, and capacity necessary to achieve licensure or certification.

Standards of Quality-

Authoritative statements of (1) minimum levels of acceptable performance or results, (2) excellent levels of performance or results, or (3) the range of acceptable performance or results.

Summary

Recently a joint venture by the Center for Clinical Quality Evaluation(CCQE) and the American Association of Cardiovascular and

Pulmonary Rehabilitation(AACVPR), has developed a Performance Evaluation System, or PES that will allow easy collection of data with which to evaluate quality of care and ensure positive patient outcomes.   The cardiac rehabilitation PES encompasses recently developed guidelines that include the process of care. The instrument is expected to have a positive affect on the outcome of care and therefore attainment of the much sought after goal, quality of care and patient satisfaction. It is through high quality health care that services or clinical care processes achieve the health outcomes desired by patients (AHCPR, 1995b). The purpose of this study was to field test the AACVPR's Process Measurement System (PES). The specific aims were: 1) to determine the utility and efficiency of the PES for capturing information from an audit of records for patients who recently completed early outpatient hospital-based CR; 2) to describe the extent to which these records document that a few key cardiac rehabilitation outcomes were achieved for these patients during their treatment; and 3) to examine rates of achievement for each outcome in groups of patients who had a specific clinical need and then received a PES defined treatment component to address that need.

Chapter II

Review of Literature

Introduction

      This review will begin with a description of the manifestations of coronary artery disease (CAD), a definition of cardiac rehabilitation services and patients who are candidates for these services. The review will then discuss current issues in health care, some advances in research and public policy, standards and variations in healthcare, and the need for outcomes-based research within the field of cardiac rehabilitation. The Cardiac Rehabilitation Performance Measurement System (PES) will then be discussed in detail as an instrument developed by the Center for Clinical Quality Evaluation and the American Association of Cardiovascular and Pulmonary Rehabilitation (CCQE/AACVPR) and as a necessary means to evaluated care.

Coronary Artery Disease and Cardiac Rehabilitation

      Manifestations of Coronary Artery Disease (CAD) are: myocardial infarction (MI), angina pectoris, silent myocardial ischemia, or sudden death. Approximately 43% of all deaths result from cardiovascular causes each year (Balady et al., 1994; Hunnik, et al., 1995; Goldman, Williams, Tsevat, & Weinstein, 1997). In recent years many of these statistics have improved due in most part to cardiac rehabilitation. CAD is a dynamic illness and not represented by a single stable event. Effective treatment requires ongoing diagnostic testing and therapeutic intervention (Wittles, Hay, & Gotto, 1997). The estimated five year cost (in 1986 U.S. dollars), for the five major CAD

events are: acute myocardial infarction (MI), $51,211, angina pectoris, $24,980, unstable angina pectoris, 40,581, sudden death, $9,078, and nonsudden death, 19,697 (Wittles et al.,1997). The high cost of CAD is reflective of the improvements in technology and more effective and expensive therapies available. Cardiac rehabilitation (CR) has numerous benefits ranging from improved exercise tolerance, BMI, plasma lipids(CHOL), quality of life, as well as reducing subsequent hospitalization cost and CAD morbidity and mortality (Lavie, & Milani, 1997; Wenger, Froelicher, Smith, 1995; Balady et al. 1994; Oldridge, et al., 1993; Lavie, & Milani, 1997; Grundy, et al., 1997; Lavie, & Miliani, 1995; Smith, et al., 1995).

The safety of participation in cardiac rehabilitation has been established. Very low rates of occurrence of MI and other cardiovascular complications are found to occur during exercise training (Wenger et al., 1995). The effect of cardiac rehabilitation on return to work rates is yet another important factor. One in every four men and women receiving social security disability allowances are considered permanently disabled by CHD (Wenger et al., 1987). Literature concludes that CR services are essential components of the "contemporary management of patients with multiple presentations of CHD..." (Wenger et al.,1995)

Cardiac Rehabilitation

The continuous increase in the cost of healthcare can also be attributed to the innovative but expensive cost of treating chronic diseases such as heart disease, cancer and AIDS. Coronary Heart Disease (CHD), is the leading cause of death in the United States. More than one in five persons in the

United States has cardiovascular disease. With 485,000 deaths annually, amongst the 1.5 million people who have an MI, this is a most pressing health issue (Balady et al., 1994). These numbers have improved since the 1960's, however, when CHD deaths and disabilities reached epidemic proportions at 50% of all deaths. Today through improved medical care and emphasis placed on control of smoking, high cholesterol, blood pressure and other risk factors the death rate resulting from heart disease has and continues, to decline. Many lives have been saved and quality of living improved by more advanced surgical techniques and the ability to do more for greater numbers of people. In 1980, one in every 400 men aged 65 and older had coronary bypass surgery. In 1990 this number increased to one in every 100 (McMannus, & Thai, 1996). Exercise, and other aspects of CR have helped to aid in the decline of cardiovascular disease. There has been a documented 20% decrease in cardiac and overall mortality when followed over 2 - 3 years post-MI (Pashkow, 1996). The estimated cost of cardiovascular disease (CVD), associated with hospital stays, health care facilities, medical personnel and the almost 468,000 coronary revascularization procedures performed each year was an estimated 56 billion in 1994 (Balady et al., 1994). Today, with an even greater emphasis placed on rehabilitation as a secondary form of prevention, drugs, research, awareness and technology, we have been able to effectively lower costs in the areas of rehospitalization, loss of wages and mortality (Wenger et al, 1995) . Over 11 million people with cardiovascular disease receive medical care. In the field of Cardiac Rehabilitation(CR) alone, there are 2.5 million potential candidates eligible for this service (Smith et al., 1995). An average of only 15% of candidates for CR actually receive this best secondary form of prevention

and most cost effective form of treatment available (Wenger et al., 1995). Even as rates in mortality have decreased, the great numbers of people who contract this disease has not changed, and even more people who do have CHD are living longer. These statistics alone, warrant further attention. The population in general is aging, and as it does more and more significant numbers of people are living with this disease. CR is the recommended way to help these people manage their cardiovascular risk factors and receive professional help. A legislative mandate has been made to aid in improvements in health care delivery, measurement and monitoring {Agency for Health Care Policy and Research (AHCPR), 1995b}. Focus on CR programs has shown much promise in the way of survival benefit, with a significant 20%-25% reduction in cardiovascular death (Balady et al., 1994, Engblom et al., 1997, Oldridge et al., 1994, Pashkow, 1996, Pashkow et al., 1995).

The World Health Organization has defined Cardiac rehabilitation as

"...the sum of activities required to influence favourably the underlying cause of the disease, as well as to ensure the patients the best possible physical, mental and social conditions so that they may, by their own efforts, preserve, or resume when lost, as normal a place as possible in the life of the community. Rehabilitation cannot be regarded as an isolated form of therapy, but must be integrated with the whole treatment of which it forms only one facet..."(p.5)

CR has five major components: exercise training, risk factor modification, educational counseling, vocational guidance and stress management training. It is a multi-disciplinary part of routine medical care

and should be considered an integral part of comprehensive cardiac care (Thompson, 1994). CR has been considered an important component of the "modern comprehensive care plan for many patients with heart disease" (Balady et al, 1994).

Current Issues in Health Care and Reform

Health care in the United States constitutes one seventh of the economy. It is an issue of great importance and one currently in the process of reform. The focus of healthcare policy has altered among three basic issues: quality, access, and cost (McManus, & Thai, 1996). These three factors influence each other in a triangular manner. With increased cost, a lower access to health care results because poor people cannot afford care and / or insurance. Access is the ability of a population to reach, obtain and afford entrance to health services (McMannus, & Thai, 1996). This results in lower quality of care for those who are uninsured or visit physicians and hospitals less frequently than those who have insurance. This trend does *not*, however result in lower health care spending. In fact, lower access leads to higher spending because lack of timely and preventative care yield more visits to the emergency room, greater expenses and more complicated treatments.

Even though the United States spends more per capita on healthcare, than any other country an increasing number, 14.7 % in 1992, of Americans cannot obtain basic health care because they are uninsured. Despite efforts to contain the costs, healthcare has outpaced the gross national product since 1961. In 1991 the dollar value rose to 859.6 billion (14.6% of the GNP). This

increase is expected to continue so that by the year 2000, 18.9 % of the GNP will be devoted to health care alone (McMannus, & Thai, 1996).

The rising cost of health care can be attributed to many factors including, increased prices due to new surgical techniques and increased costly use of medical technology. The volume and intensity of services have also risen as health care workers are doing more, for a greater number of people. In addition, as the population ages the care received, is being provided for an even longer period of time.

Unfortunately, even though health care is one of the United States largest expenditures, the reflective quality through population indices is low (McMannus, & Thai, 1996). Indeed, Congress and healthcare experts are in the process of restructuring the healthcare system. In fact, healthcare reform is in such dire need that it is rapidly moving ahead even without approved new government legislation (Nelson, Mohor, & Batalden, 1996).

Advances in Research and Public Policy

Practice guidelines are becoming instruments of public policy. As the guidelines continue to be implemented they must meet rigorous ethical standards that are as stated by Barbara Redman (1996), "...commensurate with their impact on patients and careproviders". While financial resources are dwindling for healthcare, guidelines need to be implemented to help determine which patients are or should be eligible for services, based on outcomes research and cost efficiency analysis. Outcomes based research is also needed to address issues pertaining to patients need and benefits from, specific components of cardiac rehabilitation programs. It is important

however, that guidelines not be used to legitimize the distribution of health care resources away from those groups who already disadvantaged (Redman, 1996).

Standards and Variations in Health Care

While there is ongoing debate on the issue of restructuring the health care system through finance and deliverance of care, there is a common consensus on some issues of quality and hence, standards of care. These include: 1) quality of care is not given, 2) public accountability is needed, 3) accountability requires measuring the quality of care provided to a population of patients, and 4) public policies should promote continuous improvement of quality of care (AHCPR, 1995b). It is necessary to address all of these current issues.

There are many areas of variation within the scope of healthcare and cardiac rehabilitation. These areas include: 1) settings- the guidelines are related to the care of patients with a specific clinical condition, 2) resources- there is a large amount of variation in different aspects of this area, information technology, financial, data and human resources are available to users to develop and implement the evaluation tool, for example, multihospital settings may have access to computer assisted analysis of large data sets and in other group practices, human resources are not as readily available. 3) data documentation-different users have access to different types of data. Patient health records, administrative data and patient records are all categories of data useful for measuring quality.

Changes in the delivery of rehabilitative care for patients with CHD are reflective of the changes in the demography and characteristics of the coronary population and treatment strategies for these patients. The majority of patient population in the past consisted of only those who had experienced an uncomplicated MI. Currently many patients who receive rehabilitative services are recovering from percutaneous transluminal coronary angioplasty (PTCA), coronary artery bypass surgery (CABG) or other MI revascularization methods, and services need to be expanded to more women and older adults, poor/uneducated and minorities. According to researchers Franklin, Hall, & Timmis (1997) eligibility should also include other coronary patients such as those with compensated heart failure, cardiomyopathies, cardiac transplantation, heart valve repair or replacement, pacemaker or cardioverter-defibrillator implantation. Many people, however, who were once excluded from exercise rehabilitation, now gain much benefit from gradual supervised exercise training. Broader eligibility, along with a multifocal approach to cardiac rehabilitation, can help vast numbers of patients to achieve a better quality of life through CR.

Historically much emphasis has been placed on the *outcomes* of care, in particular, quality related outcomes such as: *functional* - physical and mental health, *clinical* - morbidity and mortality, *satisfaction* - patient and family, and *cost*-direct medical and indirect social. In *Using Clinical Practice Guidelines to Evaluate Quality of Care*, authors state that "The measurement and evaluation of outcomes provided the basis for assessing the benefits of any intervention" (AHCPR, 1995b) With this in mind, the present focus of care has expanded to include the *process* of care. Process of care incorporates

preventative measures such as: diagnostic testing, procedures and treatments and other aspects of patient care (AHCPR, 1995b). By focusing on process measurements clinicians may help monitor and improve delivery of care and thus affect, in a positive way patient outcomes and cost of care (Batalden, et al, 1996).

Variation in quality, care, and services provided is a concern in all areas of healthcare.   Particularly in specialty areas that are new or rapidly developing. In a Consensus Panel Statement the American Heart Association (AHA) urges that "every effort be made throughout the spectrum of medical care to promote more comprehensive application of risk reduction in all eligible patients" (Smith et al, 1995).   This statement was published to assist with inconsistent application of risk reduction interventions that are known to significantly improve clinical outcomes (Smith et al., 1995; AHCPR, 1995b). There are numerous ways to reduce variations in the quality and raise the overall level of services. These include, but are not limited to, practice audits by practitioners groups, evaluation of treatment outcomes, and examination of the process by which care is delivered. In CR the AHCPR has recently funded a project to develop quality review criteria and performance measures based upon guideline-derived quality evaluation (AHCPR, 1995c). The goal was to translate guideline recommendations into an evaluation tool for measuring process of care (AACVPR/CCQE Final Report, 1995).   The PES is the resulting functional form of the guidelines. These efforts resulted in the Performance Evaluation System, (PES).   It is with this instrument that specific data related to delivery of care can be extracted from patient medical records. Delivery and process of care can then be linked to resulting patient

outcomes. Variations throughout the CR field can be examined, and reduced, to raise the overall level of services.

Process Evaluation System (PES)

It has been suggested that in order to improve Cardiac Rehabilitation health services need to be offered to all who have the potential to benefit from them, and that they need to be constructed according to individual risk reduction interventions and specific needs (Thompson, 1995). Cardiac Rehabilitation needs to be recognized as an essential part of comprehensive cardiac care and this care should be provided by staff who are "appropriately trained, and subjected to audit and evaluation" (Thompson, 1995).

AHCPR has examined, and recently funded, ways to evaluate the quality of care using clinical practice guidelines. Health care can "best be evaluated using an instrument that has been developed according to clear and understood methodology" (AHCPR, 1995b). Judgments then can be passed about the quality of care being delivered, in accordance with the clinical practice guidelines. Thus, hallmarks of quality care can be extracted from the guidelines and used to generate medical review criteria, performance measures and standards of quality. Medical review criteria, for example are derived from guidelines such as presence or absence of high blood cholesterol levels (CHOL). Performance levels are applied, as to which actions should be taken, according to the cholesterol values being ranked as high, moderately high, etc. Outcomes then are achieved and standards of quality then are decided. By using quality criteria and the Performance Evaluation System (PES), the degree to which care has followed specific process and achievement of aspired outcomes, can

be determined. There is a need, as stated by Thompson(1995) to "develop clinically useful assessment, audit, and evaluation tools".

The production of a PES, or instrument, to allow easy collection of data with which to evaluate quality of care and ensure positive patient outcomes has been developed by a AACVPR. The PES encompasses recently developed guidelines that include the process of care. The instrument is expected to have a positive affect on the outcome of care and therefore attainment of the much sought after goal, quality of care and patient satisfaction. It is through high quality health care that services or clinical care processes achieve the health outcomes desired by patients (AHCPR, 1995b).

The Center for Clinical Quality Evaluation has prepared reports that have resulted from the CCQE/AHCVPR Guideline Criteria Project. One such report presents an evaluation of the "feasibility" of implementing the guideline for benign prostatic hyperplasia or BPH(AHCPR, 1996d). This report describes methods used to develop the clinical performance measures for the BPH guideline and it "presents findings from applying these systems to medical records" {Agency for Health Care Policy and Research (AHCPR), 1996d}. This was the first of many similar projects to "develop, apply, and evaluate measurement criteria   based upon AHCPR-supported guidelines" (AHCPR, 1996d). Upon completion of these projects the Agency was provided with feedback on guideline implementation.

As mentioned previously, the need and demand for better quality of care and ultimately for decision making are based on information on medical services and their "cost" and "quality". Many times when available data such as medical records are used they are too easily implemented by measurement

systems. Results that are not nearly complex enough to form basis for medical decision making are produced. Rigorously tested reliability and validity would, for instance be of great value to help combat this. "...Improvements in care processes lead to better patient outcomes" (AHCPR, 1996b). Evidence based measures can be used to improve patient care and clinical outcomes if the quality of clinical care can be monitored effectively. The BPH project was expected to provide information to improve key processes of clinical care for a "given condition" by isolating some specific areas of care where improvements both significant and measurable can be made (AHCPR, 1996a). Findings suggest that there is potential improvement opportunities for management and treatment of BPH based on the performance rates for criteria in the criteria groups. It is suggested by the authors that data may "point to a starting point" for guideline users in appropriately evaluating BPH symptoms and clinically managing treatment options (AHCPR, 1996a). This same methodology has been applied in the process of creating the Cardiac Performance Evaluation System (PES) and current research suggests that evaluation and implementation could be both beneficial and successful in early outpatient hospital-based cardiac rehabilitation programs.

The criteria in this new approach, the PES, are reflective of the essential components of Cardiac Rehabilitation. These include: exercise, education, intervention and counseling. The quality review criteria and performance measures found in the PES were developed based upon the AHCPR-supported clinical practice guidelines (AHCPR, 1995b). This PES is the newest tool available for measuring quality of care and as of yet, no research has been done to determine the adequacy of the instrument or the

types of information that it may produce when used to audit patient records from Cardiac Rehabilitation programs. Performance measurements will be appropriate for use in evaluation of community based facilities and hospital based facilities and it will be possible to review large numbers of cases. All necessary data can be obtained easily from the medical records of the Cardiac Rehabilitation patients. It is suggested that quality of care and patient outcomes can be determined by the amount of cases that demonstrate care conforming to a defined set of quality process criteria derived from an expert panels' judgment on the key features of the CCQE/AACVPR Cardiac Rehabilitation Guidelines.

Thus, the purpose of this study was to field test the AACVPR's Process Measurement System (PES). This field testing was conducted at two large urban hospital-based outpatient CR programs in North Carolina. The specific aims were to: 1) to determine the utility and efficiency of the CR PES for capturing information from an audit of records for patients who recently completed a Phase II program; 2) to describe the extent to which these records document that a few key cardiac rehabilitation outcomes were achieved for these patients during their treatment; and 3) to examine rates of achievement for each outcome in groups of patients who had a specific clinical need and then received a PES defined treatment component to address that need, i.e., did a patient who's record documented an abnormality for a treatment-related criterion, contain a treatment step to address it, and a follow-up procedure to achieve the specific outcome at the end of treatment?

Summary

Progress in the medical field has consisted of new technologies in disease process, diagnosis techniques and treatment, but less attention has been paid to development of a means for systematic assessment of how healthcare is actually delivered to populations or individual patients. For example, variation in treatment is found between persons with the same basic conditions. This can result from either different treatments or different evaluations. The resulting variations in the process of healthcare, produce variations in costs of care which perhaps, leads to differences in the outcomes of care. Information is necessary to improve the delivery of healthcare and achieve desired outcomes. The ultimate goal is "transformation" of healthcare into an industry based on facts about relations between process of care and outcomes of care (AHCPR, 1995b).

Chapter III

JOURNAL MANUSCRIPT

PERFORMANCE OF A PROCESS EVALUATION SYSTEM IN OUTPATIENT HOSPITAL-BASED CARDIAC REHABILITATION

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Performance of A Process Evaluation System in Outpatient Hospital-Based Cardiac Rehabilitation

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(ABSTRACT)

This study retrospectively evaluated patient records from two cardiac rehabilitation (CR) service centers located in large urban hospitals using a Process Evaluation System (PES). The PES was recently developed through a collaborative project of the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), Madison, WI, and the Center for Clinical Quality Evaluation (CCQE), Washington, DC. The major aims were to: 1) evaluate the utility of the PES as an audit instrument for assessment of adherence to the 24 quality process criteria that comprised the PES; and 2) determine whether adherence to the PES criteria resulted in different patient outcomes for those cases where intervention need was documented at patient admission. Using the data abstraction manual and audit procedures developed by AACVPR/CCQE, a trained medical technician audited 150 CR records for consecutively treated outpatients who typically received 36 sessions of treatment in either Moses H. Cone Memorial Hospital N.C. Heart Institute, Greensboro, NC, or Carolina's Medical Center, Charlotte, NC, covering a calendar period between 1995-97. Data were pooled for analyses and included patients with one or more of the following diagnoses: myocardial infarction

(37%), angina (14%), coronary revascularization (76%), and other (18%). Technician time required to abstract a patient record was observed to improve over the review period, i.e., mean time for abstraction of the initial versus final 20 records = 13.2 min. and 4.6 min., respectively. Experience with the PES suggested a few areas where instrument revision should be considered. Adherence to the PES criteria was determined, case by case, for each of the 24 criteria. In 129 cases (86% of the sample), complete adherence was found, i.e., 100% adherence to all 24 criteria that included indicators of key clinical steps for patient intake, treatment planning, and follow-up. The remaining 21 records (14%) showed adherence to at least 21 of the 24 criteria (87.5%). Given these uniformly high levels of adherence by these two program sites, the data could not resolve the question of whether patient outcome effects were different between cases of high versus low adherence to PES. Nonetheless, outcome data were examined to evaluate achievement levels in four different areas widely considered by clinicians as important to treatment success: blood cholesterol, smoking status, exercise tolerance, and body mass index (BMI). Of the study patients diagnosed with dyslipidemia 12 of 27 (44%) had achieved levels < 200 mg/dl at treatment exit. Seven of 14 patients identified as smokers (50%) reported quitting at exit. Forty-nine patients of 117 (42%) initially had an exercise prescription level below 4 METs. Upon exit were assigned and prescriptive treadmill walking for 10 min. at levels below 4 METs, 25 were able to exceed 5 METs by treatment end. Six of 104 (6%) with BMI values > 24.9 kg/m^2 had a documented decrease in this indicator of overweight by treatment end. The PES system was developed to audit the quality of CR

process in treatment centers, as standardized by a consensus panel, to reflect the content of the evidenced-based CR guideline recently published by the US Agency for Health Care Policy and Research (*Cardiac Rehabilitation as Secondary Prevention*: #17, 1995). The findings of this study suggest that the content markers of quality process in the PES are relevant and the instrument is efficient to administer. When field tested against two urban centers in North Carolina where state statutes require program certification for CR treatment centers, uniformly high adherence to the PES criteria was found.

Future investigations should attempt to evaluate programs located in areas that do not require state certifications. The tool needs to be utilized in a variety of settings including small rural areas. A study similar to this one, yet performed on a much larger scale, perhaps to include statewide implementation, could be performed using a computer-based design. All data would be entered and analyzed directly through a database. The clinical applicability, clarity, and flexibility of the PES and even of the guidelines, need to be continuously examined. Results will provide useful information for revisions and continuous improvement of the instrument.

Introduction

Quality of care is an important component of cardiac rehabilitation (CR) programs. The Agency for Health Care Policy and Research (AHCPR) has examined, and recently funded, a project to evaluate the quality of care provided by cardiac rehabilitation programs using evidence-based clinical practice guidelines[1]. The Clinical Practice Guideline No. 17, was developed by AHCPR and the National Heart, Lung, and Blood Institute(NHLBI), to describe a uniform methodology by which to evaluate the quality of CR care, while focusing on treatment process rather than patient outcomes. The clinical practice guidelines are viewed by many as a resource to guide clinical quality improvement on a nationwide scale. Once key treatment process parameters are translated into an evaluation instrument, it can be used to determine if the care actually provided is in conformance with recommended guidelines. Recommendations and judgments can be made with the use of guidelines about health care delivery, but first, the care must be evaluated using tools rigorously developed based on these practice guidelines.

Such an instrument, or functional form of the clinical practice guidelines, has been developed by AACVPR/CCQE for use in the area of CR[2]. Today, with an even greater emphasis placed on rehabilitation as a secondary form of prevention, drugs, research, awareness, and technology, we have been able to effectively lower costs in the areas of rehospitalization, loss of wages, and mortality[1]. CR is the recommended way to help these people manage their cardiovascular risk factors and receive professional help. Focus on CR

programs has shown much promise in the way of survival benefit, with a significant 20-25% reduction in cardiovascular death[1,3-7]. Health care is one of the nations largest expenditures approaching 15 % of the gross domestic product and $500 billion annually[8-11]. Coronary heart disease (CHD) alone consumes 15% of the annual US health care budget and almost $80 billion in financial costs[11]. As expected, interest currently has broadened to encompass payment and reimbursement policies. Indeed, Congress, the Executive Branch, and Private Sector are all in the process of restructuring the health care system. A legislative mandate has been established to aid in improvements in health care delivery, measurement and monitoring[12]. With accountability a priority, purchasers, legislators, and consumer advocates are calling for public disclosure of patient satisfaction and other health-care outcomes. As competition for limited health-care resources becomes even more acute, competition for these funds will increase. One current theory suggests comparative information will then be used in choosing providers and this will in turn force attention to quality issues[13]. Outcomes will help to determine which patients are or should be eligible for services, and where funds will be allocated based on outcomes research and cost analyses. Outcomes-based research is necessary to address issues pertaining to patient needs and benefits from specific components of CR programs.

The Performance Evaluation System (PES) was produced to allow easy collection of data with which to evaluate quality of care and ensure positive patient outcomes. The instrument is expected to have a positive effect on the outcome of care, and attainment of the much sought after goal, quality of care

and patient satisfaction. Through high quality health care, these services, or clinical care processes can achieve the health outcomes desired by patients[12]. The major aims of this study were to: 1) evaluate the utility of the PES as an audit instrument for assessment of adherence to the 24 quality process criteria that comprised the PES; and 2) determine whether adherence to the PES criteria resulted in different patient outcomes for those cases where intervention need was documented at patient admission.   While related research studies have been performed in such areas as management of acute pain, and benign prostatic hyperplasia (BPH), no studies have yet been performed within the realm of cardiac rehabilitation (CR)[14].

Methods

Study patients.   Data for this study were extracted from the clinical records of 150 patients who had participated in hospital-based outpatient cardiac rehabilitation programs, which lasted approximately 36 sessions, and was performed at either Moses H. Cone Memorial Hospital N.C. Heart Institute, in Greensboro, North Carolina or Carolina's Medical Center, in Charlotte, North Carolina (Table 1). With the exception of ten records dated January 1992-November 1995 all records were from patients who had entered into rehabilitation between December, 1995 and December, 1996.   For inclusion patients must have successfully completed at least 80% of their available 36 sessions of cardiac rehabilitation within 12 weeks.   Patients were excluded from the study if for any reason they did not complete their outpatient hospital-based cardiac rehabilitation.

For each of the 150 patient records, data for the 24 quality process criteria was abstracted. For every record the process was identical, beginning with item one and finishing chronologically with item 24. Information was found or not found within the record and the appropriate code was entered into the data abstraction worksheet. In the PES documentation was defined as having "Met", "Not Met" or "Acceptable Alternative" for each criteria. Definitions and examples of the coding for each of the 24 quality process criteria were stated explicitly in the data abstraction manual. For each criteria on the data abstraction worksheet there were specific coding options for that item. For example, the criteria for admitting diagnosis contained simple codings of: 1=yes, 9=not documented, whereas item 24, referring to reassessment of exercise capabilities and a maintenance exercise prescription contained coding options such as: 1=yes, 2=reassess only, 3=prescription only, and 9=not documented. The coding process was done for all 24 criteria and for each patient. References were made to the data abstraction manual for clarification when the abstractor was unsure of how to code information for a specific criteria. The abstraction manual, along with a coded data abstraction worksheet, was used for each record. Time was recorded for each, and began when the patient medical record cover was opened. Stop time was noted when item 24 on the data abstraction worksheet was answer coded.

Evaluation of Information Yield. The evaluation was done using the CR PES inventory. Patient records, 75 from each site, were evaluated as to whether the PES contained criteria frequently documented in the records of Phase II

cardiac rehabilitation programs. The records then were audited and grouped into two groups. The first group contained those records that documented adherence to criteria (#1-#24) and the second those that failed to document adherence to criteria (#1-#24). Documentation rates for each of the criteria then were described according to the numbers of patients whose records showed 70%, 80%, 90% and 100% of the 24 target quality criteria. The yield of information derived for each of the 24 criteria were expressed as a percentage of the total cases audited.

Evaluation of Efficiency (Efficiency = Yield/Cost). The efficiency of utilizing the PES with cardiac rehabilitation program records was evaluated through examination of two variables. The first, a measure of information yield, was calculated as the percentage of patient records that contained the required information needed for the performance evaluation. The overall information yield, i.e., percent(%) of information derived from audit divided by 24 X 150 (100%) was then calculated. The calculated efficiency was considered equal to the information yield divided by the lowest estimate of abstraction time (first 20 records i.e. 10 from each site) and also by the information yield divided by the highest estimate of data abstraction time (last 20 i.e. 10 from each site). The second measure, a cost indicator, was represented by the mean and standard deviation of the time required to audit the total sample of 150 consecutive cases. The calculated efficiency is equal to the information yield divided by the lowest estimate of abstraction time and also by the information yield divided by the highest estimate of data abstraction time.

Evaluation of the Adequately Documented Patient Outcome Variables.   All of the records were also audited for four patient outcomes: weight control, smoking, cholesterol and exercise tolerance. For weight control and cholesterol, the mean change (X) in relevant cases as well as the level of improvement were described (CHOL < / = 200 mg/dl and BMI < / = 24.9 kg/m^2). For example, blood cholesterol(CHOL*)* data were entered into a spreadsheet and grouped according to: 1) those with total cholesterol levels greater than 200 mg/dl, 2) of those with CHOL levels greater than 200 mg/dl, how many records, according to the tool, were diagnosed with dyslipidemia, had intervention, and were reassessed prior to exit from the program. The remaining variables, smoking and exercise tolerance also were evaluated.   Smoking data were described according to rates of cessation by program exit, and data related to exercise capacity were described as: 1) the mean change (X) in METs, and 2) the number of patients who increased their exercise tolerance, to greater than or equal to 5 METs by program exit.

Evaluation of Success Rates.   The success rates were then analyzed for achievements of the four patient outcomes stated: weight control, smoking cessation, blood cholesterol, and exercise tolerance. The intent was to evaluate success rates for hospital-based outpatient cardiac rehabilitation records which did document adherence versus   those which *did not* document adherence to treatment and follow up results.

Statistical Analyses.   Data for each record and across all 24 abstraction criteria were entered into a spreadsheet. The investigators then pooled information according to the research questions mentioned earlier. Data reduction and frequencies and percentages were obtained via a calculator. Subject summary data was analyzed with descriptive statistics. The dependent measures were analyzed using a personal computer and Minitab as a statistical software(MINITAB INC, State College,PA). The dependent t-test to define significance of the first and last times were recorded to examine efficiency of human resources with data abstraction times for patient records. The outcomes of BMI and CHOL were analyzed at entrance and exit with a dependent t-test for determination of significance. Chi-square was performed for significance between groups of patients and between the two sites.

Results

 Utility of the PES

For purposes of this study, efficiency was evaluated as the yield (number of records), divided by cost. The data technician examined a total of 177 records, 150 of which, remained suitable for abstraction. The others (18 from Greensboro and 9 from Charlotte, N=27) were not eligible for use in this study for the following reasons: the patients did not complete their cardiac rehabilitation program(due to further illness, transportation difficulty, insurance limitations/early discharge, or if the patient expired), or the patient

was re-admitted to the hospital for various reasons and thus could not continue in the program. The cost of utilizing the PES was assessed by evaluating the technician time required to abstract a patient record. With use of the instrument, time was observed to improve throughout the course of the review period. The mean extraction time for the initial 20 records was 13.2 minutes as compared with 4.6 minutes for the final 20. In order for Clinicians to apply this information, they must take into account approximately 20 working allotted for the technician to become familiar with the abstraction tool and process. Once the technician is oriented, the total abstraction time per record is approximately equal to between five and eight minutes. One hundred records could be completed in an 8-13 hour period (500-800 minutes). This estimation of time is dependent on the organization of a particular sites' patient records. Any person having some experience with medical records, associated terminology, or clinical experience could be trained quite easily to use the PES.

Evaluation of the information yield, was measured by adherence to the 24 quality process criteria in the PES. Adherence was determined, case by case, for each of the 24 criteria and in each of the 150 cases. In 129 cases (86% of the sample), complete adherence was found, i.e., 100% adherence to all 24 criteria. The 24 quality process criteria included indicators of key clinical steps for patient intake, treatment, and follow-up. The remaining 21 cases were found to have the following rates of adherence: 15 cases had documented 23 of the 24 criteria resulting in 95.8%, three records contained 91.6% adherence or 22 of 24 criteria and lastly three records documented 21 of 24 criteria or 87.5% adherence to the PES. Cases were examined for adherence to

each of the 24 criteria, i.e., how many cases of the 150 met each criterion. Across all criterion, codings of "not documented" were minimal. Criteria two pertained to other cardiac events or diagnoses and ten of the 150 cases (6.7% of complete sample)had been coded as "not documented" for this particular item. For criteria related to relevant behavioral/psychological conditions and inadequate living/social support five and eight records respectively or 3.3% and 5.3% of total sample (N=150) were coded as "not documented". With such small numbers, it was concluded that there were no particular criteria in the instrument deemed inappropriate due to lack of record documentation.

Outcome Data for Cases Where Intervention Need Was Documented.

Outcome data is a result of process and an important consequence to consider as part of evaluation in specific treatments in health care. They are an important and necessary component of research. By examining outcomes we can assess the results of process and performance of alternative health care programs and thus observe resulting standards of care. Outcome data were examined in this study to evaluate achievement levels in four different areas widely considered by clinicians as important to treatment success: blood cholesterol, body mass index (BMI), smoking status, and exercise tolerance[1,15].

Figure 1 Insert Here

Cholesterol

Forty-five patients of the audited 150 records had a documented entrance and exit value for cholesterol recorded (refer to Figure 1). Of these, 27 patients had total cholesterol levels >200 mg/dl. For our purposes this level was considered to be dyslipidemic and intervention and reassessment followed, as recommended by the Clinical Practice Guidelines for all 27 patients. Upon reassessment 12 of these 27 who needed intervention (44 %) had achieved a reduction in total cholesterol below 200 mg/dl. Fifty-four percent, the remaining 15 patients with elevated cholesterol did not achieve a cholesterol level below </= 200 mg/dl. However, many did achieve a substantial reduction in their total cholesterol (an average decrease of 37.4 mg/dl, range 79 mg/dl - 17 mg/dl). A t-test of the mean proved significant with a mean change of -29.9, standard deviation of 42.2 and t value of -4.7 (p value=.0001).

Figure 2 Insert Here

Body Mass Index (BMI) was recorded for 143 of the 150 patients records examined in this study. The seven records for which BMI data is not given were due to extenuating circumstances, such as two patients who were not physically capable of standing to have their height recorded etc. Of the 143 records that documented an entrance and exit BMI, 104 of those revealed that the patient's BMI was above the desired range of 20-24.9 kg/m^2 [15]. The 104 entrance and exit values are shown in graph above. Six of the 104 patients

(6%) with BMI levels above the desired range were able to reach </= to 24.9 kg/m2 by treatment end. The average weightloss for the 104 patients was 4.6 pounds. A t-test of the mean revealed no significance for mean change (-0.13), with standard deviation 1.52 and p-value 0.32.

Figure 3 Insert Here

Smoking. Of 150 patients 49 were nonsmokers, while 87 had quit, according to the abstraction manual (i.e. quit=patient gives up cigarettes prior to day of the event or procedure), and 14 were documented as smokers upon entrance to the Cardiac Rehabilitation Program. Records for all 150 patients indicated baseline documentation of smoking status, intervention (if patient was currently smoking) and reassessment of smoking status, if documented as a smoker. Of the 14 smokers in this audited patient population, 7 gave up smoking, "quit" at reassessment, prior to their release from the Cardiac Rehabilitation program. Two of the patients reduced the amount they smoked according to documentation in the patient medical record (i.e. one-half pack per day). The five remaining patients were offered materials and intervention for risk factor reduction but refused all aid.

Figure 4 Insert Here

Figure 5 Insert Here

Exercise Capacity . Of 150 audited records 117 had a documented entrance and exit MET level. Seventy-seven percent (90 of 117) entered into the Cardiac Rehabilitation program able to exercise for 10 minutes at levels

only below 4 METs. Fifty-four percent (49 of 90) entered at a level below 4 METs but at reassessment were capable of MET levels at or above 4 METs. Sixty-three percent (74 of the 117 records) of the patients exited the program at or above 4 METs. Of these 74 records 43,22,6,4,2 total numbers patients were capable of exercising for 10 min. at levels equal to or above 5,6,7,8,10 METs respectively.

Discussion

The present study was conducted to retrospectively evaluate two cardiac rehabilitation programs located in large urban facilities, by using the Process Evaluation System (PES). Related research in the health area has been performed in (BPH) benign prostatic hyperplasia[14]. No studies, however, have yet been performed within the realm of cardiac rehabilitation.

The audit performed yielded an adequate data set. 129 of 150 patient records had 100% adherence to the tool(PES). Given the uniformly high levels of adherence to the PES documented by these two program sites, the data set could not resolve the question of whether patient outcome effects were different between cases of high versus low adherence to the PES. Outcome data were, however, examined to evaluate achievement levels in the four areas of: blood cholesterol, body mass index (BMI), smoking status, and exercise tolerance.

The learning curve found during a pilot study just prior to this, was replicated in the current study. The mean abstraction time for the initial 20 records (10 from each site) was 13.2 minutes as compared with 4.6 minutes

needed for the final 20. Time needed to become familiar with the instrument (terminology, coding, procedure etc.) was minimal and could easily be repeated by persons who have had even limited experience in the medical field. The findings of this study suggest that the content markers of quality process in the PES are relevant and the instrument is efficient to administer. When field tested against two urban centers in North Carolina where state statues require program certification for CR treatment centers, these centers demonstrated uniformly high adherence to the PES and a pattern of good achievement for several patient outcome measures accepted as relevant to evaluation of treatment success for individual patients.

Conclusions

Experience with the PES suggested areas where instrument revision should be considered (Table 2), e.g., the operational guidelines for extracting acceptable markers were not always clear enough or sufficiently flexible to allow determination of adherence of a record to the 24 quality process criteria. Given the uniformly high levels of adherence to the PES documented by these two program sites, the data in this study could not resolve the question of whether patient outcome effects were different between cases of high versus low adherence to PES. Nonetheless, outcome data were examined to evaluate achievement levels in four different areas widely considered by clinicians as important to treatment success: serum cholesterol, smoking status, exercise tolerance, and body mass index (BMI).   The threshold levels for outcome

criteria used here to describe achievement levels in this data set are somewhat arbitrary. However, the criteria are reflective of the standards typically suggested as meaningful for effective secondary risk reduction in CR programs[16]. A significant amount of change was seen across each of the four outcomes from entrance to exit. Not as many patients were able to achieve outcome values that equaled or were below the recommended guidelines for BMI, CHOL, smoking and exercise tolerance.

The PES system was developed to audit the quality of CR process in treatment centers, as standardized by a consensus panel to reflect the content of the evidenced-based CR guideline recently published by the US Agency for Health Care Policy and Research[1]. The findings of this study suggest that the content markers of quality process in the PES are relevant and the instrument is efficient to administer. When field tested against two urban centers in North Carolina where state statutes require program certification for CR treatment centers, these centers demonstrated uniformly high adherence to the PES and a pattern of good achievement for several patient outcome measures accepted as relevant to evaluation of treatment success for individual patients.

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Table 1. Characteristics of Patients at Time of Entry to Cardiac Rehabilitation

Physical Measures and Risk Factors	Site 1 N=75	Site 2 N=75	N=150 Combined
Height (inches)	(67.4+/-3.8)*	(68.1+/-3.8)*	(67.7+/-3.8)*
	73	**69**	**142**
Weight (pounds)	(179.8+/-40.8)*	(183.2+/-33.9)*	(181.5+/-37.5)*
	74	**72**	**146**
Cardiac Diagnoses			
Myocardial infarction	**32**	**24**	**56**
Stable angina	**6**	**15**	**21**
Revascularization	**60**	**54**	**114**
Other	**15**	**12**	**27**
Diagnosis at Baseline			
Diabetes	**15**	**17**	**32**
Hypertension	**42**	**40**	**82**
Dyslipidemia	**42**	**45**	**87**
Obesity or overweight	**43**	**48**	**91**
Current smoker	**2**	**12**	**14**
Previous smoker	**47**	**40**	**87**
Blood cholesterol	(203+/-66.8)*	(230+/-49.2)*	(228+/-50.6)*
	4	**41**	**45**
Body mass index	(28.1+/-5.47)*	(27.7+/-4.19)*	(27.9+/-4.85)*
	70	**73**	**143**
Exercise capacity	(2.4+/-.69)*	(4.1+/-1.76)*	(3.1+/-1.51)*
	68	**49**	**117**

*mean and standard deviation
(   )= Contains mean value for that item
Bold numbers relate to sample size
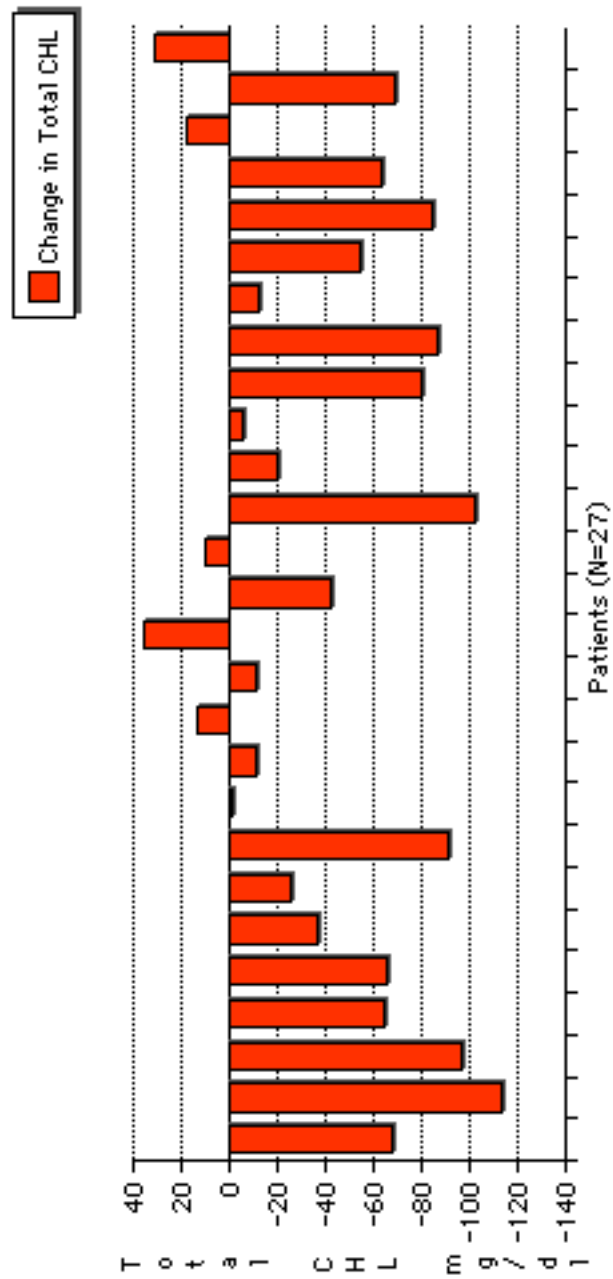
Figure 1: Change in Total Cholesterol for Patients Whose Entrance Levels Were 200 mg/dl or Above.
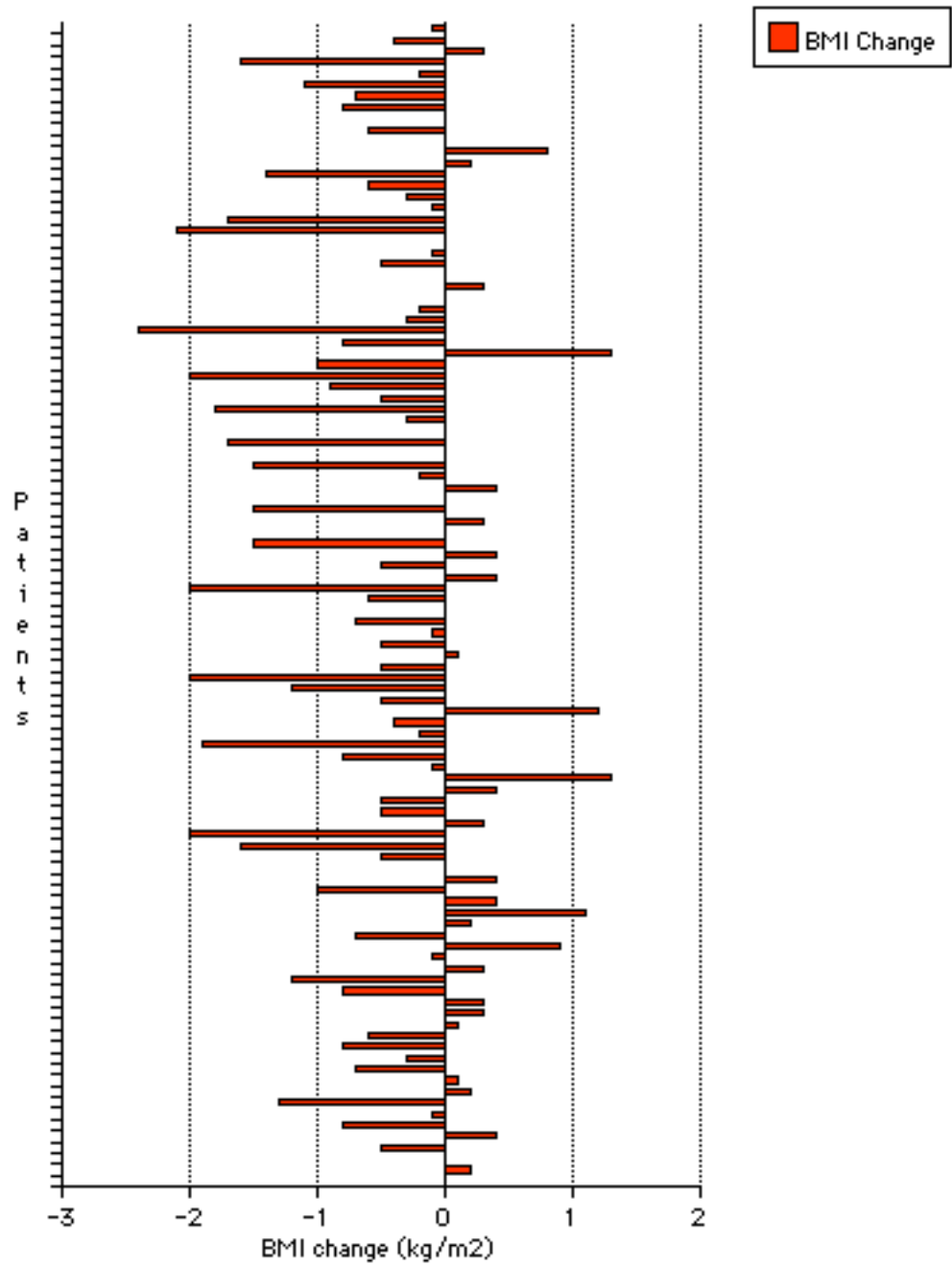
Figure 2: Change in Body Mass Index for Patients Who Entered Above 24.9 kg/m2
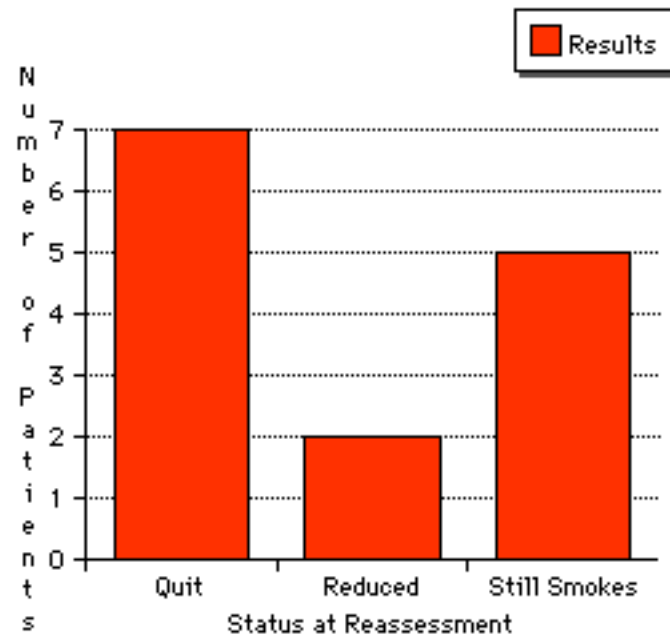
Figure 3. Results of Smoking Status Upon Reassessment
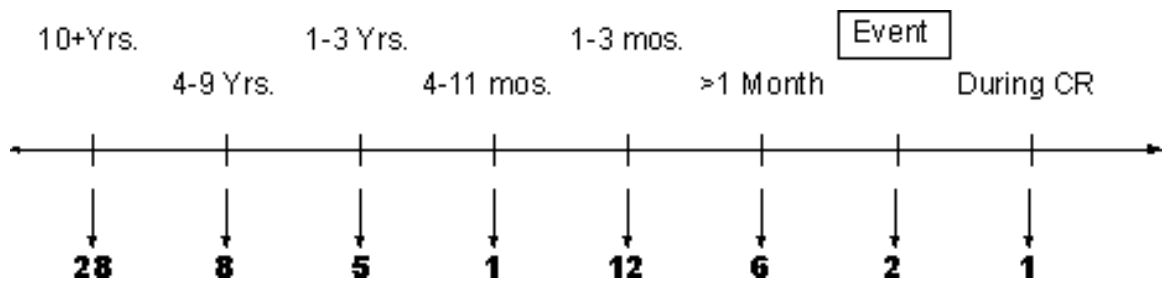
Figure 4. Timeline of Smoking Cessation for Patients Who Were Documented As Having "Quit".
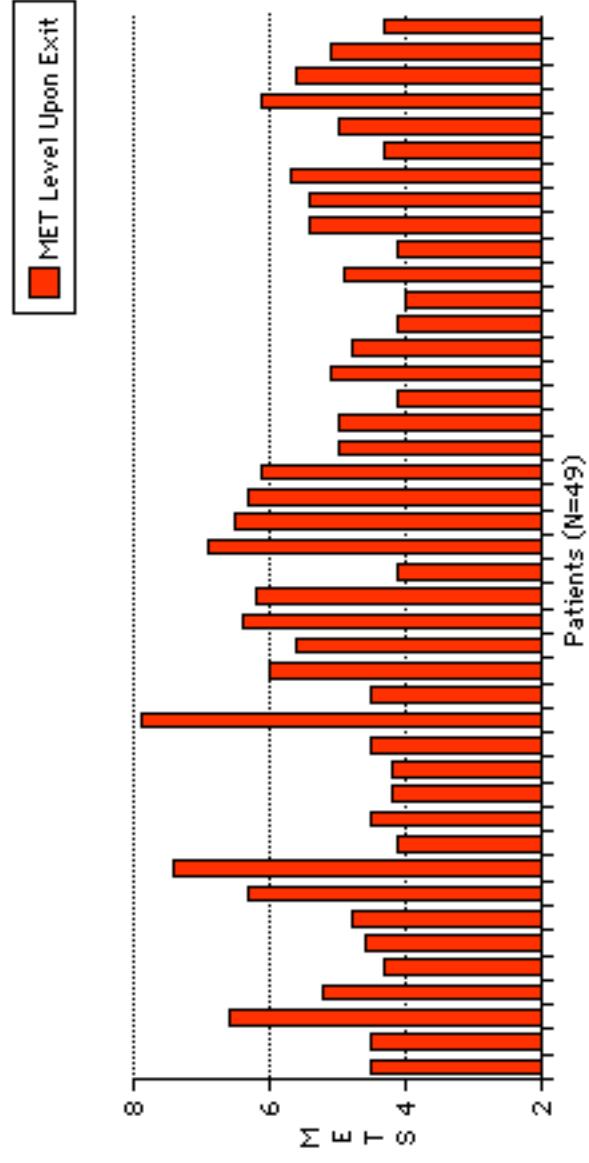
Figure 5: Exercise Capacity at Exit for Patients who entered Rehabilitation with training levels less than 4 METS

Table 2. Suggestions for Instrument Revision.

Data item	Areas of Concern	Suggestions to Improve PES
Obesity or overweight	1) A coding of 6 (height/weight) automatically calls for a coding of 7 (not applicable) for intervention and reassessment without consideration for weight status of that patient	1) Patients whose records indicate ht/wt should provide intervention and reassessment according to patient BMI etc. 2) Placement in abstraction manual and worksheet for intervention and reassessment of those patients underweight
Smoking status	1) No accounting provided for use of other tobacco products 2) Status is considered smoking history if patient quits even just a few days prior to event, procedure or diagnosis	1) Adding provisions in abstraction manual 2) Being smoke free for an entire year is usually associated with a reduced possibility of recidivism
Relevant behavioral or psychological conditions	1) No code option for patient who declines interviews and further contact from specialist	1) Expansion on item in the manual
Inadequate living arrangements/ social support	1) In the manual this item is termed "Adequate social support", thus when referencing the manual the technician is instructed to code the opposite of what is directed according to the worksheet	1) Correct wording in the instructions for item #13 to match what is required in the abstraction worksheet
Dyslipidemia	1) Baseline sample-not valid within 6-8 weeks of event	1) Allowance made for limited timeframe (i.e. premorbid values)

Chapter IV

Summary, Conclusions, and Recommendations

Summary

This study retrospectively evaluated patient records from two cardiac rehabilitation (CR) service centers located in large urban hospitals using a Process Evaluation System (PES). The PES was recently developed through a collaborative project of the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), Madison, WI, and the Center for Clinical Quality Evaluation (CCQE), Washington, DC. Patients were excluded if, for any reason, they did not complete the 12 weeks (at least 80% of the 36 available sessions) of the outpatient hospital-based CR program.

The study was conducted to: 1) evaluate the utility of the PES as an audit instrument for assessment of adherence to the 24 quality process criteria that comprised the PES; and 2) determine whether adherence to the PES criteria resulted in different patient outcomes for those cases where intervention need was documented at patient admission. Using the data abstraction manual and audit procedures developed by AACVPR/CCQE, a trained medical technician audited 150 CR records for consecutively treated outpatients who typically received 36 sessions of treatment in either Moses H. Cone Memorial Hospital, N.C. Heart Institute, Greensboro, NC, or Carolina's Medical Center, Charlotte, NC, covering a calendar period between 1995-97.

All data analyses were performed using Minitab as statistical software (MINITAB Inc. State College, PA). Chi Square analysis were used for

comparison of and between sites. Data were analyzed using paired dependent t-test and t-test of the mean. Outcome data were examined using independent and dependent t-tests along with standard deviation of the mean. Raw data were also entered into spreadsheets and grouped accordingly.   Comparisons were drawn, and frequencies and percentages   were counted and calculated from these spreadsheets.

Utility of the PES. The cost of utilizing the PES was assessed by evaluating the technician time required to abstract a patient record and this was observed to improve over the course of the review period, i.e., mean abstraction time for initial versus final 20 records = 13.2 min. and 4.6 min., respectively. Experience with the PES suggested areas where instrument revision should be considered, e.g., the operational guidelines for extracting acceptable markers were not always clear enough or sufficiently flexible to allow determination of adherence of a record to the 24 quality process criteria. Adherence to the PES was determined, case by case, for each of the 24 criteria. In 129 cases (86% of the sample), complete adherence was found, i.e. 100% adherence to all 24 criteria that included indicators of key clinical steps for patient intake, treatment planning, and follow-up. The remaining 21 records (14%) showed adherence to at least 21 of the 24 criteria (87.5%).

Adherence patient outcomes. Given the uniformly high levels of adherence to the PES documented by these two program sites, the data could not resolve the question of whether patient outcome effects were different between cases of

high versus low adherence to PES. Nonetheless, outcome data were examined to evaluate achievement levels in four different areas widely considered by clinicians as important to treatment success: blood cholesterol (CHOL), smoking status, exercise tolerance, and body mass index (BMI). Of the study patients diagnosed with dyslipidemia 12 of 27 (44%) had levels < 200 mg/dl by program exit. Seven of 14 documented smokers (50%) reported quitting at exit from treatment. Forty-nine patients of 90 (54%) who initially could only maintain treadmill walking for 10 min. at levels below 4 METs, were able to exceed this level by treatment end. Of the 49 patients who exceeded 4 METs, 24 were capable of exercising for 10 minutes at levels of at least 5 METs by treatment end. Six of 104 (6%) with BMI values > 24.9 kg/m^2 had a documented decrease in this indicator of overweight by treatment end. The 104 patients averaged a 4.6 pound weight loss by program end. Since the rehabilitation program lasted only 12 weeks the timeframe is important to consider, as well as some ways which might allow a more effective amount of weightloss by program end. An average, of just one pound per week would result in a more satisfactory decrease in total weightloss while minimizing the health risks associated with dieting extremes.

Conclusions

The PES system was developed to audit the quality of CR process in treatment centers. A process that has been standardized by a consensus panel, to reflect the content of the evidenced-based CR guideline recently published by the US Agency for Health Care Policy and Research (*Cardiac*

Rehabilitation as Secondary Prevention: #17, 1995). The findings of this study suggest that the content markers of quality process in the PES are relevant and that the instrument is efficient to administer. When field tested against two urban centers in North Carolina where state statutes require program certification for CR treatment centers, these centers demonstrated uniformly high adherence to the PES and a pattern of good achievement for several patient outcome measures accepted as relevant to evaluation of treatment success for individual patients.

Recommendations for Clinicians

Use of the PES can easily be implemented into the established routine care of a CR facility. With the use of the PES Clinicians can easily examine adherence to recommended practice guidelines within individual facilities. With repeated use, progress and improvements from year to year or even over a period of months can be compared, monitored, and improved. Comparisons to other sites can also be evaluated with this instrument. Since the PES is the functional form of the Clinical Practice Guidelines, it's use is appropriate in a variety of CR facilities. Utilization of available tools such as the PES helps to promote standards of good care that should be implemented nationwide.

Recommendations for Future Research

Outcome measures are necessary to help identify the most effective and efficient methods for delivery of cardiac rehabilitation services. As programs develop, auditing and evaluation of these services should be

incorporated. The PES is extremely valuable, for it evaluates a variety of outcomes. Assessment of the components of a program and outcome evaluation, along with a standard auditing format, such as the PES, allows for comparison among programs. If performed on a regular basis, audits can help monitor not only the programs themselves, but also individual patient treatment needs and progress. There is an urgent need for further implementation of guideline-based PES. Rebekah Murphy (1996) states that "...guidelines establish, by expert opinion, the most effective and appropriate standard of care based on current and extensive scientific research and available evidence".

Unfortunately the guidelines cannot take into account every complication that arises with CR patients. Guidelines define a standard of care, but circumstances may necessitate a variation from the guideline on the part of practitioners when deemed appropriate for a particular patient. It is important to consider that though the guidelines reflect the utmost standard of care they may not be feasible for every patient in every circumstance (Murphy, 1996).

Much research is needed to further evaluate the PES. The results of this study have shown promise in the areas of utility and efficiency. In North Carolina, a state where statutes require program certification for CR treatment centers, the programs demonstrated a uniformly high adherence to the PES and good achievement for several patient outcomes measures accepted as relevant to evaluation of treatment success.

Some suggestions for future studies should include: 1) studies similar to this one, incorporating various settings (rural, suburban) and performed on a much larger scale, 2) evaluation of the reliability between various data abstractors with similar knowledge and experience, 3) development of a computer database which would allow data to be directly entered and immediately analyzed. The use of a computer program would allow: a decrease in time needed for the abstraction procedure, a decrease in human error (transfer of coded material), a decrease in paper volume, and efficient and permanent storage of the data collected.

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APPENDIX A

DETAILED METHODOLOGY

Methodology

Permission was granted to the investigator from the Human Subjects Committee and the IRB from both hospitals prior to beginning any data collection.

 Study patients.   Data for this study were extracted from the clinical records of 150 patients who had participated in hospital-based outpatient cardiac rehabilitation programs, which lasted approximately 36 sessions, and was performed at either Moses H. Cone Memorial Hospital N.C. Heart Institute, in Greensboro, North Carolina or Carolina's Medical Center, in Charlotte, North Carolina (Table 1). With the exception of ten records dated January 1992-November 1995 all records were from patients who had entered into rehabilitation between December, 1995 and December, 1996.   For inclusion patients must have successfully completed at least 80% of their available 36 sessions of cardiac rehabilitation within 12 weeks. Patients were excluded from the study if for any reason they did not complete their outpatient hospital-based cardiac rehabilitation.

For each of the 150 patient records, data for the 24 quality process criteria was abstracted. For every record the process was identical, beginning with item one and finishing chronologically with item 24.   Information was found or not found within the record and the appropriate code was entered into the data abstraction worksheet. In the PES documentation was defined as having "Met", "Not Met" or "Acceptable Alternative" for each criteria. Definitions and examples of the coding for each of the 24 quality process

criteria were stated explicitly in the data abstraction manual. For each criteria on the data abstraction worksheet there were specific coding options for that item. For example, the criteria for admitting diagnosis contained simple codings of: 1=yes, 9=not documented, whereas item 24, referring to reassessment of exercise capabilities and a maintenance exercise prescription contained coding options such as: 1=yes, 2=reassess only, 3=prescription only, and 9=not documented. The coding process was done for all 24 criteria and for each patient. References were made to the data abstraction manual for clarification when the abstractor was unsure of how to code information for a specific criteria. The abstraction manual, along with a coded data abstraction worksheet, was used for each record. Time was recorded for each, and began when the patient medical record cover was opened. Stop time was noted when item 24 on the data abstraction worksheet was answer coded.

Evaluation of Information Yield. The evaluation was done using the CR PES inventory. Patient records, 75 from each site, were evaluated as to whether the PES contained criteria frequently documented in the records of Phase II cardiac rehabilitation programs. The records then were audited and grouped into two groups. The first group contained those records that documented adherence to criteria (#1-#24) and the second those that failed to document adherence to criteria (#1-#24). Documentation rates for each of the criteria then were described according to the numbers of patients whose records showed 70%, 80%, 90% and 100% of the 24 target quality criteria. The yield of

information derived for each of the 24 criteria were expressed as a percentage of the total cases audited.

Evaluation of Efficiency (Efficiency = Yield/Cost).   The efficiency of utilizing the PES with cardiac rehabilitation program records was evaluated through examination of two variables. The first, a measure of information yield, was calculated as the percentage of patient records that contained the required information needed for the performance evaluation. The overall information yield, i.e., percent(%) of information derived from audit divided by 24 X 150 (100%) was then calculated. The calculated efficiency was considered equal to the information yield divided by the lowest estimate of abstraction time (first 20 records i.e. 10 from each site) and also by the information yield divided by the highest estimate of data abstraction time (last 20 i.e. 10 from each site). The second measure, a cost indicator, was represented by the mean and standard deviation of the time required to audit the total sample of 150 consecutive cases. The calculated efficiency is equal to the information yield divided by the lowest estimate of abstraction time and also by the information yield divided by the highest estimate of data abstraction time.

Evaluation of the Adequately Documented Patient Outcome Variables.   All of the records were also audited for four patient outcomes: weight control, smoking, cholesterol and exercise tolerance. For weight control and cholesterol, the mean change (X) in relevant cases as well as the level of improvement

were described (CHOL < / = 200 mg/dl and BMI < / = 24.9 kg/m^2). For example, blood cholesterol(CHOL*)* data were entered into a spreadsheet and grouped according to: 1) those with total cholesterol levels greater than 200 mg/dl, 2) of those with CHOL levels greater than 200 mg/dl, how many records, according to the tool, were diagnosed with dyslipidemia, had intervention, and were reassessed prior to exit from the program. The remaining variables, smoking and exercise tolerance also were evaluated. Smoking data were described according to rates of cessation by program exit, and data related to exercise capacity were described as: 1) the mean change (X) in METs, and 2) the number of patients who increased their exercise tolerance, to greater than or equal to 5 METs by program exit.

Evaluation of Success Rates. The success rates were then analyzed for achievements of the four patient outcomes stated: weight control, smoking cessation, blood cholesterol, and exercise tolerance. The intent was to evaluate success rates for hospital-based outpatient cardiac rehabilitation records which did document adherence versus those which *did not* document adherence to treatment and follow up results.

Statistical Analyses. Data for each record and across all 24 abstraction criteria were entered into a spreadsheet. The investigators then pooled information according to the research questions mentioned earlier. Data reduction and frequencies and percentages were obtained via a calculator.

Subject summary data was analyzed with descriptive statistics. The dependent measures were analyzed using a personal computer and Minitab as a statistical software(MINITAB INC, State College,PA). The dependent t-test to define significance of the first and last times were recorded to examine efficiency of human resources with data abstraction times for patient records. The outcomes of BMI and CHOL were analyzed at entrance and exit with a dependent t-test for determination of significance. Chi-square was performed for significance between groups of patients and between the two sites.

APPENDIX B

PILOT STUDY

Introduction

A pilot study was conducted prior to the main study. The Cardiac Therapy and Intervention Center at Virginia Tech (CTIC) was the site of pilot data collection. All the same precautions were taken as in the main study for patient confidentiality and anonymity. The patients here were Phase III, however, since the purpose of the pilot data collection was to field test the Performance Evaluation System this proved to contain an adequate data set. Ten records were examined and the investigator was able to determine that: 1) the (x) mean abstraction time for all cases (N=10) was 14 minutes, 2) a learning curve is associated with continued use of the tool associated with the tool. The time needed to abstract data from the first two records was 21 minutes whereas time needed for the last two was only 8 minutes. Outcome data was collected but results were difficult to ascertain due to the small amount of records that were examined.

The results of this pilot study suggested that the PES would be an ideal instrument to field test in a larger population and at more than one site. Data regarding utility and efficiency of the PES instrument can be expanded upon by performing a study similar to this pilot study and on a much larger scale.

APPENDIX C

DATA ABSTRACTION MANUAL AND WORKSHEET

_____

3.4 Data Abstraction Worksheet

Patient ID: _____   Date: _ _/_ _/_ _
Provider ID:_____   Abstractor ID: _____

DATA ITEM	CODING OPTIONS	RESPONSE	CODE
1. Admitting cardiac diagnoses	1=yes 9=not documented	_____	DADX
a. Myocardial infarction	1=yes 9=not documented	_____	DAMI
b. Stable angina	1=yes 9=not documented	_____	DANG
c. Revascularization	1=yes 9=not documented	_____	DREV
d. Heart Failure	1=yes 9=not documented	_____	DHHF
e. Cardiac transplantation	1=yes 9=not documented	_____	DTRA
f. Other (Specify): _____	1=yes 9=not documented	_____	DOTH
BASELINE ASSESSMENT			
2. Other cardiac events or diagnoses	1=yes 2=none 9=not documented	_____	DCAR
3. Diagnoses of diabetes	1=yes 2=no 9=not documented	_____	DDIA
4. Current medications	1=yes 2=none 9=not documented	_____	MEDS
5. Documentation of physical activity	1=yes 9=not documented	_____	PHYS
6. Documentation of dietary habits	1=yes 9=not documented	_____	DIET
7. Documentation of work/occupation	1=yes 9=not documented	_____	WORK
8. Diagnoses of hypertension	1=yes 2=no 9=not documented	_____	DHTN
8a. IF item 8 is coded 2 or 9, then:	Code 7 for item 17 and item 23a.		
9. Diagnoses of dyslipidemia	1=yes 2=no 9=not documented	_____	DDYS
9a. IF item 9 is coded 2 or 9, then:	Code 7 for item 18 and item 23b.		
10. Diagnoses of obesity or overweight	1=yes 2=no 6= ht/wt documented 9=not documented	_____	DOBS
10a. IF item 10 is coded 2, 6 or 9, then:	Code 7 for item 19 and 23c.		
11. Smoking status	1=current smoker 2=smoking history 3=nonsmoker 9=not documented	_____	DSMO
11a. IF item 11 is coded 2, 3 or 9, then:	Code 7 for item 20 and item 23d.		
12. Relevant behavioral/psychological conditions	12. Relevant behavioral/psychological conditions	_____	DPSY
12a. IF item 12 is coded 2 or 9, then:	Code 7 for item 21 and 23e.		
13. Inadequate living arrangements/social support	1=yes 2=no 9=not documented	_____	DSOC
13a. IF item 13 is coded 2 or 9, then:			
14. Nutritional/dietary information	1=yes 8=Patient declined 9=not documented	_____	IDIE

DATA ITEM	CODING OPTIONS	RESPONSE	CODE
15. Baseline status assessment prior to first exercise	1=yes 6=after first, monitored exercise 9=not documented	_____	BASE
16. Exercise prescription prior to first exercise	1=yes 6=after first, monitored exercise 9=not documented	_____	EXER
17. Intervention for hypertension (see line 8a)	1=yes 7=not applicable 8=patient declined 9=not documented	_____	IHTN

DATA ITEM	CODING OPTIONS	RESPONSE	CODE
18. Intervention for dyslipidemia (see line 9a)	1=yes 7=not applicable 8=patient declined 9=not documented	_____	IDYS
19. Intervention for obesity/overweight (see line 10a)	1=yes 7=not applicable 8=patient declined 9=not documented	_____	IOBS
20. Intervention for smoking (see line 11a)	1=yes 7=not applicable 8=patient declined 9=not documented	_____	ISMO
21. Intervention for behavioral/psychological conditions (see line 12a)	1=yes 7=not applicable 8=patient declined 9=not documented	_____	IPSY
22. Intervention for inadequate living arrangements/social support (see line 13a)	1=yes 7=not applicable 8=patient declined 9=not documented	_____	ISOC
23. Reassessment of relevant risk factors	1=all reassessed 2=one or more not reassessed	_____	REAS
a. Hypertension	1=yes 7=not applicable 9=not documented	_____	RHTN
b. Dyslipidemia	1=yes 7=not applicable 9=not documented	_____	RDYS
c. Obesity/overweight	1=yes 7=not applicable 9=not documented	_____	ROBS
d. Smoking	1=yes 7=not applicable 9=not documented	_____	RSMO
e. Behavioral/psychological condition	1=yes 7=not applicable 9=not documented	_____	RPSY
24. Reassessment of exercise capabilities and maintenance exercise prescription	1=yes 2=reassess only 3=prescription only 9=not documented	_____	REXE

3.5 Data Abstraction Manual

1.   <u>Admitting cardiac diagnosis</u>

Code 1 if the baseline assessment documents one or more cardiac admitting diagnoses to the cardiac rehabilitation program.

Code 9 if the baseline assessment does not document at least one cardiac admitting diagnosis.

If item 1 is coded 9, code 9 for items 1a-f.

If item 1 is coded 1, complete items 1a through 1e as follows:

1a. Code 1 for an admitting diagnosis of myocardial infarction, including MI, AMI, or heart attack. Code 9 if the admitting diagnosis does not include myocardial infarction.

1b. Code 1 for an admitting diagnosis of stable angina, including angina or chest pain. Code 9 if the admitting diagnosis does not include stable angina.

1c. Code 1 for an admitting diagnosis of a revascularization procedure, including Coronary artery bypass graft, bypass surgery, CABG, percutaneous transluminal coronary angioplasty, PTCA, or balloon angioplasty. Code 9 if the admitting diagnosis does not include revascularization surgery.

1d. Code 1 for an admitting diagnosis of cardiac transplantation. Code 9 if the admitting diagnosis does not include cardiac transplantation.

1e. Code 1 if the admitting diagnosis is not listed.

1f. If an admitting cardiac diagnosis is documented, but not listed, in 1a-e, code 1 for item f, and specify the admitting cardiac diagnosis as documented. If no other cardiac admitting diagnoses are documented, code 9.

2.   <u>Other cardiac events. diagnoses or invasive procedures</u>

Code 1 if the baseline assessment documents one or more cardiac events, invasive

procedures or diagnoses (current or historical) in addition to the admitting diagnosis.

Code 2 if:

• the baseline assessment states that the patient's past medical history is negative for additional cardiac events, invasive procedures, or diagnoses; OR

• the baseline assessment provides a complete past medical history which has no mention of other cardiac events or diagnoses.

Code 9 if the baseline assessment does not state that the patient's history is negative for additional cardiac events, invasive procedures, or diagnoses AND no completed past medical history is present.

3.   Diagnosis of diabetes

Code 1 if:

• the baseline assessment documents a diagnosis of diabetes, including IDDM, NIDDM, AODM, Type I, or Type II; OR

• the baseline assessment documents that the patient is taking any of the insulin preparations in Table 4; OR

• the baseline assessment documents that the patient is taking any of the oral hypoglycemic agents in Table 5; OR

• the baseline assessment documents that the patient's blood sugar or blood glucose is controlled with diet or without medication.

Code 2 if the baseline assessment documents that the patient is not diabetic.

Code 9 if the baseline assessment does not document whether or not the patient is a diabetic.

TABLE 4: Insulin Preparations

Generic	Trade
Regular Insulin, Human	Humulin BR or R
	Novolin R
	Velosulin
Regular Insulin	Iletin I, Regular
	Regular Iletin II, Beef or Pork
	Regular Purified Pork insulin

Generic	Trade
NPH Insulin, Human	Humulin N
	Insulatard NPH
	Novolin N
NPH Insulin	NPH Iletin I or NPH Iletin II
	Insulatard NPH
	NPH Purified Pork Isophane
Insulin, Human regular + Human NPH mixture	Humulin 50/50 or 70/30
	Mixtard 70/30
	Novolin 70/30
Insulin, Zinc suspension	Lente, Semilente
	Ultralente
	Lente Iletin Beef or Pork

TABLE 5: Oral Hypoglycemic Agents

Generic	Trade
Acetohexamide	Dymelor
Chlorpropamide	Diabinese, Glucamide
Glipizide	Glucotrol
Glyburide	Diabeta, Micronase
Tolazamide	Tolamide, Tolinase
Tolbutamide	Oramide, Orinase
Metformin	Glucophage

4.   Current medications

Code 1 if the baseline assessment includes a list of the patient's current medications.

Code 2 if the baseline assessment states that the patient is currently taking no medications.

Code 9 if the baseline assessment does not list the patient's current medications AND does not state that the patient is currently taking no medications.

5.   <u>Documentation of habitual physical activity</u>

Code 1 if:

• the baseline assessment states that the patient has a sedentary lifestyle or limited activity level; OR
• the baseline assessment documents the patient's habitual level of physical activity, which might include their recreational exercise habits, physical activity at work, or physical activities in the home, yard, or garden; OR

• the baseline assessment includes a completed tool designed to quantify the patient's level of habitual activity.

Code 9 if the baseline assessment does not document the patient's habitual level of physical activity.

6.   <u>Documentation of dietary habits</u>

Code 1 if the baseline assessment includes documentation of the patient's usual diet, dietary habits, or food intake.

Code 9 if the baseline assessment does not include any documentation of the patient's usual diet, dietary habits, or food intake.

7.   <u>Documentation of work/occupational status or goals</u>

Code 1 if:

• the baseline assessment documents the patient's occupational status or goals, for example is working, plans to retum to work, is disabled, or is retired; OR

• the baseline assessment documents that the patient declined to provide information about their work/occupational status or goals.

Code 9 if the baseline assessment does not include any documentation of the patient's work/occupational status or goals.

8.   <u>Diagnosis of hypertension or high blood pressure</u>

Code 1 if:

• the baseline assessment documents a diagnosis of hypertension, including high blood pressure, elevated BP, or HTN; OR

• the baseline assessment states that the patient's blood pressure is "controlled" or "well controlled".

Code 2 if:
•   the baseline assessment states that the patient is not hypertensive; OR
• the baseline assessment states that the patient's blood pressure is normal.

Code 9 if the baseline assessment does not document whether or not the patient has a diagnosis of hypertension or high blood pressure.

8a.   If item 8 is coded 2 OR 9, code 7 (not applicable) for item 17.

9.   <u>Diagnosis of dyslipidemia</u>

Code 1 if the baseline assessment states that the patient has one or more dyslipidemias, including elevated (high) cholesterol or elevated (high) triglycerides.

Code 2 if:

• the baseline assessment states the patient does not have dyslipidemia; OR

• the baseline assessment documents that the patient's lipids are normal, within normal limits or WNL; OR

• the baseline assessment states that information about the patient's lipid status is not available AND documents a plan to obtain the lipid values; OR,

• the baseline assessment documents a referral to the primary care physician for assessment of lipid status.

Code 9 if the baseline assessment does not document whether or not the patient has a diagnosis of dyslipidemia.

9a.   If item 9 is coded 2 OR 9, code 7 (not applicable) for item 18.

10.   <u>Diagnosis of obesity or overweight</u>

Code 1 if the baseline assessment documents that the patient is obese, fat, has excessive body weight, or has excessive body fat.

Code 2 if the baseline assessment states that the patient is not obese, normal weight, weight proportional to height, weight within normal limits, weight WNL, or WPTH.

Code 6 if the baseline assessment does not specifically state whether or not the patient is obese, but both height <u>and</u> weight are documented.

Code 9 if the baseline assessment does not document whether or not the patient is obese.

10a. If item 10 is coded 2 OR 6 OR 9, code 7 (not applicable) for item 19.

11.   <u>Smoking status</u>

Code 1 if:

• the baseline assessment documents that the patient is a current smoker; OR

• the baseline assessment documents that the patient stopped smoking at the time of the most recent cardiac event, invasive procedure, or diagnosis.

Code 2 if the baseline assessment documents that the patient has a history of smoking but is not a current smoker.

Code 3 if the baseline assessment documents that the patient has never smoked.

Code 9 if the baseline assessment does not document the patient's smoking status.

11a. If item 11 is coded 2 OR 3 OR 9, code 7 (not applicable) for item 20.

12.   Relevant behavioral or psychological conditions

Code 1 if the baseline assessment documents the presence of depression, anxiety, stress, hostility, Type A behavior, drug or alcohol abuse, or any other relevant behavioral or psychological condition. A relevant condition is one which the baseline assessment documents as problematic (including excessive, significant, etc.) or requiring further intervention.

Code 2 if the baseline assessment states that the patient has no relevant behavioral or psychological conditions.

Code 9 if the baseline assessment does not document whether or not the patient has any relevant behavioral or psychological conditions.

12a.   If item 12 is coded 2 OR 9, code 7 (not applicable) for item 21.

13.   Adequate social support

Code 1 if the baseline assessment describes the patient's living status and arrangements and their social support, including family, as adequate, including good, sufficient, or not requiring further assessment or intervention.

Code 2 if the baseline assessment describes the patient's living status and arrangements and/or their social support, including family, as problematic, including inadequate, insufficient, or requiring further intervention.

Code 9 if the baseline assessment does not document the patient's living status and arrangement and social support system.

13a.   If item 13 is coded 2 OR 9, code 7 (not applicable) for item 22.

The following data item can be abstracted from any documentation in the cardiac rehabilitation medical record.

14.	Nutritional/dietary information

Code 1 if the cardiac rehabilitation medical record documents that the patient received general nutritional/dietary information, either individually or in a group setting.

Code 8 if the cardiac rehabilitation medical record documents that the patient declined receiving recommended general nutritional/dietary information.

Code 9 if the cardiac rehabilitation medical record does not document that the patient received general nutritional/dietary information.

Data items 15 and 16 should be answered with information documented prior to the first documented exercise session (except where noted).

15.	Baseline status assessment

Code 1 if, prior to the first exercise session, the cardiac rehabilitation medical record documents EKG data AND pulse AND blood pressure AND the patient's report of any symptoms during some form of graded exercise.

Code 6 if the first exercise session documented in the cardiac rehabilitation medical record includes EKG data AND pulse AND blood pressure AND the patient's report' of any symptoms during some form of graded exercise.

Code 9 if the cardiac rehabilitation medical record does not document EKG data AND pulse AND blood pressure AND the patient's report of any symptoms during some form of graded exercise prior to the first exercise session.

16.	Exercise prescription specified

Code 1 if, prior to the first exercise session, the cardiac rehabilitation medical record documents an exercise prescription including the mode AND intensity AND duration
AND frequency of prescribed exercise.

Code 6 if an exercise prescription including the mode AND intensity AND duration AND frequency of prescribed exercise is documented after a first, monitored exercise session.

Code 9 if the cardiac rehabilitation medical record does not document an exercise prescription including the mode AND intensity AND duration AND frequency of prescribed exercise.

The next several data Items should be answered with any documentation in the cardiac rehabilitation medical record.

17.   Intervention for hypertension

If item 8, diagnosis of hypertension, was coded 2 or 9, code 7 (not applicable) for this item.

If item 8, diagnosis of hypertension, was coded 1, then for this item:

Code 1 if:

• the record documents that the patient received written information about hypertension; OR

• the record documents that the patient received individual or group instruction about hypertension; OR

• the record documents that the patient was referred to their primary careprovider for hypertension management; OR

• the record documents that the patient was referred elsewhere outside the cardiac rehabilitation program for hypertension management, treatment, or education.

Code 8 if the record documents that the patient was offered one or more of the above education, counseling, and/or behavioral interventions for hypertension and the patient declined.

Code 9 if no education, counseling, and/or behavioral intervention to address hypertension is documented in the record.

18.   Intervention for dylipidemia

If item 9, diagnosis of dyslipidemia, was coded 2 or 9, code 7 (not applicable) for this item.

If item 9, diagnosis of dyslipidemia, was coded 1, then for this item:

Code 1 if:

• the record documents that the patient received written information about dyslipidemia; OR

• the record documents that the patient received individual or group instruction about dyslipidemia; OR

• the record documents that the patient was referred to their primary care provider
for dyslipidemia education, treatment, or management; OR

• the record documents that the patient was referred elsewhere outside the cardiac rehabilitation program for dyslipidemia management, treatment, or education.

Code 8 if the record documents that the patient was offered one or more education, counseling, and/or behavioral interventions for dyslipidemia and the patient declined.

Code 9 if no education, counseling, and/or behavioral intervention to address hypertension is documented in the record.

19.   Intervention for weight reduction

If item 10, diagnosis of obesity or overweight, was coded 2 or 6 or 9, code 7 (not applicable) for this item.

If item 10, diagnosis of obesity or overweight, was coded 1, then for this item:

Code 1 if:

• the record documents that the patient received written information about weight reduction; OR

• the record documents that the patient received individual or group instruction about weight reduction; OR

• the record documents that the patient was referred to a dietician for weight reduction; OR

• the record documents that the patient was referred elsewhere outside the cardiac rehabilitation program for weight reduction, e.g., Weight Watchers.

Code 8 if the record documents that the patient was offered one or more education, counseling, and/or behavioral intervention for weight reduction and the patient declined.

Code 9 if no education, counseling, and/or behavioral intervention for weight reduction is documented in the record.

20.   Intervention for smoking

If item 11, smoking status, was coded 2 or 3 or 9, code 7 (not applicable) for this item.

 If item 11, smoking status, was coded I, then for this item:

Code 1 if:

• the record documents that the patient received written information about smoking cessation; OR

• the record documents that the patient received individual or group instruction about smoking cessation; OR

• the record documents that the patient received a nicotine substitute such as nicotine gum or a nicotine patch; OR

• the record documents that the patient was referred elsewhere outside the cardiac rehabilitation program for smoking cessation, e.g., Smoke Stoppers.

Code 8 if the record documents that the patient was offered one or more education, counseling, and/or behavioral interventions for smoking cessation and the patient declined.

Code 9 if no education, counseling, and/or behavioral intervention for smoking cessation is documented in the record.

21. <u>Intervention for behavioral or pychological conditions</u>

If item 12, relevant behavioral or psychological conditions, was coded 2 or 9, code 7 (not applicable) for this item.

If item 12, relevant behavioral or psychological conditions, was coded 1, then for this item:

Code 1 if:

• the record documents that the patient was referred to a mental health professional; OR

• the record documents that the patient was asked to join a support group or stress management group; OR

• the record documents that the patient was begun on antidepressant or antianxiety medication or referred to the primary care physician for consideration of medication; OR

• the record documents the patient was given self-help materials; OR

• the record documents the condition will be watched/monitored; OR

• the record documents that the patient is already receiving behavioral or psychologic intervention outside the cardiac rehabilitation setting.

Code 8 if the record documents that the patient was offered one or more education, counseling, and/or behavioral interventions for a relevant behavioral or psychological condition and the patient declined.

Code 9 if no education, counseling, and/or behavioral intervention for a relevant behavioral or psychological condition is documented in the record.

22.   Intervention for inadequate living conditions or social support

If item 13, inadequate living conditions or social support, was coded 2 or 9, code 7 (not applicable) for this item.

If item 13, inadequate living conditions or social support, was coded 1, then for this
item:

Code 1 if:

• the record documents a referral to a mental health specialist, church, or community service; OR

• the record documents referral to a support group; OR

• the record documents that the patient is already receiving intervention outside the cardiac rehabilitation setting; OR

• the record documents that some other intervention has been developed, e.g., home-based monitoring or home visits.

Code 8 if the record documents that the patient was offered one or more education, counseling, and/or behavioral interventions for inadequate living conditions or social support and the patient declined.

Code 9 if no education, counseling and/or behavioral intervention for inadequate living conditions or social support is documented in the record.

Data Item 23 should be answered based on any documentation which is no earlier than one month after the patient begins the cardiac rehabilitation service, and no later than three months after the patient begins the cardiac rehabilitation service.

23.   Reassessment of relevant risk factors

Using record documentation dated after the end of the first month and before the

end of the third month of cardiac rehabilitation services, complete items 23a-e.

23a.   <u>Hypertension</u>

Code 1 if the record documents reassessment of the patient's hypertension status, including recording blood pressure measurement or communicating with the primary physician with regard to blood pressure management.

Code 7 if item 8 is coded 2 OR 9.

Code 9 if no reassessment of blood pressure status is documented.

23b.   <u>Dyslipidemia</u>

Code 1 if the record documents reassessment of the patient's dyslipidemia status, including obtaining blood lipid values or communicating with the primary physician with regard to dyslipidemia management.

Code 7 if item 9 is coded 2 OR 9.

Code 9 if no reassessment of lipid status is documented.

23c.   <u>Obesity/overweight</u>

Code 1 if the record documents reassessment of the patient's weight.

Code 7 if item 10 is coded 2 OR 6 OR 9.

Code 9 if no reassessment of the patient's weight is documented.

23d.   <u>Smoking</u>

Code 1 if the record documents the patient's smoking status.

Code 7 if item 11 is coded 2 OR 3 OR 9.

Code 9 if no reassessment of smoking status is documented.

23e.   <u>Behavioral/psychological conditions</u>

Code 1 if the record documents reassessment of the patient's behavioral/psychological status.

Code 7 if item 12 is coded 2 OR 9.

Code 9 if no reassessment of the patient's behavioral/psychological status is documented.

If all five items in 23 (a-e) are coded 1 or 7, code 1 for item 23.

If one or more items in 23 (a-e) is coded 9, code 9 for item 23.

Answer data item 24 using cardiac rehabilitation medical record documentation prior to the patient's completion of cardiac rehabilitation services.

24.　　Reassessment of exercise capabilities and maintenance exercise prescription

Code 1 if the record documents a requantification of the patient's exercise performance, including modality, intensity, duration, or frequency AND functional status, e.g., MET level, symptoms, blood pressure, heart rate, or ECG response AND a maintenance exercise prescription.

Code 2 if the record documents a requantification of the patient's exercise performance, including modality, intensity, duration, or frequency AND functional status, e.g., MET level, symptoms, blood pressure, heart rate, or ECG response but NO maintenance exercise prescription.

Code 3 if the record documents a maintenance exercise prescription but NO requantification of the patient's exercise performance.

Code 9 if the record does not document a requantification of the patient's exercise performance or a maintenance exercise prescription.

APPENDIX D

DATA COLLECTION SHEET

Outcomes Worksheet

Patient ID_____   Abstractor ID_____
Site ID_____   Date: /   /

1)   CHOLESTEROL
        Baseline (initial) value_____
        Intervention? yes / no / pt. declined
        Reassessment? yes / no/ justification_____
        Net: increase / decrease / no change
        Exit value_____

2)   WEIGHT (BMI)
        Baseline(initial) value Ht_____(cm or in)
                                 Wt_____(Kg or Lbs)
                                 BMI_____(M2/Kg)
        Intervention? yes / no / pt. declined
        Reassessment? yes / no / justification_____
        Net: increase/decrease/no change
        Exit value   Ht_____(cm or in)
                                Wt_____(Kg or Lbs)
                                BMI_____(M2/Kg)

3)   SMOKING
        Intervention? yes / no / pt. declined
        Reassessment? still smokes/quit/reduced/justification_____

4)   EXERCISE CAPACITY
        Baseline(initial) value_____(METs)
                        RPE_____
        Exit value   _____(METs)
                        RPE_____

APPENDIX E

KEY FOR RAW DATA CODES

Coding Options for Raw Data

Coding options	Meaning
1	yes
2	none/no
3	nonsmoker
6	height/weight documented
7	not applicable
8	patient declined
9	not documented

APPENDIX F

PILOT STUDY DATA

Record Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
1	1	9	9	9	9	1	9	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9
2	1	2	2	1	1	1	1	2	1	6	2	1	9	1	1	1	7	1	7	7	9	7	2	1
3	1	9	2	1	1	1	1	1	2	6	1	9	9	1	1	6	1	7	9	9	7	7	2	1
4	1	1	9	1	1	9	1	1	1	2	3	9	9	8	1	9	9	9	7	7	7	7	2	9
5	1	1	1	1	1	1	1	1	2	2	2	9	9	1	1	9	1	7	7	7	7	7	1	1
6	1	1	2	1	1	1	1	2	1	6	2	1	9	1	1	1	7	7	1	7	9	7	2	9
7	9	1	9	1	9	1	1	9	1	2	3	9	9	1	1	9	7	1	7	7	7	7	2	9
8	1	9	2	1	1	1	1	2	2	6	3	9	9	1	1	9	7	7	7	7	7	7	1	9
9	1	1	2	1	1	1	1	1	2	1	3	1	9	1	1	1	1	7	1	7	1	7	1	1
10	1	1	2	1	1	1	1	1	2	2	2	9	9	1	1	1	7	7	7	7	7	7	1	1

Record #	Smoking	Cholesterol	Exercise Tolerance	BMI
1	no	yes>200	>6 METs	<24.9
2	no	yes	yes	yes
3	quit	no	yes	yes
4	no	yes	yes	yes
5	no	no	no	yes
6	-	-	-	yes
7	no	no	yes	-
8	no	no	yes	yes
9	no	no	yes	no
10	no	no	yes	yes

Record #	Time for Abstraction
1	27
2	15
3	20
4	27
5	14
6	12
7	10
8	13
9	10
10	6
Mean Abstraction Time	14.1 minutes
Avg 1st 2 records	21 minutes
Avg last 2 records	8 minutes

APPENDIX G

RAW DATA

Criteria #

Record Site1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
1	1	9	2	1	1	1	1	1	2	2	2	2	2	1	1	1	1	7	7	7	7	7	1	1
2	1	1	2	1	1	1	1	1	2	2	2	2	2	1	6	1	1	7	7	7	7	7	1	1
3	1	1	2	1	1	1	1	1	2	6	2	1	2	1	1	1	1	1	1	7	1	7	1	1
4	1	9	1	1	1	1	1	1	1	1	3	2	2	1	1	1	7	7	7	7	7	7	1	1
5	1	1	1	1	1	1	1	2	2	6	3	2	2	1	1	1	7	7	7	7	7	7	1	1
6	1	9	1	1	1	1	1	2	2	1	2	9	9	1	6	1	1	7	1	7	7	7	1	1
7	1	1	1	1	1	1	1	1	2	1	2	1	2	1	1	1	1	1	7	7	1	7	1	1
8	1	9	1	1	1	1	1	1	1	6	3	1	2	1	1	1	7	7	1	7	1	7	1	1
9	1	1	1	1	1	1	1	2	9	1	2	1	2	1	6	1	7	7	1	7	1	7	1	1
10	1	2	2	1	1	1	1	1	2	1	2	1	2	1	1	1	1	7	7	7	1	7	1	1
11	1	1	2	1	1	1	1	1	2	1	3	2	2	1	6	1	7	1	1	7	7	7	1	1
12	1	1	2	1	1	1	1	1	1	1	2	2	2	1	1	1	1	1	1	7	7	7	1	1
13	1	2	2	1	1	1	1	2	2	1	3	2	2	1	6	1	7	7	7	7	1	7	1	1
14	1	1	1	1	1	1	1	1	2	1	2	1	2	1	1	1	1	1	1	7	7	7	1	1
15	1	2	2	1	1	1	1	1	1	2	2	2	2	1	6	1	7	7	7	7	7	7	1	1
16	1	1	2	1	1	1	1	2	1	1	2	2	2	1	6	6	1	7	7	7	7	7	1	1
17	1	2	2	1	1	1	1	1	2	1	3	1	2	1	1	1	1	7	1	7	7	7	1	1
18	1	2	2	1	1	1	1	2	2	6	2	2	2	2	1	1	1	1	7	7	1	7	1	1
19	1	1	1	1	1	1	1	1	1	1	3	2	2	1	1	1	1	7	7	7	7	7	1	1
20	1	1	2	1	1	1	1	1	2	6	2	9	9	1	6	1	1	7	7	7	1	7	1	1
21	1	2	1	1	1	1	1	1	1	1	3	2	2	1	6	1	1	7	1	7	7	7	1	1
22	1	9	2	1	1	1	1	1	2	6	2	1	2	1	6	1	1	7	7	7	1	7	1	2
23	1	2	2	1	1	1	1	1	2	1	3	2	9	1	6	1	1	7	7	7	7	7	1	1
24	1	2	2	1	1	1	1	1	2	6	3	2	2	1	6	1	1	7	7	7	7	7	1	1
25	1	2	2	1	1	1	1	1	2	1	3	1	2	1	6	1	1	7	1	7	1	7	1	1

26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
7	2	7	7	7	2	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
1	1	1	1	2	1	1	2	1	2	2	1	2	1	1	1	1	2	1	2	1	1	1	1	1
7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
7	1	7	1	1	7	7	7	1	1	7	7	7	7	1	1	1	7	7	1	1	7	7	7	1
7	7	1	1	7	7	7	1	1	1	1	1	1	1	7	1	1	1	8	1	1	1	7	1	1
7	7	1	1	7	1	1	1	1	7	7	1	1	7	1	1	1	7	7	1	7	1	1	7	7
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
6	9	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	1	6	6	6	6
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	2	2	7	2	2	2	2	2
1	1	1	1	2	1	1	2	1	2	2	1	2	1	1	2	1	2	1	2	1	1	1	1	1
3	2	2	2	2	2	3	3	2	2	3	2	2	2	3	2	2	2	2	2	3	2	3	2	2
6	6	2	1	1	2	2	1	1	2	2	2	2	1	1	1	2	2	1	1	2	2	1
2	9	1	1	2	2	2	1	1	1	1	1	2	1	1	1	1	1	2	1	1
2	2	2	1	2	1	1	2	1	2	2	1	2	1	1	1	2	2	1	2	1	1	2	2
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
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9	2	1	1	2	2	1	1	2	2	2	1	2	1	1	1	2	2	1	2	2	1	2
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	1	1	1	1	1	1	1	7	1	1	1	7	1	1	1	7	1	1	7	1	1	7	1	1	1
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Site 2	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
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3	1	1	2	1	1	1	1	1	1	1	2	2	2	1	1	1	1	1	7	7	7	7	1	1
4	1	9	2	2	1	1	1	1	1	6	2	2	2	1	1	1	1	1	1	7	7	7	1	1
5	1	1	2	1	1	1	1	2	1	6	2	1	2	1	1	1	7	1	7	7	1	7	1	1
6	1	1	1	1	1	1	1	1	2	1	2	2	2	1	1	1	1	1	7	7	7	7	1	1
7	1	9	2	1	1	1	1	2	2	6	2	2	2	1	1	6	1	1	1	7	7	7	1	1
8	1	9	1	1	1	1	1	2	1	1	2	2	2	1	1	6	7	7	7	7	7	7	1	1
9	1	9	1	1	1	1	1	2	2	6	3	2	2	1	1	1	7	1	1	7	7	7	2	1
10	1	1	2	1	1	1	1	1	1	2	2	2	2	1	1	1	7	7	7	7	7	7	1	1
11	1	1	2	1	1	1	1	1	2	6	3	2	7	1	1	1	1	7	7	1	7	7	1	1
12	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	7	1	1	1	1
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21	1	2	2	1	1	1	1	2	1	1	2	2	2	1	1	1	7	7	1	7	7	7	1	1
22	1	1	2	1	1	1	1	2	1	1	1	2	2	1	1	1	7	7	1	7	7	2	1	1
23	1	1	2	1	1	1	1	2	2	1	2	1	2	1	1	1	7	1	1	1	1	7	1	1
24	1	1	2	1	1	1	1	2	1	1	2	1	2	1	1	1	7	1	1	7	1	7	1	1
25	1	2	2	1	1	1	1	2	1	1	1	1	2	1	1	1	7	1	1	1	8	7	1	1

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3 3 2 1 3 3 2 3 2 2 2 2 3 3 3 2 2 2 3 2 2 2 2 2 2
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1 1 1 1 1 1 1 1 9 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
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1 1 1 2 2 1 1 2 1 1 1 2 2 2 1 2 1 1 1 2 2 1 1 1
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50
```

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Data matrix (columns 51–75):

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	7	7	7	7	7	7	7	7	1	1	7	7	7	7	1	7	7	7	7	7	7	7	1	1	7
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	1	1	1	7	1	7	1	8	1	7	1	7	1	7	8	1	1	7	1	1	1	7	1	1	1
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	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
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	1	1	1	1	1	1	1	1	1	1	1	1	1	8	1	1	1	1	1	1	1	1	1	1	1
	2	2	2	2	2	2	2	2	1	1	2	2	2	2	2	1	2	2	2	2	2	2	2	1	2
	2	1	2	2	2	2	2	2	2	1	2	2	2	2	2	1	2	1	1	1	2	2	2	1	2
	1	2	3	2	2	3	2	2	3	1	2	2	3	1	2	1	3	1	2	3	2	1	2	1	3
	1	1	1	2	1	2	1	1	1	2	1	1	1	2	1	1	1	2	1	1	1	2	1	1	1
	1	1	1	1	2	1	1	2	1	1	1	2	2	2	1	1	2	1	1	1	2	2	2	2	1
	1	1	2	2	1	1	1	2	1	1	2	2	1	1	2	1	2	2	2	2	2	1	2	1	1
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
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	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
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	2	2	1	2	2	2	2	1	2	2	1	1	2	2	1	1	2	1	2	2	2	1	1	1	2
	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

APPENDIX H

OUTCOME RAW DATA

Outcome Data	Cholesterol	
Patient ID #		
Site 1	Entrance	Exit
27	153	215
40	146	177
51	227	159
61	287	174
Site 2		
3	260	163
4	200	136
5	245	179
10	175	202
11	233	196
12	200	211
17	284	258
20	165	113
23	249	158
24	293	292
27	199	155
28	230	219
30	228	241
31	251	240
32	203	154
33	252	204
36	212	248
37	214	191
38	235	193
39	204	215
40	210	184
42	204	214
43	345	243
44	207	190
45	226	206
46	204	198
49	364	284
51	231	144
53	255	243
54	257	203
55	161	159
59	328	244
60	258	195
63	202	182
64	171	156
66	201	219
67	241	162
68	236	167
69	315	284
72	140	158
75	160	187

Outcome Data	BMI				
Site 1	Entrance	Exit	Site 2	Entrance	Exit
1	26.2	26.2	71	25	25
2	26.2	26.4	72	25.5	24.9
3	28.7	28.7	73	32	30
4	31.4	30.9	74	25.6	26.6
5	27.3	27.7	75	20.7	20.9
6	31.3	30.3	76	44.3	13.8
7	33.7	32.7	77	23.2	22.7
8	28.2	26.9	78	29.1	29.5
9	44.9	45.1	79	22.7	23.3
10	29.9	30	80	28.5	27
11	32	31.3	81	28	28
12	29	28.7	82	25.8	26.1
13	29.4	28.6	83	26.4	24.9
14	23.5	24.1	84	29.5	29.5
15	27.7	27.1	85	33.1	33.5
16	27.5	27.6	86	25	24.8
17	30.6	20.9	87	24	24
18	29.2	29.5	88	31	29.5
19	32.4	31.6	89	29	29
20	31.6	30.4	90	24	24.2
21	26.4	26.7	91	28	26.3
22	24.9	24.7	92	28	28
23	23.5	24.1	93	31	30.7
24	24	23.6	94	25.5	23.7
25	31.4	31.3	95	26.7	26.2
26	25.5	26.4	96	29.9	29
27	24.2	24	97	28	26
28	23.1	22.6	98	35	34
29	23.1	29.5	99	26.9	28.2
30	29.4	28.7	100	26.8	26
31	21.3	21.9	101	31.1	28.7
32	25.8	26	102	24.4	25
33	21	21.6	103	32.7	32.4

Site 1	Entrance	Exit	Site 2	Entrance	Exit
34	30.9	32	104	26.7	26.5
35	26.5	26.9	105	29	29
36	30.1	29.1	106	29.9	30.2
37	27.3	27.7	107	20.2	20
38	27.6	27.6	108	22.8	22.6
39	19.6	18.9	109	29	29
40	21.3	21.4	110	26.9	26.4
41	26.6	26.1	111	37.3	37.2
42	26.8	25.2	112	31	31
43	23.4	24	113	29.7	27.6
44	26.2	24.2	114	24.2	24.2
45	30	30.3	115	26.3	24.6
46	33.5	33	116	27.6	27.5
47	32.6	32.1	117	24	22.7
48	23.5	23.5	118	26.3	26
49	26.2	26.6	119	24.5	25.3
50	24.4	23.5	120	32.2	31.6
51	19.1	19.5	121	23	23
52	24.6	23.8	122	24	23
53	30.4	31.7	123	27.7	26.3
54	31.1	31	124	24.5	24.6
55	51.3	50.5	125	33.7	33.9
56	24.5	25.5	126	30.3	31.1
57	23.6	24	127	29.1	29.1
58	43.5	41.6	128	23.8	25.4
59	19.7	21.3	129	33.4	32.8
60	39.2	39	130	28	28
61	26.9	26.5	131	24.4	24.4
62	27.3	28.5	132	20.2	20.1
63	33.4	32.9	133	29	28.2
64	26.7	25.5	134	30.5	29.8
65	27.8	25.8	135	35.1	34
66	29.7	29.2	136	20	20
67	27.6	27.7	137	32	31.2
68	25.6	25.1	138	27	25.4
69	28	27.9	139	31.8	32.1
70	26.8	26.1	140	23.5	25.3

Site 2	Entrance	Exit
141	24.7	24.6
142	27	26.6
143	26	25.9

Outcome Data Exercise Capacity
Patient ID #

Site 1	Entrance	Exit	Site 2	Entrance	Exit
1	2.9	4.5	1	2.8	3.6
2	1.5	2.5	2	1.8	2.5
3	1.8	3.5	3	2.8	3.8
4	1	4.5	4	5.6	7.4
5	2.8	3.5	5	6.2	8.3
6	2.3	6.6	6	10.2	16.5
7	2.3	3.8	7	2.3	3.4
10	2.3	2.7	8	7	10.1
11	2.3	2.8	10	4.9	3.9
13	4.2	5.3	12	4.5	5.4
14	2.7	5.2	13	7	4.6
15	4.3	5.2	14	1.6	4.9
16	1.3	4.3	23	5.1	5.4
17	2.3	4.6	24	3.1	4.1
18	2.3	3.4	27	5	5.6
19	2.6	4.8	29	3.8	5.4
20	2.9	3.9	30	5.4	5.4
21	4.5	4.8	33	2.5	2.4
22	2.3	3.3	35	5.1	6
23	3.3	2.9	36	3.3	5.4
24	2.3	2.4	37	9	8.3
26	2.3	3	38	1.9	5.7
27	2.3	6.3	39	2	4.3
28	2.3	3.1	40	3.3	3.6
29	4.9	3.9	42	4.1	6.2
30	2.1	7.4	43	3.6	5
31	2.3	2.8	44	3.3	6.1
32	2.3	2.7	47	2.1	5.6
33	1.5	2.4	48	3.6	5.1
34	1.4	3.3	50	3.8	4.3
35	3.5	4.1	52	3.6	4.9
37	2.9	4.5	53	4.5	4.8
38	2.3	4.2	55	3.8	5.5
39	2.3	2.8	56	6.4	6.4

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Site 1	Entrance	Exit	Site 2	Entrance	Exit
40	2.3	4.2	57	4.5	5.4
41	1.8	4.5	58	2.1	4.1
42	2.3	3.3	59	2.9	2.9
43	2.1	7.9	62	4.5	6.4
44	2.3	4.5	63	3.1	4.5
45	2.3	3.5	64	2.8	3.6
46	1.4	6	65	4.8	4.8
47	2.3	5.6	66	2.3	4.6
48	2.3	6.4	67	2.8	3.3
49	1.4	6.2	69	4.5	4.5
50	2.3	4.1	70	4.5	6.5
51	2.1	6.9	71	4.1	5
52	2.1	6.5	72	4.1	4.1
53	2.3	6.3	74	4.6	4.6
54	2.3	6.1	75	3.8	4.3
55	2.3	3			
57	1.8	2.2			
59	2.3	3.4			
60	1.9	3			
61	2.3	5			
62	2.3	5			
63	2.1	3.3			
64	2.3	4.1			
65	2.3	5.1			
66	2.3	3.4			
67	2.3	3.7			
68	2.6	4.8			
69	2.3	3.8			
70	3.6	4.1			
71	2.3	3.5			
72	2.5	3.7			
73	1.8	4			
74	2.3	3.3			
75	2.5	3.9			

| Outcome Data | Smoking | | |
| Patient ID # | | | |
Site 1	Exit	Site 2	Exit
1	2	1	3
2	2	2	1
3	2	3	2
4	3	4	2
5	3	5	2
6	2	6	2
7	2	7	2
8	3	8	2
9	2	9	3
10	2	10	2
11	2	11	3
12	2	12	1
13	3	13	2
14	3	14	2
15	2	15	3
16	2	16	3
17	2	17	3
18	3	18	2
19	2	19	3
20	2	20	2
21	3	21	2
22	2	22	1
23	2	23	2
24	3	24	2
25	3	25	1
26	3	26	3
27	2	27	3
28	2	28	2
29	2	29	1
30	2	30	3
31	2	31	3
32	3	32	2
33	3	33	3
34	2	34	2

Patient#			
Site 1	Code	Site 2	Code
35	2	35	2
36	3	36	2
37	2	37	2
38	2	38	3
39	2	39	3
40	3	40	3
41	2	41	2
42	2	42	2
43	2	43	2
44	2	44	3
45	3	45	2
46	2	46	2
47	3	47	2
48	2	48	2
49	2	49	2
50	1	50	2
51	3	51	1
52	2	52	2
53	2	53	3
54	2	54	2
55	3	55	2
56	2	56	3
57	2	57	2
58	2	58	2
59	2	59	3
60	3	60	1
61	2	61	2
62	3	62	2
63	2	63	3
64	2	64	1
65	1	65	2
66	3	66	1
67	3	67	3
68	2	68	1
69	3	69	2
70	3	70	3
71	3	71	2
72	2	72	1

	Patient#			
	Site 1	Code	Site 2	Code
	73	3	73	2
	74	2	74	1
	75	2	75	3

coding options

1	current smoker
2	smoking history
3	nonsmoker
9	not documented

SMOKING

pt id

50	intervention/quit day of event(9/10/96)	1
65	intervention/quit(11/96)	1
2	intervention/quit	1
12	intervention/reduced 1/2 pack(quit New Years' Res)12/96	2
22	intervention/still smokes	3
25	intervention/quit in CR (no date)	1
29	intervention/quit in CR (no date)	1
51	intervention/quit in CR (no date at reassessment)	1
60	intervention/quit (day of event) at reassessment cessation continues	1
64	pt declined intervention/still smokes	3
66	pt declined inter/still smokes reluc. to quit at reassessment	3
68	pt declined/still smokes	3
72	inter/reduced	2
74	pt declined inter/still smokes	3

Results

Quit	7
Reduced	2
Still Smokes	5

Patient ID # Site 1	Entrance Height(in.)	Weight (lbs)	Exit Weight (lbs)
1	69	177.2	176.8
2	67	167	168.2
3	63	161.4	162
4	69	211.8	209
5	65	164	166.2
6	70.6	220	214.4
7	65	202	196.8
8	64	164	156.4
9	*	*	*
10	62.5	248.8	250
11	65	179.8	180.2
12	*	142.6	145.4
13	70	222.2	217.7
14	68.5	193.2	191
15	68	192.8	187.6
16	61	124.2	127.2
17	72	203.2	198.8
18	71	196.6	197.2
19	71	174.6	*
20	67	195.2	197
21	65.3	176.8	178.2
22	72	238.4	232
23	72	232.2	223.6
24	65	176	*
25	71	188.6	191
26	67	158.6	157.6
27	67	150.2	154
28	72	176.2	173.2
29	67	200.2	199.9
30	59.6	128.6	133.2
31	62	119.2	*
32	67	154.6	154
33	60	118	115.2
34	66	182.6	182.4
35	69.5	201.6	197.2

Patient ID # Site 1	Entrance Height(in.)	Weight (lbs)	Exit Weight (lbs)
36	63	119.8	123.6
37	70.5	182.4	190
38	70	146.2	150
39	67	197.2	204.1
40	73	200.8	203.6
41	75.6	244.8	236.6
42	72.3	202.2	205.4
43	71	197	197
44	64.5	115.6	111.4
45	68	139.6	140.4
46	71	190	187
47	71.5	194.6	183
48	67	149.4	153
49	73	198.2	182.8
50	65	180.2	182
51	72	245.8	242
52	73.3	247.8	244.2
53	70	163.6	163.5
54	72	190.2	193
55	65	146.6	141.2
56	65	114.6	117.4
57	63	138.8	134
58	67	194	202
59	64	217	216
60	61.5	275.6	271
61	63	137.8	143.4
62	71	168.4	171.4
63	60	222	212
64	67	125.6	135.8
65	67	250.4	249
66	64	156	154
67	68.6	182.8	190.8
68	71.5	242.2	239
69	60.3	137.8	131.6
70	63.1	157	146
71	66.1	184	181
72	67.1	176.2	177

Patient ID # Site 1	Entrance Height(in.)	Weight (lbs)	Exit Weight (lbs)
73	69.1	173.6	170
74	66.1	173.6	173
75	70	186.6	181.6

* no data available

Patient ID # Site 2	Entrance Height(in.)	Weight (lbs)	Exit Weight (lbs)
1	64	145	145
2	67.5	164	160
3	67	201	191
4	76	213	211
5	*	121	122
6	64	133.5	131
7	62	240	237
8	59	144	146.3
9	*	219.5	210
10	71	162	166
11	72	210	199
12	*	*	*
13	67	164	166
14	*	*	*
15	*	*	*
16	75	266	269
17	63	143	141
18	69	164	165
19	64	182	173
20	70	198	198
21	69	161.9	159.9
22	72	197.8	194
23	70	199	195
24	73	232	231
25	69.5	182	163
26	71	190	187
27	68	197	195
28	71	205	198
29	72	253	251
30	71	192	201
31	68.5	176.9	172.7

Patient ID # Site 2	Entrance Height(in.)	Weight (lbs)	Exit Weight (lbs)
32	*	190	191
33	63	175	162
34	62	133	135
35	69	220	218
36	73	200	198
37	70	195	195
38	70	208	208
39	59.8	100.5	99
40	70	159	158
41	70.5	206	207
42	67	171	169
43	71	266	265
44	68.5	212	208
45	61.5	170	158
46	69.5	165	165
47	72	192	172.5
48	68	175.8	180
49	63	136	131
50	72.5	196	192
51	66	151	156
52	68	212	208
53	64	138	138
54	70.5	175	161
55	66	172	163
56	68	161	162
57	69	227	217.5
58	61	160	164
59	65	174	174
60	70	166	177
61	60.5	174	171
62	70	193	193
63	61	130	129
64	71	144	143.5
65	72	214	208
66	69	202	201
67	66	218	211
68	69	135	135
69	71	231.5	227

Patient ID # Site 2	Entrance Height(in.)	Weight (lbs)	Exit Weight (lbs)
70	66.5	200	202
71	68	171	167
72	68	154	162
73	71.5	180	179
74	73	194	199
75	66.5	164	163

* no data available

Patient Site 1	Time Minutes	Patient Site 2	Time Minutes
1	25	1	27
2	19	2	23
3	14	3	10
4	8	4	14
5	8	5	7
6	13	6	10
7	7	7	12
8	9	8	12
9	10	9	19
10	13	10	4
11	7	11	9
12	7	12	7
13	10	13	8
14	9	14	18
15	6	15	11
16	6	16	8
17	9	17	5
18	6	18	8
19	6	19	6
20	6	20	8
21	9	21	7
22	6	22	7
23	7	23	5
24	5	24	9
25	7	25	8
26	8	26	9
27	13	27	3
28	8	28	6
29	8	29	5
30	6	30	4
31	5	31	9
32	9	32	4
33	7	33	9
34	5	34	2
35	5	35	7
36	6	36	6
37	6	37	6

Patient Site 1	Time Minutes	Patient Site 2	Time Minutes
38	5	38	3
39	6	39	4
40	4	40	3
41	7	41	9
42	4	42	5
43	5	43	4
44	5	44	5
45	5	45	5
46	10	46	4
47	7	47	3
48	6	48	6
49	7	49	4
50	8	50	4
51	10	51	5
52	4	52	6
53	4	53	5
54	5	54	4
55	6	55	6
56	5	56	4
57	7	57	5
58	6	58	6
59	7	59	5
60	3	60	5
61	10	61	3
62	6	62	4
63	8	63	4
64	10	64	4
65	7	65	4
66	7	66	4
67	5	67	4
68	7	68	7
69	4	69	4
70	4	70	3
71	6	71	3
72	4	72	3
73	4	73	5
74	4	74	4
75	8	75	2

VITA

Deborah Marie Paulus was born on June 21, 1972, in Del Rio, Texas to the parents of John and M. Christine Paulus. She lived in Del Rio until the age of three. Debbie then spent 14 years overseas, the first seven of which was spent at Hahn Air Force Base in Germany, and the second seven, at Mildenhall AFB in England. During her time in England, Debbie became very involved with a nearby stable, taking riding lessons and eventually teaching some classes for the (RDA) Riding for the Disabled. Debbie, moved once more in December, 1988, to Alexandria, Virginia where her family still currently resides. She attended and graduated from Hayfield Secondary School in June, 1990.

Debbie's experience with the horses led her to pursue three years of a Biology degree at Virginia Tech in hopes of going on to practice veterinary medicine. During her senior year, she heard about the Cardiac Therapy and Intervention Center at Virginia and was able to meet Dr. Shala Davis and Dr. William Herbert. Brief exposure to the CTIC program and course work led Debbie to believe that she would rather work with people than animals. Soon, she was well on her way to a degree in Exercise Science and a minor in Biology. Debbie graduated with her Bachelor of Science in December of 1994 and entered into the Masters' program in Clinical Exercise Physiology during the Fall semester of 1995.

During the past two years as a graduate student, Debbie has worked with and supervised the exercise of an elderly man who has dementia. She has

worked with his family and physician to help develop a personalized home exercise program for him. She has taken advantage of the resources located at the Virginia Maryland Regional College of Veterinary Medicine by taking some physiology classes. Debbie plans to take ACSM's Exercise Specialist in the Fall of this year and is currently looking forward to employment.