

PIMI
DATA TAPE CODING MANUAL
TABLE OF CONTENTS

Section	Form Number	Page Number
General Introduction		I
Description of Variables on the Data Tape		III
Data Tape Specification		iii
Special Considerations		iv
Glossary of Abbreviations		v
Further Information on PIMI		vi
Arrangement of Files by Source		vii
Neurology History and Examination	Form 02	1-3
Confirmation of Eligibility	Form 03, 3N,3R	4, 70
History and Physical Exam	Form 04	5-8
Exercise Treadmill Test	Form 06	9-12, 53
Radionuclide Record		
Mental Stress RVG	Form 7M	13-17
Physical Stress RVG	Form 7P	18-22
Autonomic Testing Procedures	Form 09	23-24
Sensory Perception Test	Form 12	25
Abdominal Obesity Ancillary Study	Form 20	26
Psychometric Instruments		27-28, 51, 52
Beck Depression Inventory	Form 31	
Spielberger State Anxiety Inventory (STAI Form Y-1)	Form 32	
Spielberger Trait Anxiety Inventory (STAI Form Y-2)	Form 33	
Cloninger Temperament and Character Inventory (TCI)	Form 34	
Cook-Medley Hostility Scale (CMS)	Form 35	
Anginal Syndrome Questionnaire (ASQ)	Form 36	
Self-Analysis Anger Expression Questionnaire (AX)	Form 37	
Modified Autonomic Perception Questionnaire (MAPQ)	Form 38	
Toronto Alexithymia Scale (TAS)	Form 39	
Radionuclide Core Laboratory RVG Analysis	Form 73	29-33,48-49
Diary		34-35
Inventory		36
AECG Core Lab Data		37-38, 47
Rest and Exercise ECG Core Lab Data		39-42, 50, 53
Biochemistry Core Lab Data		43-35, 61-63, 73-75
Angina		46
Hemodynamic		54-56, 77-78
Vascular Resistance Reactivity		57-59, 71-72
Ischemia		60, 76
Post NTG and Post Exercise		64
Autonomic Function		65
Heart Rate Variability		66-69

General Introduction

The Psychophysiological Investigations of Myocardial Ischemia (**PIMI**) was a **multicenter** study of psychophysiological factors related to both symptomatic and asymptomatic cardiac ischemia. The study population consisted of 196 patients recruited from four **Clinical** Units all of which were also Clinical Units for the Asymptomatic Cardiac Ischemia Pilot (**ACIP**) Study. Patients eligible for **PIMI** were identified through the screening process established for the enrollment of patients in ACIP.

In addition to the four Clinical Units, a Clinical Coordinating Center, Ambulatory **ECG** (**AECG**) Core Laboratory, Rest and Exercise ECG Core Laboratory, Biochemistry Core Laboratory, Radionuclide Core Laboratory and the National Heart, Lung, and Blood Institute (**NHLBI**) Project Office participated in the **PIMI** Study.

The primary goal of **PIMI** was to test the basic hypothesis: "manifestations and expressions of cardiac ischemia are influenced by specified psychophysiological mechanisms." The specific relationships to be investigated were:

1. Patients who are susceptible to mental stress ischemia (indexed by new left ventricular wall motion abnormalities) would display more ischemia during daily activities and would have ambulatory ischemia at lower heart rate and activity level thresholds than patients who are not susceptible.
2. Cardiovascular and catecholamine reactivity to mental stress would be predictive of severity of mental stress ischemia and of ambulatory ischemia.
3. **β -endorphin** responses to mental stress and to exercise would be predictive of asymptomatic ischemia.
4. Patients with symptomatic ischemia and those with asymptomatic ischemia would show differences in each of the following at rest and after response to stresses (exercise and/or mental tests):
 - a. somatic sensory perception;
 - b. autonomic nervous system reflexive control of the heart;

- c. β -endorphin responses; and,
 - d. psychosocial characteristics,
5. Mental stress would produce different hormonal and perceptual responses than exercise.
 6. Asymptomatic ischemia would be associated with a lesser severity of ischemia than symptomatic ischemia
 7. The location of the ischemic myocardium would be inferior in a higher proportion of patients with asymptomatic ischemia than of patients with symptomatic ischemia
 8. The latency interval between the onset of ST segment depression and the onset of ischemic pain would be related to:
 - a. somatic sensory perception;
 - b. autonomic nervous system reflexive control of the heart;
 - c. β -endorphin responses: and,
 - d. psychosocial characteristics.

The PIMI Clinical Unit Investigators enrolled 196 patients with stable coronary artery disease verified by angiography or documented myocardial infarction (MI) and ECG evidence of ischemia during exercise treadmill testing. Each patient was monitored for ischemia during a 48-hour ambulatory ECG (AECG), performed a bicycle exercise test and mental stress tests (a Speech test and the Stroop Color Word test). The Clinical Unit Investigators also enrolled 29 individuals presumed to be free of coronary disease to establish reference values for cardiac responses to mental stress as measured by radionuclide studies (Reference Group Study). The radionuclide criteria for mental stress ischemia, based on the results for these 29 patients, were defined as new or worsened regional wall motion abnormalities on both images or decrease in ejection fraction (EF) $> 8\%$ in either image taken during a mental stress test. In addition, ST-segment depression ≥ 1 mm on ECG or AECG obtained during testing were interpreted as indicating ischemia

The tape contains data for 196 patients enrolled in **PIMI** and the 29 **patients** enrolled in the Reference Group Study. Patients were enrolled from January 1, 1993 through September 7, 1994. Separate files were created for the **PIMI** patients and the Reference Group Study patients.

Description of Variables on the Data Tape

The analysis file documentation contains the items, variable names and possible codes.

Copies of **PIMI** forms with annotations denoting the variable names are being submitted in a separate binder with this manual (see Section 2).

Data Tape Specification

The accompanying tape is g-track, unlabeled, with a density of 6,250 bpi, volume M24554. Tape specifications: SAS **datasets** version 6.07, in transport format. The SAS default file specifications are record length 80, blocksize 8000, fixed block. The code used to copy the files to tape as well as to **uncopy** from tape to the database is provided below. A copy of the transport order produced from the SAS transport run is enclosed in the box with the tape.

CODE USED TO CREATE SAS TRANSPORT FILE ON TAPE M24554

```
data _null_;
call system ('mt -f / dev/rmt/2hn fsf 0');
run;
libname newlib xport '/dev/rmt/2hn';
libname oldlib '/udd/ragpi/finalssd';
proc copy in =oldlib out = newlib memtype =data;
run;
endsas;
```

CODE TO COPY TRANSPORTED DATA BACK OUT FROM TAPE

```
data _null_;
call system ('mt -f /dev/rmt/2h fsf 0');
run;
libname newlib xport '/dev/rmt/2h';
libname oldlib 'luddragpiltest';
proc copy in = newlib out = oldlib;
run;
endsas;
```

The tape contains 48 SAS files corresponding to PIMI forms or data files. SAS output documenting each variable with means for continuous variables and frequency distributions for discrete variables is being submitted in a separate binder (see Section 3).

Special Considerations

- a) Separate files are provided for enrolled PIMI patients (N = 196) and Reference Group Study patients (N = 29).
- b) The original identification number containing clinic and patient number has been replaced with a new sequence number, **NEWID 1-96** for enrolled patients and 29 numbers chosen from 1-31 for Reference Group Study patients.
- c) Time is recorded in military time.
- d) Days to event, procedure or visit are calculated **with reference** to study enrollment date. Time to an event, procedure or visit occurring on the same date as study enrollment is defined as zero days. Time of qualifying procedures occurring prior to study enrollment are reported as negative numbers.
- e) Visit type is coded as follows:

QVOO	Qualifying Visit
V1MS	Visit 1 Mental Stress
V1PS	Visit 1 Physical Stress
V2MS	Visit 2 Mental Stress
V248	Visit 2 48-hour AECG
V1M1	Visit 1 Mental Stress task #1
V1M2	Visit 1 Mental Stress task #2
V2M1	Visit 2 Mental Stress task #1
V2M2	Visit 2 Mental Stress task #2

GLOSSARY OF ABBREVIATIONS

ACE	Angiotensin converting enzyme
AE	Arterial elastance
AECG	Ambulatory electrocardiogram
BB	Beta-blocker
BP	Blood pressure
bpm	Beats per minute
CABG	Coronary artery bypass graft surgery
CAD	Coronary artery disease
CHF	Congestive heart failure
CI	Cardiac index
c o	Cardiac output
ECG	Electrocardiogram
EDV	End diastolic volume
EF	Ejection fraction
ESV	End systolic volume
ETT	Exercise Treadmill Test, Exercise Tolerance Test
HF	High frequency
HH:MM:SS	Time format - hours:minutes:seconds
IV	Intravenous
IVCD	Idioventricular conduction defect
LF	Low frequency
LV	Left ventricular
METS	Metabolic equivalents (measure of workload on ETT)
MI	Myocardial infarction
MS	Mental stress
N-N	The interval between R waves in normal QRS complexes
NTG	Nitroglycerin
PER	Peak empty rate
PFR	Peak filling rate
PNN50	The percentage of N-N intervals which are > 50 msec
PS	Physical stress (bicycle exercise)
PTCA	Percutaneous transluminal coronary angioplasty
RBBB	Right bundle branch block
RPE	Rating of perceived exertion
RPP	Rate pressure product
R-R	The interval between successive R waves on the ECG
RVG	Radionuclide ventriculogram
s v	Stroke volume
SVT	Supra ventricular tachycardia
SWI	Stroke work index
TPE	Time to peak empty
TPF	Time to peak filling

FURTHER INFORMATION ON **PIMI**

For further information on the **PIMI** study, the user is directed to the following publications,

A. MANUSCRIPTS PUBLISHED

1. Goldberg AD, Becker **LC**, Bonsall R, Cohen JD, Ketterer MW, Krantz DS, Light KC, McMahon RP, **Noreuil T**, Pepine CJ, Raczynski J, Stone PH, Strother D, Taylor H, Sheps DS for the **PIMI** Investigators. Ischemic, hemodynamic, and **neurohormone** responses to mental and exercise stress: Experience from the Psychophysiological Investigations of Myocardial Ischemia (**PIMI**). *Circulation* 1996;94:2402-2409.
2. Becker LC, Pepine CJ, Bonsall R, Cohen JD, Goldberg AD, Coghlan C, Stone PH, **Forman S**, Knatterud **G**, Sheps DS, Kaufmann PG for the **PIMI** Investigators. Left ventricular, peripheral vascular, and **neurohumoral** responses to mental stress in normal middle-aged men and women: Reference group for the Psychophysiological Investigations of Myocardial Ischemia (**PIMI**) Study. *Circulation* 1996;94:2768-2777.

B. MANUSCRIPTS SUBMITTED FOR EDITORIAL REVIEW

1. Kaufmann PG, McMahon RP, Becker LC, Bertolet B, Bonsall R, Chaitman B, Cohen JD, **Forman S**, Goldberg AD, Freedland K, Ketterer MW, Krantz DS, Pepine CJ, Raczynski J, Stone PH, Taylor H, Knatterud GL, Sheps DS for the **PIMI Investigators**. The Psychophysiological Investigations of Myocardial Ischemia (**PIMI**) Study: Objective, methods, and variability of measures. Submitted to *Circulation*, December 21, 1995. Submitted to *Psychosomatic Medicine* May 15, 1996. Accepted pending revision August 1996. Resubmitted February 7, 1997. Accepted.
2. **Carney RM**, McMahon RP, Freedland KE, Becker L, Krantz DS, Proschan MA, Raczynski JM, Ketterer MW, Knatterud GL, Light K, Lindholm L, Sheps DS for the **PIMI Investigators**. The reproducibility of mental stress-induced myocardial ischemia in the Psychophysiological Investigations of Myocardial Ischemia (**PIMI**). Submitted to *Psychosomatic Medicine* May 15, 1996. Accepted pending revision August 1996. Resubmitted February 7, 1997. Accepted.

PIMI ANALYSIS FILES
ARRANGEMENT OF FILES BY SOURCE

PART I: PIMI PATIENTS

Source	SAS File Name	Number of Records	Number of Variables
Form 02	FORM02.SSD01	196	54
Form 03	FORM03.SSD01	196	7
Form 04	FORM04.SSD01	196	63
Form 06	FORM06.SSD01	196	88
Form 7M	FORM7M.SSD01	255	110
Form 7P	FORM7P.SSD01	196	127
Form 09	FORM09.SSD01	196	53
Form 12	FORM1 2.SSD01	436	12
Form 20	FORM20.SSD01	83	6
Form 31-39	PIPSYC.SSD01	449	37
Form 73	FORM73.SSD01	447	122
Diary Page	PIDIARY.SSD01	2320	35
<u>Inventory</u>			
Eligibility Record Inventory	PIINV.SSD01	196	a
<u>AECG Core Lab Data</u>			
Preliminary Eligibility	AECGELIG.SSD01	196	3
Summary Data (all visits)	PIST.SSD01	677	26
<u>Rest and Exercise ECG Core Lab Data</u>			
Rest Data	ECGREST.SSD01	196	17
QV ETT Data	ETTQV.SSD01	196	32
Bicycle Exercise Data	ETTFU.SSD01	697	32
<u>Biochemistry Core Lab Data</u>			
Biochemistry Measurements	BLOODB.SSD01	196	

PIMI ANALYSIS FILES

Source	SAS File Name	Number of Records	Number of Variables
CALCULATED VARIABLES			
Angina	ANGINA.SSD01	196	8
QV AECG	AECGQV.SSD01	196	5
Radionuclide	RVGALL.SSD01	196	51
V1 PS Physical Stress Bicycle	BIKEV1PS.SSD01	196	28
Psychometric Measures VIPS	PSYCPS.SSD01	196	23
Psychometric Measure V1 MS	PSYCMS.SSD01	196	4
QV ETT Exercise Treadmill Test	CALETTQV.SSD01	196	23
Hemodynamic	HRBP.SSD01	196	73
Vascular Resistance Reactivity	COPVR.SSD01	196	68
Ischemia	MSPS.SSD01	196	23
Biochemistry	CHEM.SSD01	196	67
Post Nitroglycerin Substudy	POSTNTG.SSD01	91	16
Heart Rate and BP during Autonomic Function Tests	AUTOHRBP.SSD01	174	24
24-Hour Heart Rate Variability	HRV24.SSD01	168	43
Heart Rate Variability During Mental Stress	HRVMS.SSD01	156	56

PART II: REFERENCE GROUP STUDY

Source	SAS File Name	Number of Records	Number of Variables
FORM 02	REFPIO2.SSD01	29	49
FORM 3N/3R	REFPI3N.SSD01	29	5
FORM 04	REFPIO4.SSD01	29	63
FORM 7M	REFPI7M.SSD01	29	110
FORM 12	REFPI12.SSD01	29	12
FORM 20	REFPI20.SSD01	15	6
FORM 31-32	REFPSYC.SSD01	29	6
FORM 73	REFPI73.SSD01	29	122
AECG Core Lab Summary Data	REFPIST.SSD01	29	26
Biochemistry Core Lab Measurements	REFBLDB.SSD01	29	27
CALCULATED VARIABLES			
Vascular Resistance Reactivity	REFPVR.SSD01	29	41
Biochemistry	REFBLCAL.SSD01	29	68
Ischemia	REFMS.SSD01	29	29
Hemodynamic	REFHRBP.SSD01	29	63