Antiarrhythmics Versus Implantable Defibrillators Trial (AVID)
2000 Preliminary Dataset

NHBLI N01-HC-25117

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Contents

A. Description of the Population

The patient data in this CD includes information on all patients enrolled in the AVID trial (randomized and observational phases) and the AVID registry. The total population for the trial is 1016 patients and, for the registry, 4595 patients.

Users of this data tape are *strongly* urged to study carefully the AVID Protocol, Manual of Operations, and sample forms before attempting to retrieve data or perform statistical analyses from this data set. The AVID protocol and data structure are complex. The Protocol and Manual of Operations are in files PROTOCOL.DOC and MANOP.DOC, respectively, in the DOC directory.

Every effort possible has been made to protect the confidentiality of the individual patients, and the data set meets the guidelines of part V.B.1-5 of the 03/29/2000 *NHLBI Policy for Distribution of Data* except for some data included at the insistence of NHLBI. The identification number assigned to each case in this data set has no relationship with the patient (e.g. order of enrollment) or with the clinical center at which the patient was recruited. All dates are given in days since index arrhythmia, and the index arrhythmia date itself is omitted. Variables that could easily be used to identify patients have been omitted or recoded. Follow-up of randomized patients is as given in the next section, although the censor date for an individual patient will be the date that patient was last contacted rather than the official study end date. Vital status of almost all patients (randomized and registry-only) was obtained through the National Death Index Service (NDI).

AVID chronology

AVID screened its first registry patient in June 1993 and randomized its first patient into the trial on June 2, 1993. Patients who passed the screening criteria were entered into the registry, regardless of arrhythmia type. Registry patients who had an eligible arrhythmia type and passed further screening criteria on the registry form were approached for randomization into the AVID trial.

Screening changed slightly in August 1993 to allow another randomization-ineligible arrhythmia type (unexplained syncope) into the registry. It was changed slightly once more, in May 1994, to record cases where consent was required (by a site's IRB) for a patient to be included in the registry but was not given. Other than wording clarifications, randomization exclusions on the registry form were first changed in August 1994. At that time, 2 obsolete exclusions regarding thoracotomy and CABG were dropped, and 1 regarding amiodarone exposure was modified. In March 1995 an exclusion was added where excess arrhythmia made crossover likely.

Patients passing the criteria for randomization and giving consent to be randomized were randomly assigned to ICD or antiarrhythmic drugs. Patients randomized to drugs and having a contraindication to sotalol were assigned to amiodarone therapy. Drug-randomized patients without a contraindication to sotalol were further randomized to amiodarone or sotalol.

AVID ceased enrolling patients in the trial and the registry as of April 7, 1997 at the recommendation of its Data and Safety Monitoring Board. Analyses on the randomized phase of the trial are censored as of this date. After 4/7/97, sites contacted their trial patients and advised them on therapy options based on the preliminary AVID results. Regardless of whether the patients chose to change therapy at that time, observational follow-ups were continued. Follow-up was terminated as of

November 1, 1997 for 14 sites having 67 active patients. Follow-up for the remaining patients was terminated as of August 31, 1998.

Results for the primary endpoint, all-cause mortality, were reported for the 1016 trial patients (The AVID Investigators, "A Comparison of Antiarrhythmic Drug Therapy With Implantable Defibrillators in Patients Resuscitated from Near-Fatal Sustained Ventricular Arrhythmias" N Engl J Med 1997:337:1576-1583). These patients are identified by a random sequential ID between 0001 and 1016. Registry patients not randomized are identified by a random sequential ID from 1017 to 4595. For randomized-phase analyses, exposure to therapy and events are counted from randomization through approximately April 7, 1997 or the date of death or loss to follow-up. For observational analyses on randomized patients, exposure is counted from randomization through end of observational study, death, or loss to follow-up. For analyses on registry patients, exposure is counted from index arrhythmia date through end of NDI follow-up or death.

B. Description of the Data Set

The AVID data and documentation are delivered on a CD. The data files are in the DATA directory of the CD and are written in ASCII as export files to SAS.

There are two data files for each of the 29 form types being delivered, a total of 58 data files. The first of the two files contains the SAS data step commands necessary to load the data contained in the second file into a SAS save file. The actual data are contained in the second of the two files. Thus, the first four files in the DATA directory are:

1) RT00.SAS: SAS data step to load AVID "Common Information Record" variables
2) RT00.DAT: Data corresponding to the "Common Information Record"
3) RT01.SAS: SAS data step to load the Screen and Registry form data, and NDI follow-up for the 4,595 registry patients
4) RT01.DAT: Screen, Registry, and NDI data

Each form is assigned a unique record type number, designated as variable RTNUMxx in file RTxx.SAS. The number “xx” corresponds to the number in the lower right corner of each paper form, except as noted in the detailed descriptions of each record type.

Randomized patients have been assigned random 4-digit sequence numbers 0001 – 1016. This variable is in each RTxx.SAS file and is called SEQNUMxx. Registry-only patients have been assigned random 4-digit sequence numbers 1017-4595 (variable SEQNUM01 in RT01.SAS, the only record type with registry-only patients).

Below (on pages 7 - 9) is given an example of the SAS data step for the Holter record (AVID 08), file RT08.SAS. This file contains formatting information necessary to read the corresponding data file RT08.DAT.

The example contains some formatting information for coded values (e.g. 0 = “No”, 1 = “Yes”). Missing values for variables are designated in the data as required by SAS as ".", "A", "B", or "C". All missing values are equivalent. The INFILE command:

```
INFILE  rt08.dat  LRECL= 82  LINESIZE= 81  MISSOVER PAD;
```

defines the length of the data record. For the Holter record, the data are written in records of 82 characters. The last character of each data record is an 'X'.

The INPUT command which follows describes the variables and their location in the data record. For example, the variable RTNUM08 begins in column position 1, is numeric and takes up 3 character positions. The second variable, SEQNUM08, begins in column position 4 and takes 5 character positions. Both these variables are numeric. DAYS08 is a numeric variable beginning in column 9 and also takes 5 character positions.

Most variables are integer; there are some real numbers, which will have a fixed number of decimal places. Most times are coded as integers (seconds since midnight), although some may be coded HH:MM:SS, where HH is two digits for the hour (24-hour clock), MM is two digits for minute, and SS is two digits for seconds.

Value labels for categorical variables are given at the beginning of the file and can be matched with the appropriate variables with the FORMAT command immediately following the INPUT command. The LABEL command defines labels for the variables. These correspond as closely as possible with the descriptions on the actual forms.

Following the SAS data step is a sample of the data for the Holter record described.

```
* SIR/DBMS 4.0 SAS PROC STEP FROM DATABASE: AVID     11/21/00 12:13:44;

PROC FORMAT PRINT;

*  FORMAT T1X IS DEFINED FOR VARIABLE RANPHS08;

  VALUE T1X
    0               = 'No'
    1               = 'Yes';

*  FORMAT T2X IS DEFINED FOR VARIABLE REASON08;

  VALUE T2X
    1               = 'Baseline'
    2               = 'Suppression testing';

*  FORMAT T3X IS DEFINED FOR VARIABLE TXNONE08;

  VALUE T3X
    0               = 'Some therapy'
    1               = 'No therapy';

*  FORMAT T4X IS DEFINED FOR VARIABLE TXICD08;

  VALUE T4X
    0               = 'Not ICD'
    1               = 'ICD';

*  FORMAT T5X IS DEFINED FOR VARIABLE TXANTI08;

  VALUE T5X
    0               = 'Not antiarr'
    1               = 'Antiarr drug';

*  FORMAT T6X IS DEFINED FOR VARIABLE DRAMIO08;

  VALUE T6X
    0               = 'Not amiodarone'
    1               = 'Amiodarone';

*  FORMAT T7X IS DEFINED FOR VARIABLE DRSOT08;

  VALUE T7X
    0               = 'Not sotalol'
    1               = 'Sotalol';

*  FORMAT T8X IS DEFINED FOR VARIABLE DROTH08;

  VALUE T8X
    0               = 'No other antiarr'
    1               = 'Other antiarr';

* SIR/DBMS 4.0 SAS DATA STEP FROM DATABASE: AVID     11/21/00 12:13:44;

*  Commands involving file name specifications may
```

```
   require alteration according to operating system
   requirements and the version of SAS being used.;

*  REQUIRED RECORD LENGTH FOR DATA IS 82 CHARACTERS;
*  EACH OBSERVATION WILL PRODUCE 1 RECORD;

DATA;

  MISSING A B C;

  INFILE   rt08.dat  LRECL= 82  LINESIZE= 81
           MISSOVER  PAD;

  INPUT
   #1
    @1        RTNUM08   3.
    @4        SEQNUM08  5.
    @9        DAYS08    5.
    @14       RANPHS08  2.
    @16       REASON08  2.
    @18       TXNONE08  2.
    @20       TXICD08   2.
    @22       TXANTI08  2.
    @24       DRAMIO08  2.
    @26       AMIOMG08  6.
    @32       DRSOT08   2.
    @34       SOTMG08   6.
    @40       DROTH08   2.
    @42       TMANAL08  7.
    @49       VPDS08    11.
    @60       COUPLT08  11.
    @71       RUNS08    11.;

  FORMAT
    RANPHS08 T1X.
    REASON08 T2X.
    TXNONE08 T3X.
    TXICD08  T4X.
    TXANTI08 T5X.
    DRAMIO08 T6X.
    DRSOT08  T7X.
    DROTH08  T8X.;

  LABEL
              RTNUM08  = 'Record Type Number'
              SEQNUM08 = 'Patient sequence number'
              DAYS08   = 'Start of recording - days > index event'
              RANPHS08 = 'Form applies to randomized phase'
              REASON08 = 'Reason for recording'
              TXNONE08 = 'Current study tx none'
              TXICD08  = 'Current study tx ICD'
              TXANTI08 = 'Current study tx antiarr drug'
              DRAMIO08 = 'Amiodarone study tx'
              AMIOMG08 = 'Amiodarone mg per day'
              DRSOT08  = 'Sotalol study tx'
```

```
              SOTMG08  = 'Sotalol mg per day'
              DROTH08  = 'Other antiarr study tx'
              TMANAL08 = 'Length of analyzable recording [sec]'
              VPDS08   = 'Total VPDs'
              COUPLT08 = 'Total couplets at rate ge 100 bpm'
              RUNS08   = 'Total runs at rate ge 100 bpm';

RUN;
```

Sample Data from Holter (AVID 08) Records

1		2							3		4		5	6	7	8
8	8	17	1	1	1	0	0	0	.	0	.	0	85800	552	0	0X
8	38	3	1	1	1	0	0	0	.	0	.	0	73860	1181	11	0X
8	48	29	1	1	1	0	0	0	.	0	.	0	65340	1962	62	2X
8	75	19	1	1	1	0	0	0	.	0	.	0	86400	59	59	1X
8	75	31	1	2	0	0	1	0	.	1	320	0	86400	32	298	16X
8	84	69	1	1	1	0	0	0	.	0	.	0	80040	9313	2507	2242X
8	84	87	1	2	0	0	1	1	400	0	.	0	86400	180	5	1X
8	85	6	1	1	0	0	1	0	.	1	480	0	86400	222	4	10X
8	85	25	1	2	0	0	1	1	400	0	.	0	85620	44	0	0X
8	86	10	1	1	1	0	0	0	.	0	.	0	86400	723	6	3X
8	94	10	1	1	1	0	0	0	.	0	.	0	81000	2691	28	8X
8	106	70	1	1	1	0	0	0	.	0	.	0	90780	361	36	2X
8	107	8	1	1	1	0	0	0	.	0	.	0	89160	26	0	0X
8	121	16	1	1	1	0	0	0	.	0	.	0	75420	362	8	1X
8	123	10	1	1	1	0	0	0	.	0	.	0	82200	5734	0	13X
8	134	-1	1	1	1	0	0	0	.	0	.	0	86340	4691	297	180X
8	148	42	1	1	1	0	0	0	.	0	.	0	86460	135	0	1X
8	156	954	1	2	0	0	1	1	200	0	.	0	84660	4	0	0X
8	158	17	1	1	1	0	0	0	.	0	.	0	68400	0	0	0X
8	188	7	1	1	1	0	0	0	.	0	.	0	88920	1170	12	1X
8	219	15	1	1	1	0	0	0	.	0	.	0	88800	638	0	0X
8	264	0	1	1	1	0	0	0	.	0	.	0	55020	1567	0	0X
8	264	11	1	2	0	0	1	0	.	1	160	0	87900	196	0	0X
8	276	11	1	1	1	0	0	0	.	0	.	0	88140	412	1	0X
8	283	8	1	1	1	0	0	0	.	0	.	0	82980	497	0	0X
8	322	23	1	1	0	0	1	1	400	0	.	0	83100	202	0	0X
8	324	12	1	1	1	0	0	0	.	0	.	0	55800	231	0	0X
8	326	3	1	1	1	0	0	0	.	0	.	0	90000	7038	339	2X
8	337	11	1	1	1	0	0	0	.	0	.	0	68400	28	0	0X
8	365	8	1	1	1	0	0	0	.	0	.	0	88380	252	0	0X
8	375	10	1	1	1	0	0	0	.	0	.	0	61800	687	35	1X
8	387	2	1	1	1	0	0	0	.	0	.	0	79140	1448	4	0X
8	389	20	1	1	0	0	1	0	.	1	160	0	82800	209	1	0X
8	441	29	1	1	1	0	0	0	.	0	.	0	72000	240	5	0X
8	480	6	1	1	0	0	1	1	1200	0	.	0	90600	6152	244	15X
8	482	4	1	1	1	0	0	0	.	0	.	0	66000	88604	0	0X
8	513	13	1	1	1	0	0	0	.	0	.	0	78240	11779	0	1X
8	517	4	1	1	1	0	0	0	.	0	.	0	85320	22	0	0X

C. Description of the Record Types

Supplied on the CD are two types of documentation for each record type.
In the FORMS directory each record type xx has one or more files RTxx*.*. Most record types will have one file RTxx.PDF, an annotated sample data form in PDF format. Exceptions are listed below (files RTxx.DOC are Word documents describing the record type and variables).

Each record type also has a codebook file RTxxCB.TXT in the CODEBOOK directory. These files are plain ASCII text files, up to 80 characters wide (fixed font) and formatted for printing 60 lines per page. These may be useful for getting the codes for categorical variables if they aren't clear from the annotated data forms and for verifying that your statistical package has read the data correctly.

D. Description of the Forms

The AVID forms are associated with the record types in the database as follows:

Rec Type	Corresponding form/information
01	Common Information Record – Patient-level information including treatment arm and survival (RT00.DOC)
02	Screen, Registry, and NDI follow-up (RT01.DOC, RT01A.PDF, and RT01B.PDF)
02	Baseline
03	Concurrent Drugs
04	ECG
05	Random
06	Labdata
07	EPS
08	Holter
09	Initiation of Antiarrhythmic Drug
10	ICD Implantation
11	Hospitalization
12	Follow-up
14	ICD Evaluation (only page 1 of RT14.PDF applies; see RT99)
15	Adverse Symptoms
16	Change in Study Therapy
18	Death (RT17.PDF, RT18.PDF)
21	Recurrent Arrhythmia
22	Lead and Generator Information
24	ICD Implantation Complications
26	End of Randomization Status
27	End of Observational Phase Status
29	Blinded Review of Randomized Phase Deaths (no PDF file; variables are similar to correspondingly-named variables in RT18)
40	Patient Quality of Life at Baseline

41 Patient Quality of Life at 3-month Follow-up
42 Patient Quality of Life at 6-month Follow-up
43 Patient Quality of Life at Annual Follow-ups
44 Patient Quality of Life at Semi-annual Follow-ups
99 ICD Episodes and Therapies (RT99.DOC, page 2 of RT14.PDF)

Each record type from 02 to 99 has a variable RANPHSxx that is described in the codebook but is not on the annotated forms. This variable will be useful in doing analyses using only the randomized phase data. RANPHSxx defines whether the record should be used in randomized phase analyses and normally has the values 1 = yes and 0 = no, meaning that when doing randomized phase analyses you should use only records with RANPHSxx = 1. For two record types, 11 and 26, RANPHSxx has three values: 2 = use entire form, 0 = don't use form; RANPHS11 = 1 means use only reason for hospital admission and antiarrhythmic tx at admission (but not events or procedures during hospitalization), and RANPHS26 = 1 means use only page 1 variables (vital status and antiarrhythmic tx at end of randomized phase).