

NEW EVOLVING ROLES IN RESEARCH FOR NURSES USING SAS
DEVELOPMENT OF AN END-USER SUPPORT SYSTEM AND COORDINATION
OF A RESEARCH TEAM

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INTRODUCTION:

Research is a process that requires the completion of an orderly course of events ultimately resulting in new conclusions and discoveries. The development and implementation of these outcomes enhance, improve, and advance technology and business transaction. When this systematic procedure is haphazardly performed, quality research is jeopardized and the resulting data can be compromised or flawed.

The Mayo Medical Foundation strives to blend the importance of research and education with clinical care to maintain a high standard of service. The Division of Thoracic and Cardiovascular Surgery actively engages in researching various areas of treatment and procedures, as do many other departments. This results in an overload of work for the Section of Biostatistics and a delay in study analysis.

The education of fellows, residents, and consultants in research development and the implementation of the SAS® System for data collection, storage, and analysis improved our research activity and decreased the lag time in obtaining data analysis results. Individual education is augmented with the use of a departmental manual entitled, "Guide to Clinical Research."

Research is a continuing wheel of interaction between the resident, staff consultant, data analyst, statistician, and nurse investigator. The nurse investigator provides on going guidance throughout the study process and is the hub of the research wheel coordinating and directing each step of the study process.

SAS is a beginning to end solution for research. The SAS System is an integrated system of application software. Its modular design allows for additional capabilities to be added as the organizational needs develop. It provides for the data driven tasks of data access, data management, data analysis, and data presentation. All aspects are used in our projects.

RESEARCH STEPS:

Development of a Hypothesis

A blending of a review of the current literature on a specific subject looking at previous outcomes with tentative assumptions and theories is needed to formulate workable hypothetical questions.

Intra-Clinic Avenues of Study Regulation

New study subjects are submitted to the Medical Industry Relations Committee within Mayo to prevent duplications of studies and conflicts of interest. Registration of the study subject eliminates unproductive staff effort, and increases Mayo publications and presentations.

The Internal Institutional Review Board requires a written request for acceptance of the project thus maintaining control in the research arena. This results in continued high standards of research activity.

Example letter to Institutional Review Board: Appendix 1

Development of Clinical Criteria and Measures

The detection and identification of the important and specific facts of data are necessary to prove the hypothesis along with necessary dates and diagnostic results to produce viable statistical conclusions. Finally, the necessary data points are formulated into a format compatible to computer entry and retrieval.

Example collection form: Appendix 2

Identify Study Population

This is done by direct patient selection and enrollment, or electronic retrieval from Diagnostic and Surgical Indices or subject specific databases stored or transferred using SAS/ACCESS.[®] SAS/ACCESS is a family of individual interfaces that provide a direct and transparent link between the SAS System and other databases.

Complying with State and Federal Regulations

Patient confidentiality is important and all patients are advised of on going research and allowed the ability to refuse enrollment. Patients refusing have a flag placed in their file for identification purposes. Compliance information is also available on the intranet and stored in an accessible SAS data set.

Example flag:

Research Alert The information in this medical record cannot be used for research without this patient's consent. If you wish to have more information about research restrictions and the procedure for proper selection of potential candidates for research projects/studies, please access the Mayo Web Site at http://www.mayoweb.edu or call the Mayo Institutional Review Board at 4-2329.

Implementation of Data Collection - SAS Computer Entry System

A general SAS/AF® application wraps the necessary data management functions and commonly used tasks across all of the project. Within the application SAS/FSP® using FSEDIT, data collection screens are developed to simulate the format of the data collection paper forms used by the investigator. This provides for ease of data entry and less entry error.

Screen customizations are added such as repeated variables, autosave, colors, highlighting, minimums, maximums, capitalization, protected fields, etc. using SAS/FSP. Enhancement features provide for interactive data entry and editing. Some variables such as age are formulated using program definition mode and screen control language (SCL) to calculate the variable values based on specific user entered data and then displaying the result or total in specified fields.

Codes and edits are added allowing for entry into the SAS data set parameters to describe how the fields are to be formatted upon exit. At the time of exit, the formats of specific variables are created. Screen control language (SCL) is built in to reside behind the screens to do editing and to direct the use of the formatted values.

Links to registration, patient compliance, or other SAS databases are provided using SAS/ACCESS. This allows for prefilling of the designated variables and provides verification along with the convenience of saving data entry time.

The investigator is introduced to his study database and instructed on the execution commands. This allows the investigator personal control of his or her data. It provides easy viewing in data sheet format with built-in edit and error checking.

Also provided for the investigators use is an in-house macro developed by Mayo programming staff. When executed, it runs a distribution list of all existing variables with variable name and label. It also provides mean, standard deviation, median, minimum, and maximum on all continuous variables. This gives an immediate first overlook of the entire database with summary statistics and provides for editing before analysis.

This produces a flexible system that allows for the removal or addition of data points in a timely and easily performed manner. The database is in SAS/SHARE® which allows for access by the primary investigator, nurse investigator, data analyst or statistician as needed with little or no delay.

Example distribution list: Appendix 3

Example data screen:

```

FSEDIT APPL1.S1671399-----New Screen 1:
Command ***>
  Clinic  EXCLUDE (1=Yes)
  Date Birth  Sex  Race  Ethnicity  Age  Height  Weight  BMI
  Last  Title  First  Middle  Suffix
  Address at Last Diagnosis
  City  State  Zip
  Residence at Diagnosis
  Telephone
  Fax
  E-mail
  
```

Statistical Analysis

The nurse investigator provides personal care of the data, evaluates and interprets the data, develops statistical reports, and works directly with the data analyst and statistician to generate in depth statistical analysis using SAS/ASSIST.[®]

SAS/ASSIST is a menu driven task orientated system that enables access, management, analysis and presentation of the data. The system is designed so end users can accomplish data tasks with minimal effort and limited programming knowledge.

Subsetting of the database using Data Management is often necessary to enable analysis of streamlined groups of data. Sorting of the data into various ascending or descending orders, or writing of where clauses to specify unique variables or values are examples of some types of subsetting. Subset under Data Management also provides for the decreasing of the number of variables in your subset and building of new variables. These can be standard or calculated variables such as age or time variables.

Example - Data Management - Subset SAS/ASSIST:

Data Management Menu

ACTIVE	EDIT/REMOVE	CREATE/IMPORT	DATA ACCESS
SUBSET/COPY	COMBINE	SORT	
UTILITIES	INDEX	UNLOCK	HELP

Place cursor on your selection and press the enter key.

SAS/ASSIST: Subset or Copy a Data Set

<Active data set:> SASUSER.HOUSE

<Output data:> -REQUIRED- Will be created as a: DATA SET

Subset and transform the data:

<Currently selected observations:> -ALL-

<Currently selected variables:> -ALL-

<Transform existing variables:> -NONE-

<Define new variables:> -NONE-

The data analysis window is used to provide frequency distributions and median, mean, standard deviation, minimum, maximum, etc. calculations.

Example - Data Analysis SAS/ASSIST:

Primary Menu

TUTORIAL	DATA MGMT	REPORT WRITING	GRAPHICS
DATA ANALYSIS	PLANNING TOOLS	DIS	
RESULTS	SETUP	INDEX	EXIT

Place cursor on your selection and press the enter key.

The Results Manager displays saved tasks and is the place where all saved tasks and source coding can be managed. It allows the filing of any task that has been built using the point and click choice of building a program or the actual selections visual in the SAS window. When selections have been chosen in a SAS/ASSIST window, these selections can be saved to the Result Manager to be used at a later date. Choosing Save or Save As saves the parameters from the window. Choosing Save as Source saves the generated source code. At this point the source code or SAS window can be recalled, edited, or additional variables or a where clause, etc. can be added. The types of changes and degree of difficulty are dependent on the ability of the end user, and will grow as his or her knowledge of the SAS system develops. The Nurse Investigator uses the Result Manager to build and store programs or tasks for the investigator to execute. These specialized programs are saved in the same library as the data. These production programs allow the primary investigator control and analysis of his or her data while allowing the nurse investigator the ability to insure quality data results.

Example - Results Manager SAS/ASSIST:

File Customize Locals Help

Active data set: SASUSER.HOUSES Subset data: NO

Save As

Type: ASSIST (LISTING)

Name: HOUSES

Description: Houses Listing Report

Catalog: SASUSER.PRIVATE

OK Cancel

Save as Window

File Customize Locals Help

Active data set: AIRLINE.DELAY Subset data: NO

Save As

Type: SOURCE

Name: DELAY

Description: Average Delay by Flight

Catalog: SASUSER.PRIVATE

OK Cancel

Save as Source Window

These are just some of the sections of SAS/ASSIST used to coordinate and analyze the study data. SAS/ASSIST is a multitask oriented system providing many functions. SAS/ASSIST can grow as the abilities of the end user grow and develop.

CONCLUSION

Conscientious accurate research is vital to the advancement of education and improvement of patient care.

The nurse investigator carries out the roles of team facilitator, research educator, coordinator, data administrator, and patient liaison, thus improving the accuracy and consistency of research. These roles also decrease the time commitment of the data analyst and statistician freeing them to do the advanced analyses of the data.

RESULTS

During the first 18 months following implementation of this system of research management in the Division of Thoracic and Cardiovascular Surgery, 14 staff and 30 fellows and residents have participated in 62 clinical studies. The total patient enrollment was 12,644. At the present time 32 of the studies have been completed and accepted for presentations and publications. The interest and the number of clinical studies continues to increase. The SAS system allows for data administration and end user support to multiple projects, and can be administrated by a single advanced end user.

REFERENCES:

SAS Institute Inc., Doing More with SAS/ASSIST Software, Cary, NC: SAS Institute Inc., (1992)

SAS Institute Inc., Getting Started with the SAS System Using SAS/ASSIST Software, Cary, NC: SAS Institute Inc., (1991)

SAS Institute Inc., SAS/ASSIST Software: Changes and Enhancements, Cary, NC: SAS Institute Inc., (1995)

Anderson, Betty, Guide to Clinical Research, Rochester, MN: Mayo Foundation, (1997)

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Appendix 1:

F.J. Puma, M.D.
Cardiovascular Surgery
5-200 St. Marys
Extension 5-7866

September 8, 1995

Ms. Bertha Port
Secretary, IRB Committee
Siebens 6

Dear Ms. Port:

I am writing to you regarding a study which is entitled "Long-Term Follow-up of Surgical Repair of Complete Atrioventricular Canal Defects." This project is being supervised by Dr. Frank J. Puma, and facilitated by Betty J. Anderson, R.N., Study Coordinator. The sample size is approximately 300 patients and will involve retrospective chart data review. Patient confidentiality will be maintained, and only patients with research authorization will be reviewed. A follow-up letter will be sent out to each of the 300 patients so as to obtain long-term follow-up. Enclosed is a copy of the follow-up questionnaire that has been used in the past for previous studies on patients who have undergone open-heart surgery. We will plan for the questionnaire data to be collected by the Survey Research Center. Data entry and analysis will be undertaken with the supervision of the Section of Biostatistics here at the Mayo Clinic. The study will be funded by the Division of Thoracic and Cardiovascular Surgery.

Previous studies have been published on this subject with good results. We wish to provide the Mayo Clinic experience in this area, and feel it will be the largest cohort of patients published to date. Each patient history will be reviewed for information pertaining to cardiac disease and health status.

I would appreciate it if you would grant approval of the study so the follow-up letters can be sent out in the near future.

Thank you.

Sincerely,

John C. Doe, M.D.
Chief Resident Associate
Division of Thoracic & Cardiovascular Surgery

JCD:sml
Enclosures

Appendix 2:

Investigators:

Dr. M. Seina

Dr. Z. Aler

Dr. J. Oell

June 14, 1996

LEFT ATRIAL MYXOMA AND MITRAL REGURGITATION
RIGHT ATRIAL MYXOMA AND TRICUSPID REGURGITATION

Name _____

____ - ____ - ____ Clinic number

____ Gender - (1=Male, 2=Female)

____ - ____ - ____ Date of birth

____ - ____ - ____ Date of 1st Mayo myxoma surgery

____ - ____ - ____ Date of discharge

SYMPTOMS - (0=No, 1=Yes)

____ Congestive heart failure

____ Emboli - systemic

____ Hypertension

____ Pulmonary edema

____ History SBE

____ Syncope

____ History of MI

____ Hemoptysis

____ Other _____

____ SOB - dyspnea

____ Cough

____ Edema - generalized

____ Confusion

____ Angina/chest pain

____ Pericarditis

____ Fever unknown origin

____ Dysrhythmia

Duration of symptoms _____ (weeks)

Etc.

Appendix 3:

REOPERATION AV CANAL

09:42 Tuesday, January 28, 1997

All Variables within data set APPL1.S1677600

Variable	Label	Value	Count	%	Cum	%
SEX	GENDER	Missing	2			
		1	7	50		50
		2	7	50		100
RACE	RACE	Missing	4			
		11	6	50		50
		1	6	50		100
DOWN	DOWNS	Missing	1			
		0	11	73		73
		1	4	27		100
RAST	RASTELLI CLASS	Missing	2			
		1	9	64		64
		3	5	36		100

Continuous (>20 values) Variables within APPL1.S1677600

VARNAME	VARLABEL	NOBS	NMISS	N	MEAN	STD	MIN	MAX
AGE	Age symptomatic	16	8	8	18.475	41.25	0.300	120.000
						MEDIAN - 3.000		
FLOW	Flow ratio initial	16	13	3	3.040	1.272	1.680	4.200
						MEDIAN - 3.240		
PULMR	Rp initial cath	16	14	2	4.200	0.707	3.700	4.700
						MEDIAN - 4.200		
SYSTR	Rs initial cath	16	14	2	25.450	13.51	15.90	35.000
						MEDIAN - 25.450		
WT	Weight initial	16	4	12	29.783	34.36	5.000	118.000
						MEDIAN - 17.000		