

A SAS/AF® Application for Linking Demographic & Laboratory Data For Participants in Clinical & Epidemiologic Research Studies

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ABSTRACT

The delivery population and their offspring at two local hospitals are consented and screened for cytomegalovirus (CMV) infection as part of a research project in the Department of Pediatrics at the University of Alabama at Birmingham. Letters are sent to all mothers with the laboratory results for both mother and newborn. Depending on the results of the screening, the mothers are eligible to participate in either a CMV vaccine trial or an epidemiologic study of CMV immunity. CMV positive children are eligible to participate in a study of congenital CMV infection and outcome. A SAS/AF® application (v. 6.12) was developed to collect demographics, initial contact information, and laboratory data on every woman and newborn screened for CMV. Either laboratory or clinical personnel and data entry operators enter the data collected into the application. The application allows for data entry and editing, generation of reports and lists, and saving of data subsets for importing into WordPerfect® macros to create result letters and contact summary sheets for the follow-up of potential study participants. Reasons for participation or nonparticipation for each study are also recorded and tables generated. This application makes these tasks relatively simple to accomplish by all study personnel.

INTRODUCTION

We developed an application that includes collection, management, and tracking of screening data for three research projects in the Department of Pediatrics, Division of Infectious Diseases, at the University of Alabama at Birmingham. Women who deliver at University Hospital and Cooper Green Hospital are approached by study nurses during their stay at the hospital and asked to consider whether she and her newborn would be willing to participate in a series of CMV research studies at UAB. If the mother agrees to consider participation, a tube of blood is obtained from the hospital laboratory and a saliva sample is collected from her infant. The women are informed that a letter will be mailed with both her and her newborn's CMV laboratory test results. Depending on the test results, a woman may be eligible to participate in either a CMV vaccine trial or a follow-up study of CMV immunity in young mothers. Also if an infant is CMV positive then the infant and parents are eligible to participate in a longitudinal study of children with congenital CMV infection.

The primary goal of the SAS/AF® application described in this paper is to provide demographic information, address and laboratory data for potentially eligible women for three active CMV studies currently being conducted at UAB. A secondary goal of the application is to maintain information about whether a potentially eligible woman enrolls or if not, her reason for not participating. To accomplish these goals, requires repeated daily or weekly activities and also data entry by multiple users with little computer experience. The activities and specific tasks considered when developing the SAS/AF® application are listed in Table 1.

We created our SAS/AF® Frame Application in Version 6.12 of the SAS system on the Windows 95/ Windows NT platform. The main menu of the application presents the user with five choices including a data entry menu, data editing menu, posting test results menu, lists and data menu, and visit outcome menu (Fig. 1). The widgets used on this frame are Icons with a Command Push Button to exit the application. By pressing the appropriate Icon the user enters the next frame. In this paper we will focus on the Data Entry Menu and the Lists and Data Menu of the application. The other menu options will only be discussed briefly since the methods used for these sections are similar to those described in the Data Entry section of the application.

Table 1. Activities included in SAS/AF® application

Activities	Specific Tasks Needed
1. Link demographic information on women with CMV test results for each mother and child	1. Assign screening ID number 2. Enter demographic data by data entry operator 3. Enter address information by data entry operator 4. Enter mother's test results by lab personnel 1 5. Enter newborn's test results by lab personnel 2 6. Ability to edit or update data previously entered
2. Generate letters with test results to mail to women	1. Create subsetted SAS® data sets by test results and time frame 2. Save and export subsetted SAS® data sets 3. Create a WordPerfect® macro to import data sets and merge test result letters for all women and newborns tested.
3. Generate lists and contact forms of eligible participants for studies	1. Create subsetted SAS® data sets by test results and time frame 2. Either generate print out within SAS® or save and export subsetted SAS® data sets 3. Create a WordPerfect® macro to import data sets and merge contact forms for eligible participants. These forms are generated and completed by clinical personnel
4. Provide enrollment data or reason for not participating for each woman screened	1. Enter enrollment data or reason refused to participate for potentially eligible participants by clinical personnel (obtained from study contact forms). 2. Generate summary tables of both numbers of enrollees and numbers of potentially eligible participants not enrolled by reason for each study.

Figure 3

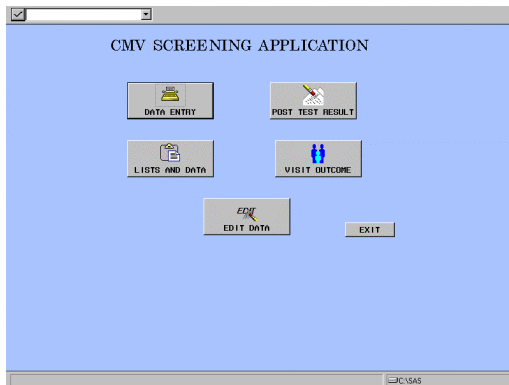


Figure 1

Data Entry Frame:

The data entry menu allows the user to enter new demographic information or new addresses for delivery patients screened for CMV infection (Fig. 2). The widgets used on the frame are Icons and a Command Push Button similar to the Main Frame of the application. The icons and choices within this menu are described in the following paragraphs:

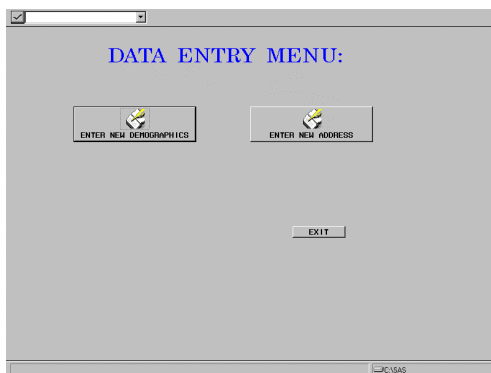
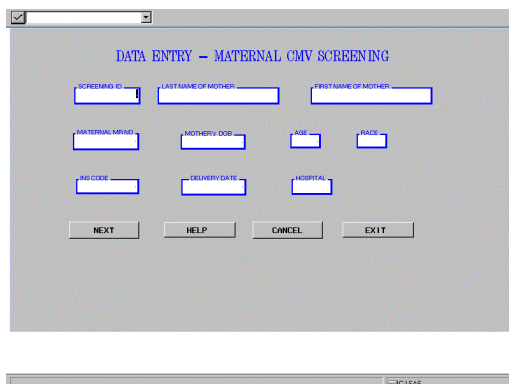


Figure 2

Enter New Demographics:

In this frame, demographic information is entered for all the women tested at either University Hospital or Cooper Green Hospital (Fig. 3). The demographic information is entered into the data set by the data entry operator, with the address information and CMV laboratory results entered by other study personnel later.



The entry frame for entering new demographic data has a Data Form with Input Field widgets for entering the data, Command Push Buttons and an Icon for moving to the Help frame. The field for maternal age is calculated based on the mother's date of birth and the delivery date entered by the user. The hospital is automatically filled in based on the screening ID number entered. A number beginning with a 1 indicates a University Hospital delivery and a number beginning with a 2 indicates a Cooper Green Hospital delivery. The user is able to add another entry by pressing the "Next" Command Push Button. If the user needs clarification on the coding of the variables on the Data Form, the user may press the "Help" Push Button (Fig. 4). A frame appears that gives a description of the variables and the acceptable formats and values for the variables. If the "Cancel" Command Push Button is pressed the current entry is not saved and the user is returned to the previous frame, whereas if the "Exit" Command Push Button is pressed the data will be saved and the user is returned to the previous frame.

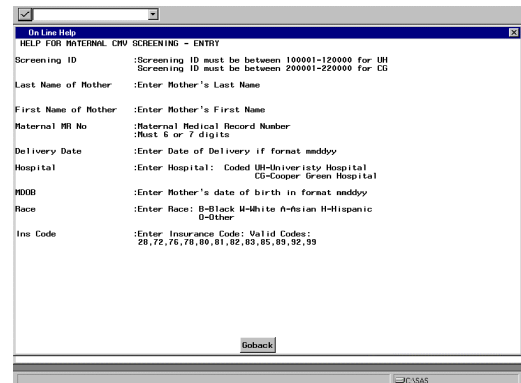


Figure 4

The SCL for the New Demographic entry frame calls the Data Form and enables a row to be added when indicated. The INIT section of the SCL for the Data Form sets all the fields to missing and the cursor appears in the first Input Field. The MAIN section of the SCL for the Data Form progresses the cursor through the Input Fields after each field is completed and the enter key is pressed. Logic checks have been programmed into the SCL to verify that the values entered for screening ID number and medical record number are within predefined ranges. Race and insurance code are also checked and only the predefined values for these variables can be entered. Other field edits are also available for specific variables. Any missing field is queried prior to exiting the frame in an attempt to minimize missing data. A small frame appears asking the user if the value for this field is missing (Fig. 5). The user is asked to answer yes or no. Once the response is made the user is returned to the Data Form to either enter the missing value or exit the frame.

Enter New Addresses:

In this frame, the mailing addresses of the participants screened for CMV at University Hospital and Cooper Green Hospital are entered into the data set. Upon selecting the Enter New Address Icon, the user is presented with a frame asking how they would like to search, by either name or number. Choosing the "Search by Name" Icon presents the user with a frame consisting of a Toolbar,

Extended Text Entry, and a Data Table (Fig. 6). The Toolbar contains of the letters of the alphabet. Upon pressing a letter, the Data Table is sorted by the mothers' names. The user can further narrow the search by entering more letters of the name in the Extended Text Entry field. By double clicking on a row in the Data Table, the Data Form frame for entering the screening addresses displays the selected woman's observation.

Figure 5

NAME	SCREENID	D_DATE
BROOKS, CINDY	100001	05/26/99
SMITH, ASHLEY	100002	05/26/99
JONES, ALICE	100003	05/26/99
DAVIS, MARY	100004	06/01/99
ROGERS, TAMMY	100005	06/01/99
DOCKOUR, JANE	100006	06/01/99
WILLIAMS, SARAH	100007	06/01/99
SAUNDERS, KATE	100008	06/01/99
SMITH, STACIA	100009	06/01/99
DOE, JANE	100010	06/01/99
BRUMBACH, KAREN	100011	06/01/99

Figure 6

The SCL for the Searching by Name frame enables a single observation to be displayed on the Data Form. The `_SET_INSTANCE_METHOD_` and the `_SELECT_` methods identify the row selected from the Data Table and then displays the Address Entry frame with the Data Form. The Toolbar displaying the alphabet is controlled by separate SCL, as is the Extended Text Entry.

The Search by Number frame is similar to the Search by Name frame except there is no Toolbar (Fig. 7). The SCL for the Searching by Number frame is similar to the SCL for the Searching by Name frame. The user enters the screening number of the woman in the Extended Text Entry and presses the enter key. The Data Table is sorted and displays the requested observation. By double clicking on the observation in the Data Table, the Address Entry frame with the Data Form displays the selected mother's observation (Fig. 8).

The Address Entry frame consists of a Data Form with Input Fields and Command Push Buttons. All fields are protected and cannot be altered except for the street address and zip code fields. The SCL for the frame calls the Data Form and specifies the row to be displayed. The DFINIT section of the SCL for the Data Form begins by opening a zip code data set that is used to look up and fill in the city and state fields on the Data Form when a zip code is entered. The INIT section sets the cursor in the address field for the user to begin entering the street address. The MAIN section of the SCL moves the cursor to the zip code field when the street address has been entered. After the zip code field is entered, the zip code data set is searched and the city and state fields are filled in on the Data Form. The user

may use the Command Push Buttons as previously described in the Enter New Demographics Frame.

NAME	SCREENID	D_DATE
BROOKS, CINDY	100001	05/26/99
SMITH, ASHLEY	100002	05/26/99
JONES, ALICE	100003	05/26/99
DAVIS, MARY	100004	06/01/99
ROGERS, TAMMY	100005	06/01/99
DOCKOUR, JANE	100006	06/01/99
WILLIAMS, SARAH	100007	06/01/99
SAUNDERS, KATE	100008	06/01/99
SMITH, STACIA	100009	06/01/99
DOE, JANE	100010	06/01/99
BRUMBACH, KAREN	100011	06/01/99
DAVIS, EMILY	100012	06/01/99

Figure 7

Figure 8

Edit Screening Data Frame:

The Editing Screening Data section of the application is very similar to the Address Entry section previously described. The user is asked to search by mother's name or by mother's screening number. The user is then presented with the Toolbar, Extended Text Entry, and Data Table for searching by name and the Extended Text Entry and Data Table for searching by number. The SCL behind the search frames are identical to the SCL used in the Address Entry search frames for calling the frame with the Data Form. The Edit frame consists of a Data Form identical to the Data Form used to enter the demographics except for the mother's laboratory data displayed at the bottom of the form. All fields are unprotected so changes may be made to the observation. The SCL for this frame and the Address Entry frame are the same. Both frames enable a single observation to be displayed on the Data Form using the `_SET_INSTANCE_METHOD_` and the `_SELECT_` methods. The SCL for the Edit Data Form is similar to the SCL for the Data Form for Entering Demographics except the fields are not set to missing. The SCL Code has also been added to the Edit Data Form to check the values for the test date and CMV laboratory test (IMX) fields. A positive or negative result is automatically filled in based on the value entered in the IMX field. The Command Push Buttons are the same as on the Demographics Entry Data Form.

Post Test Results Frame:

In this section the laboratory personnel enter the results for the CMV tests that were completed for the mothers and babies screened in the hospital. The user is presented with two choices, either enter "Maternal CMV Screening" results or enter "Newborn CMV Screening" results. The paths the two options take are nearly identical leading to another menu asking how the user would like to search, by mother's name or by screening number. Again, the search frames and SCL have been previously described for the Address Entry and Editing the Screening Data frames. However, the Data Forms presented after the search for the observation are different since different information is needed for entering laboratory results.

The Data Form for the Maternal CMV Result has the demographic information for the observation filled in and only the test date, and CMV test results (IMX value, and IMX result) are entered (Fig. 9). The positive or negative result is calculated in the SCL for the Data Form based on the IMX value entered. The demographic data fields on the form are protected and the user may only access the test date and CMV test fields. Once the user has recorded the laboratory results for the observation they may proceed using the Command Push Buttons.

Figure 9

The Data Form for the Newborn CMV Results has the demographic information for the observation filled in and only the test date, gender of the infant, infant's medical record number, and infant's test result are entered by the user. The demographic data fields are protected and the user only has access to the fields for recording the infant and test result information.

Lists and Data Menu Frame:

Once the demographic information, addresses, and laboratory results are entered into the application, lists and letters may be generated. The Lists and Data menu frame allows the user to print listings or save data sets by selecting either the "Print Listings" or "Save Data Sets" Icon on the frame (Fig 10).

Figure 10

Print Listings Frame:

Upon selection of the "Print" Icon, the user is able to generate either a listing of participants screened or a list of CMV laboratory results for participants. Both choices are similar and only differ in the output generated. The following paragraph describes only the screening listing frame.

Screening Listing Frame:

Once the user enters the demographic information on the participants, a list may be generated recording all the forms entered that day. The objects on the frame are a Radio Box that selects the choice of hospital and Input Fields for recording the screening number range requested by the user (Fig. 11). The "Print" Icon is pressed after the user has selected the hospital and the range generating the requested print out. A Command Push Button is used for exiting the frame.

Figure 11

The SCL for the frame primarily controls the "Print" Icon. When the "Print" Icon is pressed by the user the data is subsetted by the hospital selected by the user. The data is further subsetted by screening ID number using a WHERE command within a Submit Continue block. Finally, the data is sorted by hospital and screening ID number and the PROC PRINT command is issued listing the labels and variables for the report.

Save Data Sets Frame:

The main menu for saving data sets gives the user six different data sets that may be created from the demographic information, address and laboratory data already entered into the application (Fig. 12). The widgets and SCL used are very similar so only the generation of the positive letter data set will be described below.

Positive Letters Frame:

The purpose of this frame is to create a data set that contains the name and addresses of all participants who were CMV positive for a specific time frame. The created data set is then imported into WordPerfect to be used to generate letters to mail the CMV positive test results to the participants (Fig. 12). The widgets on the frame consist of Input fields for recording the screening ID number, an Icon that initiates the SCL creating the data set, Graphic Text objects for displaying the text on the frame and a Command Push Button for exiting the frame.

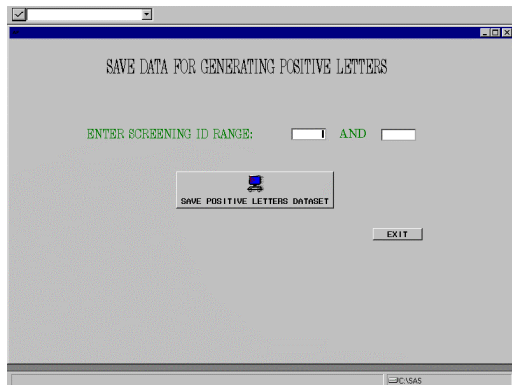


Figure 12

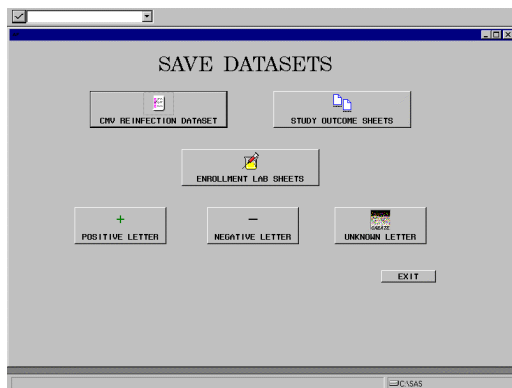


Figure 13

The letters are generated and mailed weekly to participants. The data sets for the letters are subsetting by time frame and by CMV test results. Once the Icon is pressed the SCL for the frame is initiated within a SUBMIT CONTINUE routine. The data set is called and subsetting by the screening ID range entered and by a CMV test result equal to positive. The name, address, screening ID number, and test result variables are kept and the new data set is saved as a DBF file for importing into WordPerfect®. Once the data set is saved the user exits the application and opens WordPerfect®. A WordPerfect® macro that imports the DBF file creating a WordPerfect® data file and merges the data with the positive form letter is executed (Fig. 14). These letters can then be printed and mailed to the women.

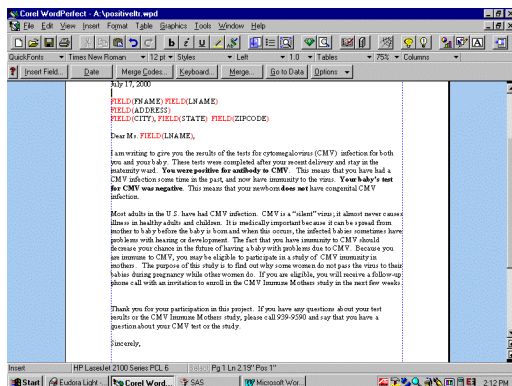


Figure 14

Visit Outcome Menu Frame:

Information of whether a woman enrolls in a study or the reason she does not participate in a study is recorded in the Visit Outcome section of the application. Upon entering this section of the application, the user may choose to record "CMV Immunity Study" outcomes or "Vaccine Study" outcomes by selecting the appropriate Icon. The methods, widgets, and SCL for recording outcomes for either study are very similar. We will discuss the "Vaccine Study" section in more detail below:

Vaccine Study Outcomes Frame:

The menu frame for entering visit outcomes for the vaccine study allows the user to select either a search by name frame or screening number frame. These search frames use the same methods and subclasses of Toolbar, Extended Text Entry, and Data Table as previously discussed in this paper.

Report Visit Outcome Frame:

Once an observation is selected in the Data Table, the report visit outcome frame is called where the user can enter an outcome for the observation selected (Fig. 15). Demographic information appears on the frame for the user to verify they have selected the correct individual. These Input Fields are protected and the user is prompted to begin entering information at the enrollment date Input Field. The enrollment date, patient's study number (PIN), and initials Input fields are completed if the woman is enrolled (indicated by outcome=1). Otherwise these fields are skipped and only the outcome code is entered for the observation. Should the user need to review of the codes for outcome the "Help" Icon calls a help screen. The user continues entering data using either the Command Push Buttons to cancel or exit the frame.

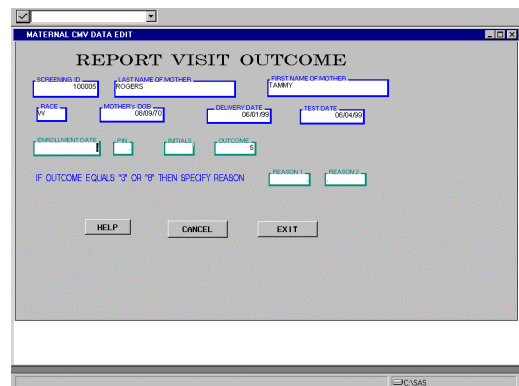


Figure 15

CONCLUSION

The use of a SAS/AF® Frame Application enables the entry, editing and generating of letters and lists to be easily accomplished by all study personnel. The application streamlines routine daily and weekly study activities for the three research studies in our department. Also the application is simple to use for users with little computer experience. An application of this type could easily be revised for use in the data management of other research studies.

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