

An Interactive Randomization Program

Diane L Fairclough, DrPH

University of Colorado Denver
School of Medicine

Diane.Fairclough@uchsc.edu

Setting and Goals

Setting:

1. Multicenter Randomized Clinical Trial
2. Two alternative therapies
3. Multiple therapists, some qualified to deliver only one of the therapies

Goals:

1. Registration of subject
2. Random assignment of treatment
3. Assignment of therapist
4. Notification of therapist
5. Interactive and efficient

SAS Application

- Single SAS program which utilizes ...
 - **Windows Interface** and **Global Macro Variables** to collect information about new subject
 - **Import** to obtain randomization history
 - **Data steps** and **Procs** to generate random assignments
 - **Filename MAIL email** to notify therapist
 - **Export** to update randomization history
 - **Macros** to organize the steps

- Interacts with ACCESS database

•

StudyID	RandID	Site	Strata	TxGroup	RandDate	RandUser	TherInit	Active	Initials	AgeYr	Strata1	Strata2
502	1001	1	2	2	10/4/2007	eva	AC	1	GJ	17	1	1
505	1002	1	4	1	10/10/2007	eva	EI	1	RS	14	1	2
506	1003	1	4	1	11/15/2007	eva	DH	1	RS	17	1	2
515	1004	1	2	2	11/13/2007	eva	ES	1	TB	17	1	1
522	1005	1	3	1	11/21/2007	eva	EI	1	MI	12	1	2
519	1006	1	3	1	11/21/2007	eva	EI	1	LM	12	1	2
523	1007	1	3	2	11/26/2007	eva	AC	1	LJ	11	1	2
521	1008	1	4	2	11/26/2007	eva	DH	1	SS	16	1	2
533	1009	1	4	2	11/30/2007	eva	DH	1	AC	13	1	2
538	1010	1	4	2	12/12/2007	eva	ES	1	mb	16	1	2
545	1011	1	3	2	12/12/2007	eva	AC	1	hd	12	1	2
556	1012	1	7	1	1/25/2008	eva	MD	1	CF	12	2	2
560	1013	1	4	1	2/5/2008	eva	ES	1	NC	16	1	2
562	1014	1	3	1	2/13/2008	eva	AC	1	MN	12	1	2
559	1015	1	4	2	2/22/2008	eva	EI	1	ad	16	1	2
572	1016	1	3	1	2/25/2008	eva	DH	1	mw	9	1	2
578	1017	1	2	1	2/27/2008	eva	EI	1	MB	15	1	2

Therapists

4/7/2008

TherID	TherInit	TherMax	TherCBT	TherSNDT	TherEmail	TherFirst	TherLast
1	ES	5	0.5	0.5	'EllenS@upmc.edu'	Ellen	Sxxxxx
2	MD	3	1	0	'MarkD@upmc.edu'	Matt	Dxxxxx
3	EI	3	1	0	'Eval@chp.edu'	Eva	lxxxxx
4	JW	0	0	0	'JaneW@med.umich.edu'	Jane	Wxxxxx
5	AC	3	0.5	0.5	'AurtherC@pitt.edu'	Aurther	Cxxxxx
6	DH	5	0	1	'DebbiH@upmc.edu'	Debbi	Hxxxxx
7	LG	5	1	0	'LeslieG@upmc.edu'	Leslie	Gxxxxx
8	CF	2	0.5	0.5	'CindyF@upmc.edu'	Cindy	Fxxxxx

Organization - Macros

Login	}	Runall
GetData		
NewData		
Balance		
AssgnTher		
Update		

```
%macro RunAll;
  %Login;
  *** Check Password ***;
  %if %upcase(&PW)=RANDOM %then %do;
    * Reads data from ACCESS Database *;
    %GetData;
    * Queries data on new subject *;
    %Newdata;
    *** Randomize new subject ***;
    %if %upcase(&Confirm)=Y %then %do;
      %Balance;      * Assign therapy *;
      %AssgnTher;   * Assign therapist *;
      %Update;      * Update database *;
    %end;
  %end;
%mend;
```

Windows Interface - Login

Obtains user name, password and site

```
%macro Login; *** User login ***;
  *** Declares global macro variables USER, PW and Site ***;
  %global USER PW Site;

  *** Queries User Name, PW and Site ***;
  %window interface1 color=yellow
  #5 @15 "*** Randomization Program ***"
  #7 @15 "Please type in your username and password"
  #9 @15 'User Name:                ' +1 USER 6 ATTR=UNDERLINE REQUIRED=YES
  #11 @15 'Password:                 ' +1 PW 6 ATTR=UNDERLINE REQUIRED=YES DISPLAY=
  #13 @15 'Site (1=Pitt,2=Boston)' +1 SITE 1 ATTR=UNDERLINE REQUIRED=YES
  #24 @15 "Press ENTER to continue";
  %display interface1;
%mend;
```

Windows Interface - NewData

```
%macro NewData;
  *** Declares global macro variables ***;
  %global StudyID Initials Strata1 Strata2 AgeYr Confirm;
  *** Queries Data on Child to be Randomized ***;
  %window interface2 color=grey
  #5 @15 "*** Randomization Program (Cont) ***"
  #7 @15 "Please type in the following information"
  #8 @15 'Childs Study ID:                ' +1 StudyID 3 ATTR=UNDERLINE REQUIRED=
  #9 @15 'Childs Initials:                 ' +1 Initials 3 ATTR=UNDERLINE REQUIRED=
  #10 @15 'Diagnosis (1=Crohns D 2=Colitus):' +1 Strata1 1 ATTR=UNDERLINE REQUIRED=
  #11 @15 'Sub-Syndromal(1) or Syndormal(2)' +1 Strata2 1 ATTR=UNDERLINE REQUIRED=
  #12 @15 'Age in Years (9-17 only):       ' +1 AgeYr 2 ATTR=UNDERLINE REQUIRED=
  #15 @15 'Have all eligability requirement been satisfied?'
  +2 Confirm 1 ATTR=UNDERLINE REQUIRED=Yes
  #20 @15 "Press ENTER to continue";
  %display interface2;
```

```

*** Creates messages when entries are incorrect ***;
window ReEnter color=grey
group=problem1
  #3 @15 'Diagnosis must be either 1=Crohns D 2=Colitus'
  #4 @15 "Delete and ReEnter:" +1 Strata1 1. ATTR=UNDERLINE REQUIRED=YES
  #6 @15 "Press ENTER to continue"
group=problem2
  #9 @15 'Severity must be either 1=Sub-Syndromal or 2=Syndormal'
  #10 @15 "Delete and ReEnter:" +1 Strata2 1. ATTR=UNDERLINE REQUIRED=YES
  #12 @15 "Press ENTER to continue"
group=problem3
  #15 @15 'Age in Years must be between 9 and 17'
  #16 @15 'Press Delete x2 and ReEnter:' +1 AgeYr 2. ATTR=UNDERLINE REQUIRED=YI
  #18 @15 "Press ENTER to continue" ;

*** Compute Strata and Send Message if a problem ***;
Strata1=&Strata1+0; * Site *;
if &Strata1 ^in(1,2) then display ReEnter.Problem1;
Strata2=&Strata2+0; * Severity *;
if &Strata2 ^in(1,2) then display ReEnter.Problem2;
AgeYr=&AgeYr+0;
if &AgeYr <9 or &AgeYr>17 then display ReEnter.Problem3;
Strata3=(9<=AgeYr<=12)+(13<=AgeYr<=17)*2; * Age Group *;

```

Randomization

1. Get # in each group for stratum
2. Calculate the Balance: # in Group 1 - # in Group 2
3. Generate random value from uniform distribution
4. Compare that value with (.5-balance*2)

Balance	-2	-1	0	1	2
.5-balance*2	.9	.7	.5	.3	.1

```

*** Generates random number and assignment ***;
balance=TxGroup1-TxGroup2;
random=ranuni(int(Time())); * Random Number *;
if random le (.5-balance*.2) then TxGroup=1;
else TxGroup=2;

```

Notification - Window

```

*** Selects address of assigned Therapist and Creates a Macro Variable TherLIST ***;
data addcontacts;
  merge work.Therapist work.Ther4(in=ok);
  by TherInit;
  if ok;
  CALL SYMPUT('TherLIST',TherEmail); run;

data addcontacts;
  merge addcontacts work.random;
  rename Select=Active;
*** Displays the results ***;
window ShowRan color=yellow
  #5 @10 "The assigment for:"
    +1 Initials PROTECT=YES AUTOSKIP=YES
    +2 "Study ID:" +1 StudyID PROTECT=YES AUTOSKIP=YES
    +2 "is" +1 TxGroup PROTECT=YES AUTOSKIP=YES
  #7 @10 "Diagnosis:" +1 Strata1 PROTECT=YES AUTOSKIP=YES
    +3 "Severity: " +1 Strata2 PROTECT=YES AUTOSKIP=YES
    +3 "Age (yrs):" +1 AgeYr PROTECT=YES AUTOSKIP=YES
  #10 @10 "The assigned therapist is:"
    +2 TherFirst PROTECT=YES AUTOSKIP=YES
    +2 TherLast PROTECT=YES AUTOSKIP=YES
  #12 @15 "who currently has"
    +1 TherActive PROTECT=YES AUTOSKIP=YES
    +1 "patients"
  #18 @10 "Type ENTER to continue";
display ShowRan; run;

```

Notification - E mail

```

*** Sends E-mail Message to Therapist and PI ***;
FILENAME MAIL EMAIL EMAILSYS=MAPI
  TO=("&TherLIST")
  CC=("szigethye@upmc.edu")
  From=("diane.fairclough@uchsc.edu")
  SUBJECT="New Randomization"
  ;
Data _NULL_;
  Set Addcontacts;
  File MAIL;
  Put @1 TherFirst "-";
  Put @4 "You have been assigned patient"
    +1 Initials
    +1 "(Study ID " StudyID)";
  Put @4 "who has been assigned to the " TxGroup txgroup.;
  Put @14 "Diagnosis:" +1 Strata1;
  Put @14 "Severity: " +1 Strata2;
  Put @14 "Age (yrs):" +1 AgeYr;
run;

```

Fairclough, Diane

From: Szigethy, Eva [szigethy@upmc.edu]
To: szigethy@upmc.edu
Cc: Fairclough, Diane
Subject: New Randomization
Attachments:

Sent: Mon 24-Mar-08 1:38 PM

Eva -

You have been assigned patient bs (Study ID 589)
who has been assigned to the SNTD
Diagnosis: Crohns
Severity: Syndromal
Age (yrs): 17

Summary

- **Macro variables, Windows Interfaces, Filename Mail can produce very interactive, user friendly applications**
 - **User running this program has NO SAS training!**
- **SAS versus ACCESS or Excel database**