An Introduction to the Development and Implementation of a Longitudinal Health Survey: The ABCs

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Cardiac Surgery Research

Inova Heart & Vascular Institute

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Overview of Course & Welcome Remarks

Team Member Introductions

- Lisa M. Martin, MA, PhDc – Manager, Biostatistics & Epidemiology and Research Administrator
- Sharon L. Hunt, MBA – Senior Database Administrator
- Linda L. Henry, PhD, RN – Clinical Research Administrator
- Scott D. Barnett, PhD – Manager, Epidemiology & Biostatistics
- Eder Lemus, MA – Research Assistant
- Niv Ad, MD – Director
- Research Project Associate – TBD

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Participant Introductions

- Warm-Up Exercise
  - Name
  - Affiliation
  - Background
  - Why did you come to this course?

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Overview of Course & Welcome Remarks

Learning Objectives

- #1 Upon completion of this course, the participant will be able to list and discuss the essential elements involved in designing and implementing an intensive longitudinal study that combines clinical and health survey data.
- #2 Upon completion of this course, the participant will be able to discuss the challenges and limitations in data collection and management of a longitudinal study that combines clinical and health survey data.
- #3 Upon completion of this course, the participant will demonstrate an understanding of the process necessary to develop and implement a survey based longitudinal study.

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Overview of Course & Welcome Remarks

Purpose

- To present the mechanisms needed to design and implement a successful longitudinal health survey research study that uniquely combines health-related quality of life (HRQL) data with ongoing clinical data.
- What are the necessary elements to consider?
  - Overall resources, design, questionnaires, data collection implementation, data management, usage of clinical data, reporting of results
- What are the benefits to a longitudinal health survey design?
- What are the challenges to a longitudinal health survey design?
- What are some ways to overcome the challenges?

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Designing a Longitudinal Health Survey Study: Overview & How to Begin

Presented By:
Lisa M. Martin, MA, PhD Candidate

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Design

- Case Control
  - One type of epidemiological study design used to identify factors that may contribute to a medical condition by comparing a group of patients who have that condition with a group of patients that do not
  - Less-expensive, can be carried out by small teams or individual researchers in single facilities
  - Case-control studies use patients who already have a disease or other condition and look back to see if there are characteristics of these patients that differ from those who don't have the disease

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Design

- Cross-Sectional
  - Also known as Cross-sectional analysis - class of research methods that involve observation of some subset of a population of items all at the same time, in which, groups can be compared at different ages with respect of independent variables, such as IQ and memory
  - Fundamental difference between cross-sectional and longitudinal studies
    - Cross-sectional studies take place at a single point in time
    - Longitudinal study involves a series of measurements taking over a period of time
  - Cross-sectional studies are used in most branches of science, in the social sciences and in other fields as well

Designing a Longitudinal Health Survey Study: Overview & How to Begin

Design

- Longitudinal
  - Correlational research study that involves repeated observations of the same items over long periods of time, often many decades
  - Unlike cross-sectional studies, longitudinal studies track the same people, and therefore the differences observed in those people are less likely to be the result of cultural differences across generations
  - Used in medicine to uncover predictors of certain diseases
  - Repeated observation at the individual level means more power than cross-sectional observational studies
    - Ability to exclude time-invariant unobserved individual differences

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Design

- Longitudinal
  - Allow social scientists to distinguish short from long-term phenomena
  - Types include cohort studies and panel studies.
    - Cohort = defined as a group experiencing some event (birth, event) in a selected time period, and studying them at intervals through time
    - Panel = cross-sectional and survey it at (usually regular) intervals
  - A retrospective study is a longitudinal study that looks back in time. For instance a researcher may look up the medical records of previous years to look for a trend

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Design

- Longitudinal
  - Decisions to Make
    - How long do you want the study follow-up to be?
    - At what time points is it logical to collect your data?
    - What is feasible?
      - Goes along with available resources to be discussed shortly

Designing a Longitudinal Health Survey Study: Overview & How to Begin

Design

- Institutional Review Board (IRB)

  Subject Protection
  - Is your study ethical?
  - Is there potential harm to the subject?
  - Are your subjects properly protected?
  - Will you need to consent the subjects?
  - Internal versus External IRB
  - Multiple site studies typically require the study to be IRB approved at all sites
  - Online training course for certification
    - NIH = http://cme.cancer.gov/c01/nih_intro_01.htm

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Things to Consider

- Resources
  - Budget
    - Personnel
      - Enrollment, data management, clinical, data analysis
    - Supplies
      - Paper, printing, envelopes, labels, postage (out & return), long-distance phone charges, licensing fees for questionnaires, incentives, computer hardware & software, etc.
      - Baseline and longitudinally (which grows exponentially over time)

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Things to Consider

- Ways to Increase Response Rate
  - Incentives
    - Gift card giveaway; something to include with mailing, etc.
  - Keep in Touch Letters
    - At interval time points when no survey is due
  - Thank You Postcards
    - Thanking them for their response to the survey

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Things to Consider

- Ways to Increase Response Rate
  - Reminder Postcards
    - 2 Weeks after mailing when they have not responded
  - Follow-Up Phone Calls
    - 2 Weeks after mailing begin phone calls to subjects
  - Re-Sending of Surveys
    - Re-send surveys after a pre-determined time of no-response

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	Week One	Week Two	Week Three	Week Four
Baseline Data Collection	M T W Th F	M T W Th F	M T W Th F	M T W Th F
SF-12 Schedule Data Entry				
Maze 3 Month Phone Calls				
Maze 3 Month Check—Apollo				
Data Entry — Baseline				
Data Entry — F/U				
CSR Voice Mailbox				
Reminder Postcard Mailing				
Monthly Phone F/U for no returns				
Re-Sending of Maze Forms if No Response				
Phone Call Reconcilliation — F/U				
Response Book Data Entry				
Monthly F/U Mailing				
Preparation for next month's mailing				

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	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	AA
1		Year 1													Year 2												
2		09-05	10-05	11-05	12-05	01-06	02-06	03-06	04-06	05-06	06-06	07-06	08-06	Year Total	09-06	10-06	11-06	12-06	01-07	02-07	03-07	04-07	05-07	06-07	07-07	08-07	Year Total
3	Cardiac Study Recruitment	21	47	46	47	34	23	35	24	21	21	14	25	358	50	50	50	50	50	50	50	50	50	50	50	50	600
4	Maze Study Recruitment	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
5	**Total**	**31**	**57**	**56**	**57**	**44**	**33**	**45**	**34**	**31**	**31**	**24**	**35**	**478**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**720**
6	Cardiac 6 Month Follow-Up							21	47	46	47	34	23	218	35	24	21	21	14	25	50	50	50	50	50	50	440
7	Cardiac 3 Month KIT Letter				21	47	46	47	34	23	35	24	21	298	21	14	25	50	50	50	50	50	50	50	50	50	50	510
8	Cardiac 12 Month Follow-Up													0	21	47	46	47	34	23	35	24	21	21	14	25	358
9	Cardiac 18 Month KIT Letter													0							21	47	46	47	34	23	218
10	Cardiac 24 Month Follow-Up													0													0
11	Cardiac 30 Month KIT Letter													0													0
12	Cardiac 36 Month Follow-Up													0													0
13	Cardiac 42 Month KIT Letter													0													0
14	Cardiac 48 Month Follow-Up													0													0
15	Cardiac 54 Month KIT Letter													0													0
16	Cardiac 60 Month Follow-Up													0													0
17	**rdiac Follow-Up Total**	**0**	**0**	**0**	**21**	**47**	**46**	**68**	**81**	**69**	**82**	**58**	**44**	**516**	**77**	**85**	**92**	**118**	**98**	**98**	**156**	**171**	**167**	**168**	**148**	**148**	**1526**
18	Maze 3 Month Follow-				10	10	10	10	10	10	10	10	10	90	10	10	10	10	10	10	10	10	10	10	10	10	120
19	Maze 6 Month Follow-							10	10	10	10	10	10	60	10	10	10	10	10	10	10	10	10	10	10	10	120
20	Maze 9 Month Follow-										10	10	10	30	10	10	10	10	10	10	10	10	10	10	10	10	120
21	Maze 12 Month Follow-													0	10	10	10	10	10	10	10	10	10	10	10	10	120
22	Maze 18 Month Follow-													0							10	10	10	10	10	10	60
23	Maze 24 Month Follow-													0													0
24	Maze 30 Month KIT													0													0
25	Maze 36 Month Follow-													0													0
26	Maze 42 Month KIT													0													0
27	Maze 48 Month Follow-													0													0
28	Maze 54 Month KIT													0													0
29	Maze 60 Month Follow-													0													0
30	**Total**	**0**	**0**	**0**	**10**	**10**	**10**	**20**	**20**	**20**	**30**	**30**	**30**	**180**	**40**	**40**	**40**	**40**	**40**	**40**	**50**	**50**	**50**	**50**	**50**	**50**	**540**
31																											
32	**Monthly Follow-Up**	**0**	**0**	**0**	**31**	**57**	**56**	**88**	**101**	**89**	**112**	**88**	**74**	**696**	**117**	**125**	**132**	**158**	**138**	**138**	**206**	**221**	**217**	**218**	**198**	**198**	**2066**
33																											
34																											
35	**Overall Monthly**	**31**	**57**	**56**	**88**	**101**	**89**	**133**	**135**	**120**	**143**	**112**	**109**	**1174**	**177**	**185**	**192**	**218**	**198**	**198**	**266**	**281**	**277**	**278**	**258**	**258**	**2786**
36																											
37																											
38																											
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SF-12 Budget-2005-2006 | SF-12 Budget Sept 2006-Aug 2012 | **Numbers Timeline 2005-2011**

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	A	AB	AC	AD	AE	AF	AG	AH	AI	AJ	AK	AL	AM	AN	AO	AP	AQ	AR	AS	AT	AU	AV	AW	AX	AY	AZ	BA
1		Year 3													Year 4												
2		09-07	10-06	11-07	12-07	01-08	02-08	03-08	04-08	05-08	06-08	07-08	08-08	Year Total	09-08	10-08	11-08	12-08	01-09	02-09	03-09	04-09	05-09	06-09	07-09	08-09	Year Total
3	*Cardiac Study Recruitment*	50	50	50	50	50	50	50	50	50	50	50	50	600	50	50	50	50	50	50	50	50	50	50	50	50	600
4	*Maze Study Recruitment*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
5	**Total**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**720**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**720**
6	*Cardiac 6 Month Follow-Up*	50	50	50	50	50	50	50	50	50	50	50	50	600	50	50	50	50	50	50	50	50	50	50	50	50	600
7	*Cardiac 3 Month KIT Letter*	50	50	50	50	50	50	50	50	50	50	50	50	600	50	50	50	50	50	50	50	50	50	50	50	50	600
8	*Cardiac 12 Month Follow-Up*	50	50	50	50	50	50	50	50	50	50	50	50	600	50	50	50	50	50	50	50	50	50	50	50	50	600
9	*Cardiac 18 Month KIT Letter*	35	24	21	21	14	25	50	50	50	50	50	50	440	50	50	50	50	50	50	50	50	50	50	50	50	600
10	*Cardiac 24 Month Follow-Up*	21	47	46	47	34	23	35	24	21	21	14	25	358	50	50	50	50	50	50	50	50	50	50	50	50	600
11	*Cardiac 30 Month KIT Letter*							21	47	46	47	34	23	218	35	24	21	21	14	25	50	50	50	50	50	50	440
12	*Cardiac 36 Month Follow-Up*													0	21	47	46	47	34	23	35	24	21	21	14	25	358
13	*Cardiac 42 Month KIT Letter*													0							21	47	46	47	34	23	218
14	*Cardiac 48 Month Follow-Up*													0													0
15	*Cardiac 54 Month KIT Letter*													0													0
16	*Cardiac 60 Month Follow-Up*													0													0
17	**Cardiac Follow-Up Total**	**206**	**221**	**217**	**218**	**198**	**198**	**256**	**271**	**267**	**268**	**248**	**248**	**2816**	**306**	**321**	**317**	**318**	**298**	**298**	**356**	**371**	**367**	**368**	**348**	**348**	**4016**
18	*Maze 3 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
19	*Maze 6 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
20	*Maze 9 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
21	*Maze 12 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
22	*Maze 18 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
23	*Maze 24 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
24	*Maze 30 Month KIT Letter*							10	10	10	10	10	10	60	10	10	10	10	10	10	10	10	10	10	10	10	120
25	*Maze 36 Month Follow-Up*													0	10	10	10	10	10	10	10	10	10	10	10	10	120
26	*Maze 42 Month KIT Letter*													0							10	10	10	10	10	10	60
27	*Maze 48 Month Follow-Up*													0													0
28	*Maze 54 Month KIT Letter*													0													0
29	*Maze 60 Month Follow-Up*													0													0
30	**Maze Follow-Up Total**	**60**	**60**	**60**	**60**	**60**	**60**	**70**	**70**	**70**	**70**	**70**	**70**	**780**	**80**	**80**	**80**	**80**	**80**	**80**	**90**	**90**	**90**	**90**	**90**	**90**	**1020**
31																											
32	**Monthly Follow-Up**	**266**	**281**	**277**	**278**	**258**	**258**	**326**	**341**	**337**	**338**	**318**	**318**	**3596**	**386**	**401**	**397**	**398**	**378**	**378**	**446**	**461**	**457**	**458**	**438**	**438**	**5036**
33																											
34																											
35	**Overall Monthly Total**	**326**	**341**	**337**	**338**	**318**	**318**	**386**	**401**	**397**	**398**	**378**	**378**	**4316**	**446**	**461**	**457**	**458**	**438**	**438**	**506**	**521**	**517**	**518**	**498**	**498**	**5756**
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	A	BB	BC	BD	BE	BF	BG	BH	BI	BJ	BK	BL	BM	BN	BO	BP	BQ	BR	BS	BT	BU	BV	BW	BX	BY	BZ	CA
1		Year 5													Year 6												
2		09-09	10-09	11-09	12-09	01-10	02-10	03-10	04-10	05-10	06-10	07-10	08-10	Year Total	09-10	10-10	11-10	12-10	01-11	02-11	03-11	04-11	05-11	06-11	07-11	08-11	Year Total
3	*Cardiac Study Recruitment*	50	50	50	50	50	50	50	50	50	50	50	50	600	50	50	50	50	50	50	50	50	50	50	50	50	600
4	*Maze Study Recruitment*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
5	**Total**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**720**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**60**	**720**
6	*Cardiac 6 Month Follow-Up*	50	50	50	50	50	50	50	50	50	50	50	50	600	50	50	50	50	50	50	50	50	50	50	50	50	600
7	*Cardiac 3 Month KIT Letter*	50	50	50	50	50	50	50	50	50	50	50	50	600	50	50	50	50	50	50	50	50	50	50	50	50	600
8	*Cardiac 12 Month Follow-Up*	50	50	50	50	50	50	50	50	50	50	50	50	600	50	50	50	50	50	50	50	50	50	50	50	50	600
9	*Cardiac 18 Month KIT Letter*	50	50	50	50	50	50	50	50	50	50	50	50	600	50	50	50	50	50	50	50	50	50	50	50	50	600
10	*Cardiac 24 Month Follow-Up*	50	50	50	50	50	50	50	50	50	50	50	50	600	50	50	50	50	50	50	50	50	50	50	50	50	600
11	*Cardiac 30 Month KIT Letter*	50	50	50	50	50	50	50	50	50	50	50	50	600	50	50	50	50	50	50	50	50	50	50	50	50	600
12	*Cardiac 36 Month Follow-Up*	50	50	50	50	50	50	50	50	50	50	50	50	600	50	50	50	50	50	50	50	50	50	50	50	50	600
13	*Cardiac 42 Month KIT Letter*	35	24	21	21	14	25	50	50	50	50	50	50	440	50	50	50	50	50	50	50	50	50	50	50	50	600
14	*Cardiac 48 Month Follow-Up*	21	47	46	47	34	23	35	24	21	21	14	25	358	50	50	50	50	50	50	50	50	50	50	50	50	600
15	*Cardiac 54 Month KIT Letter*							21	47	46	47	34	23	218	35	24	21	21	14	25	50	50	50	50	50	50	440
16	*Cardiac 60 Month Follow-Up*													0	21	47	46	47	34	23	35	24	21	21	14	25	358
17	**Cardiac Follow-Up Total**	**406**	**421**	**417**	**418**	**398**	**398**	**456**	**471**	**467**	**468**	**448**	**448**	**5216**	**506**	**521**	**517**	**518**	**498**	**498**	**535**	**524**	**521**	**521**	**514**	**525**	**6198**
18	*Maze 3 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
19	*Maze 6 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
20	*Maze 9 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
21	*Maze 12 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
22	*Maze 18 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
23	*Maze 24 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
24	*Maze 30 Month KIT Letter*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
25	*Maze 36 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
26	*Maze 42 Month KIT Letter*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
27	*Maze 48 Month Follow-Up*	10	10	10	10	10	10	10	10	10	10	10	10	120	10	10	10	10	10	10	10	10	10	10	10	10	120
28	*Maze 54 Month KIT Letter*							10	10	10	10	10	10	60	10	10	10	10	10	10	10	10	10	10	10	10	120
29	*Maze 60 Month Follow-Up*													0	10	10	10	10	10	10	10	10	10	10	10	10	120
30	**Maze Follow-Up Total**	**100**	**100**	**100**	**100**	**100**	**100**	**110**	**110**	**110**	**110**	**110**	**110**	**1260**	**120**	**120**	**120**	**120**	**120**	**120**	**120**	**120**	**120**	**120**	**120**	**120**	**1440**
31																											
32	**Monthly Follow-Up**	**506**	**521**	**517**	**518**	**498**	**498**	**566**	**581**	**577**	**578**	**558**	**558**	**6476**	**626**	**641**	**637**	**638**	**618**	**618**	**655**	**644**	**641**	**641**	**634**	**645**	**7638**
33																											
34																											
35	**Overall Monthly Total**	**566**	**581**	**577**	**578**	**558**	**558**	**626**	**641**	**637**	**638**	**618**	**618**	**7196**	**686**	**701**	**697**	**698**	**678**	**678**	**715**	**704**	**701**	**701**	**694**	**705**	**8358**
36																											
37																											
38																											
39	KIT = Keep In Touch																										
40																											

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Cardiac Surgery Research

Designing a Longitudinal Health Survey Study: Overview & How to Begin

	A	B	C	D	E	F	J	K	L
1	**Budget for Follow-Up Study**	**Sept 2006-Aug 2007**	**Sept 2007-Aug 2008**	**Sept 2008-Aug 2009**	**Sept 2009-Aug 2010**	**Sept 2010-Aug 2011**			
2	**Questionnaire Administration and Long-Term Follow-Up**								
3	***Baseline (All Patients)***							2007-2008	
4	Questionnaire Copying ($0.04/sheet)	$28.80	$28.80	$28.80	$28.80	$28.80		Copying/Printing	$33.60
5	Letterhead ($60/box 500)	$86.40	$86.40	$86.40	$86.40	$86.40		Postage	$0.00
6	Readmission Magnet	$187.20	$187.20	$187.20	$187.20	$187.20		Office Supplies	$187.20
7	Maze Patient PHI Form Copying ($0.04/sheet)	$4.80	$4.80	$4.80	$4.80	$4.80		Letterhead	$86.40
8	Total	**$307.20**	**$307.20**	**$307.20**	**$307.20**	**$307.20**		Total	**$307.20**
9	***3 Month Follow-Up (Maze Patients)***								
10	Copying ($0.04/sheet)	$19.20	$19.20	$19.20	$19.20	$19.20			
11	Questionnaire Mailing Postage ($0.60/packet)	$72.00	$72.00	$72.00	$72.00	$72.00			
12	Questionnaire Return Postage ($0.32/piece)	$34.56	$34.56	$34.56	$34.56	$34.56		2007-2008	
13	Labels ($18.92/box 3000)	$7.56	$7.56	$7.56	$7.56	$7.56		Copying/Printing	$133.20
14	Letterhead ($60/box 500)	$14.40	$14.40	$14.40	$14.40	$14.40		Postage	$182.16
15	Mail-out Envelopes ($96/box 500)	$23.04	$23.04	$23.04	$23.04	$23.04		Office Supplies	$7.56
16	Return Envelopes (#10 $25/box 500)	$6.00	$6.00	$6.00	$6.00	$6.00		Letterhead	$43.44
17	Readmission Postcard	$33.60	$33.60	$33.60	$33.60	$33.60		Total	**$366.36**
18	Drawing Flyer	$2.40	$2.40	$2.40	$2.40	$2.40			
19	Thank You Postcard	$30.24	$30.24	$30.24	$30.24	$30.24			
20	Thank You Postcard Postage	$25.92	$25.92	$25.92	$25.92	$25.92			
21	No Reponse Postcard	$3.36	$3.36	$3.36	$3.36	$3.36			
22	No Reponse Postcard Postage	$2.88	$2.88	$2.88	$2.88	$2.88			
23	Drawing Announcement Postcard	$44.40	$44.40	$44.40	$44.40	$44.40			
24	Drawing Announcement Postcard Postage	$46.80	$46.80	$46.80	$46.80	$46.80			
25	Total	**$366.36**	**$366.36**	**$366.36**	**$366.36**	**$366.36**			
26	***3 Month Keep In Touch (Cardiac Patients)***							2007-2008	
27	Letterhead ($60/box 500)	$61.20	$72.00	$72.00	$72.00	$72.00		Copying/Printing	$0.00
28	Labels ($18.92/box 3000)	$3.21	$3.78	$3.78	$3.78	$3.78		Postage	$234.00
29	Mail-out Envelopes ($50/box 500)	$51.00	$60.00	$60.00	$60.00	$60.00		Office Supplies	$3.78
30	KIT Mailing Postage ($0.39/packet)	$198.90	$234.00	$234.00	$234.00	$234.00		Letterhead	$132.00
31	Total	**$314.31**	**$369.78**	**$369.78**	**$369.78**	**$369.78**		Total	**$369.78**

SF-12 Budget-2005-2006 | **SF-12 Budget Sept 2006-Aug 2012** | Numbers Timeline 2005-2011

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Cardiac Surgery Research

Designing a Longitudinal Health Survey Study: Overview & How to Begin

	Budget for Follow-Up Study	Sept 2006-Aug 2007	Sept 2007-Aug 2008	Sept 2008-Aug 2009	Sept 2009-Aug 2010	Sept 2010-Aug 2011			
32	*6 Month Follow-Up (Cardiac Patients)*								
33	Copying ($0.04/sheet)	$88.00	$120.00	$120.00	$120.00	$120.00			
34	Questionnaire Mailing Postage ($0.60/packet)	$264.00	$360.00	$360.00	$360.00	$360.00			
35	Questionnaire Return Postage ($0.32/piece)	$112.64	$153.60	$153.60	$153.60	$153.60		2007-2008	
36	Labels ($18.92/box 3000)	$41.58	$56.70	$56.70	$56.70	$56.70		Copying/Printing	$690.00
37	Letterhead ($60/box 500)	$52.80	$72.00	$72.00	$72.00	$72.00		Postage	$891.60
38	Mail-out Envelopes ($96/box 500)	$84.48	$115.20	$115.20	$115.20	$115.20		Office Supplies	$56.70
39	Return Envelopes (#10 $25/box 500)	$22.00	$30.00	$30.00	$30.00	$30.00		Letterhead	$217.20
40	Readmission Postcard	$123.20	$168.00	$168.00	$168.00	$168.00		Total	**$1,855.50**
41	Drawing Flyer	$8.80	$12.00	$12.00	$12.00	$12.00			
42	Thank You Postcard	$98.56	$134.40	$134.40	$134.40	$134.40			
43	Thank You Postcard Postage	$84.48	$115.20	$115.20	$115.20	$115.20			
44	No Reponse Postcard	$33.60	$33.60	$33.60	$33.60	$33.60			
45	No Reponse Postcard Postage	$28.80	$28.80	$28.80	$28.80	$28.80			
46	Drawing Announcement Postcard	$162.80	$222.00	$222.00	$222.00	$222.00			
47	Drawing Announcement Postcard Postage	$171.60	$234.00	$234.00	$234.00	$234.00			
48	Total	**$1,377.34**	**$1,855.50**	**$1,855.50**	**$1,855.50**	**$1,855.50**			
49	*6 Month Follow-Up (Maze Patients)*								
50	Copying ($0.04/sheet)	$24.00	$24.00	$24.00	$24.00	$24.00			
51	Questionnaire Mailing Postage ($0.60/packet)	$72.00	$72.00	$72.00	$72.00	$72.00			
52	Questionnaire Return Postage ($0.32/piece)	$34.56	$34.56	$34.56	$34.56	$34.56		2007-2008	
53	Labels ($18.92/box 3000)	$11.34	$11.34	$11.34	$11.34	$11.34		Copying/Printing	$138.00
54	Letterhead ($60/box 500)	$14.40	$14.40	$14.40	$14.40	$14.40		Postage	$182.16
55	Mail-out Envelopes ($96/box 500)	$23.04	$23.04	$23.04	$23.04	$23.04		Office Supplies	$11.34
56	Return Envelopes (#10 $25/box 500)	$6.00	$6.00	$6.00	$6.00	$6.00		Letterhead	$43.44
57	Readmission Postcard	$33.60	$33.60	$33.60	$33.60	$33.60		Total	**$374.94**
58	Drawing Flyer	$2.40	$2.40	$2.40	$2.40	$2.40			
59	Thank You Postcard	$30.24	$30.24	$30.24	$30.24	$30.24			
60	Thank You Postcard Postage	$25.92	$25.92	$25.92	$25.92	$25.92			
61	No Reponse Postcard	$3.36	$3.36	$3.36	$3.36	$3.36			
62	No Reponse Postcard Postage	$2.88	$2.88	$2.88	$2.88	$2.88			
63	Drawing Announcement Postcard	$44.40	$44.40	$44.40	$44.40	$44.40			
64	Drawing Announcement Postcard Postage	$46.80	$46.80	$46.80	$46.80	$46.80			
65	Total	**$374.94**	**$374.94**	**$374.94**	**$374.94**	**$374.94**			
66	*9 Month Follow-Up (Maze Patients)*								
67	Copying ($0.04/sheet)	$19.20	$19.20	$19.20	$19.20	$19.20			

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Designing a Longitudinal Health Survey Study: Overview & How to Begin

N334

	A	B	C	D	E	F	J	K	L
1	**Budget for Follow-Up Study**	**Sept 2006-Aug 2007**	**Sept 2007-Aug 2008**	**Sept 2008-Aug 2009**	**Sept 2009-Aug 2010**	**Sept 2010-Aug 2011**			
299	Labels ($18.92/box 3000)	N/A	N/A	N/A	N/A	$11.34		Copying/Printing	
300	Letterhead ($60/box 500)	N/A	N/A	N/A	N/A	$14.40		Postage	
301	Mail-out Envelopes ($96/box 500)	N/A	N/A	N/A	N/A	$23.04		Office Supplies	
302	Return Envelopes (#10 $25/box 500)	N/A	N/A	N/A	N/A	$6.00		Letterhead	
303	Readmission Postcard	N/A	N/A	N/A	N/A	$33.60		Total	
304	Drawing Flyer	N/A	N/A	N/A	N/A	$2.40			
305	Thank You Postcard	N/A	N/A	N/A	N/A	$30.24			
306	Thank You Postcard Postage	N/A	N/A	N/A	N/A	$25.92			
307	No Reponse Postcard								
308	No Reponse Postcard Postage								
309	Drawing Announcement Postcard	N/A	N/A	N/A	N/A	$44.40			
310	Drawing Announcement Postcard Postage	N/A	N/A	N/A	N/A	$46.80			
311	Total	**N/A**	**N/A**	**N/A**	**N/A**	**$374.70**			
312	***Miscellaneous***								
313	SF-12 Licensing Fee	$1,700.00	$1,700.00	$1,700.00	$1,700.00	$1,700.00			
314	SAS Licensing Fee	$1,000.00	$1,000.00	$1,000.00	$1,000.00	$1,000.00			
315	Long Distance Calling	$28.98	$28.98	$28.98	$28.98	$28.98			
316	Database Administrator Time	$39,175.20	$39,175.20	$39,175.20	$39,175.20	$39,175.20			
317	Nurse Administrator Time	$29,250.00	$29,250.00	$29,250.00	$29,250.00	$29,250.00			
318	Research Administrator Time	$20,340.00	$20,340.00	$20,340.00	$20,340.00	$20,340.00			
319	Ink Cartridges ($124.45/ea)	$373.35	$497.80	$622.25	$746.70	$871.15			
320	Visa Gift Card Giveaway	$600.00	$600.00	$600.00	$600.00	$600.00			
321	Charts (Maze Only)	$200.00	$200.00	$200.00	$200.00	$200.00			
322	Computer Hardware/Software	$2,000.00	$2,000.00	$2,000.00	$2,000.00	$2,000.00			
323	Total	$94,667.53	$94,791.98	$94,916.43	$95,040.88	$95,165.33			
324	***Project Setup***								
325	Initial Setup of Project (DA, RA, NA salaries)	$70,560.00							
326	**Total Costs**	$170,173.39	$103,042.75	$105,808.73	$108,574.72	$111,169.37			
327									
328									
329								**2007-2008 All Timepoints**	
330								**Copying/Printing**	**$2,712.24**
331								**Postage**	**$3,933.56**
332								**Office Supplies**	**$403.97**
333								**Letterhead**	**$1,201.00**
334								**Total**	**$8,250.77**

SF-12 Budget-2005-2006 | **SF-12 Budget Sept 2006-Aug 2012** | Numbers Timeline 2005-2011

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Data Collection and Management: Things to Consider

Presented By:

Sharon L. Hunt, MBA

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Management of Research Data

- Software and data management needs identified
- New data
  - Data selection and source
    - One record or many
  - Eliminate data redundancy
  - Data validation
  - Data collection form
  - Database development
- Merging old and new data
  - Linking fields
  - Consistent data definitions
- Updating research data
- Security
- Availability of data for other research

Software and Data Management Needs

1) Identify current data storage options and ability to export existing data
2) Database storage of new data and methods of exporting/importing data
3) Data management requirements
4) Data analysis requirements

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Software Recommendations

1) Excel
   - For importing/exporting or sharing files
2) Access
   - For easy database design and function
3) SAS or SPSS
   - Fairly easy data and dataset management
   - For statistical analysis

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Evaluation of New Data

Data selection and source

1) Identify actual data elements needed for entire project
2) Identify source(s) of data elements
3) Identify source(s) as one master, many detail records or combination of both
4) Reduce or eliminate data redundancy
5) Keep in mind data definitions
6) Begin formulating data validation process

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Data Collection Form

- Patient identifiers, time frame, date of original event
- Linking elements to existing data
- Include new data elements-
  - Keep in mind the way data is stored
    - Time frame of questions
    - Text vs. numeric
    - Size of fields
    - Format of fields in each software product
  - Keep in mind how the data is to be used-
    - Y/N versus the number of an event
    - Are dates of events required?
- As you design form keep in mind flow of questions for both the person completing survey and the person inputting the data

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Database Development

- Linking fields identified and formatted exactly same between all databases

  Try to establish system of importing data from original source versus hand entering
- May need to pull some data from existing database
- Layout of database should be the same as data collection form

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Database Development

- Consider types of users and identify security level for each user-some read only versus full rights
- Database should allow these options for full user-record editing, record duplication, adding new records, deleting records and undoing operations
- Begin field validations-set limits on fields but keep in mind this will ‘set limit’ on fields
- Begin formulating validation queries and establish a protocol for examining data

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Merging Old and New Data

- Identify all patient specific identifiers
  - Medical Record Number
  - Social Security Number
  - Event number
  - Sub-event number
  - Name
  - Date of event
  - Combination of above
- May need to create an identifier that is unique

Review Data Definitions and Selection Choices

- Review each offered data selection set
- Reconcile choices-
  - May need to create new choices
  - May need to eliminate choice

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Updating Research

- Always look ahead to updating data
  Continuously or set times for updates

- Is data coming in at specific times so you can estimate exactly how many records are needed?
- Is data arriving at multiple,

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Security

- Who has access to data and what level of access
- Back-ups

Availability of Data for Other Research

If the database is developed correctly it should be a source for all related research

- ✓ This is totally dependent on linking parameters, quality of the data and the ability to export/import data
- ✓ Ultimately the greatest complement you can have as a data manager is to have your data requested and available for all research endeavors

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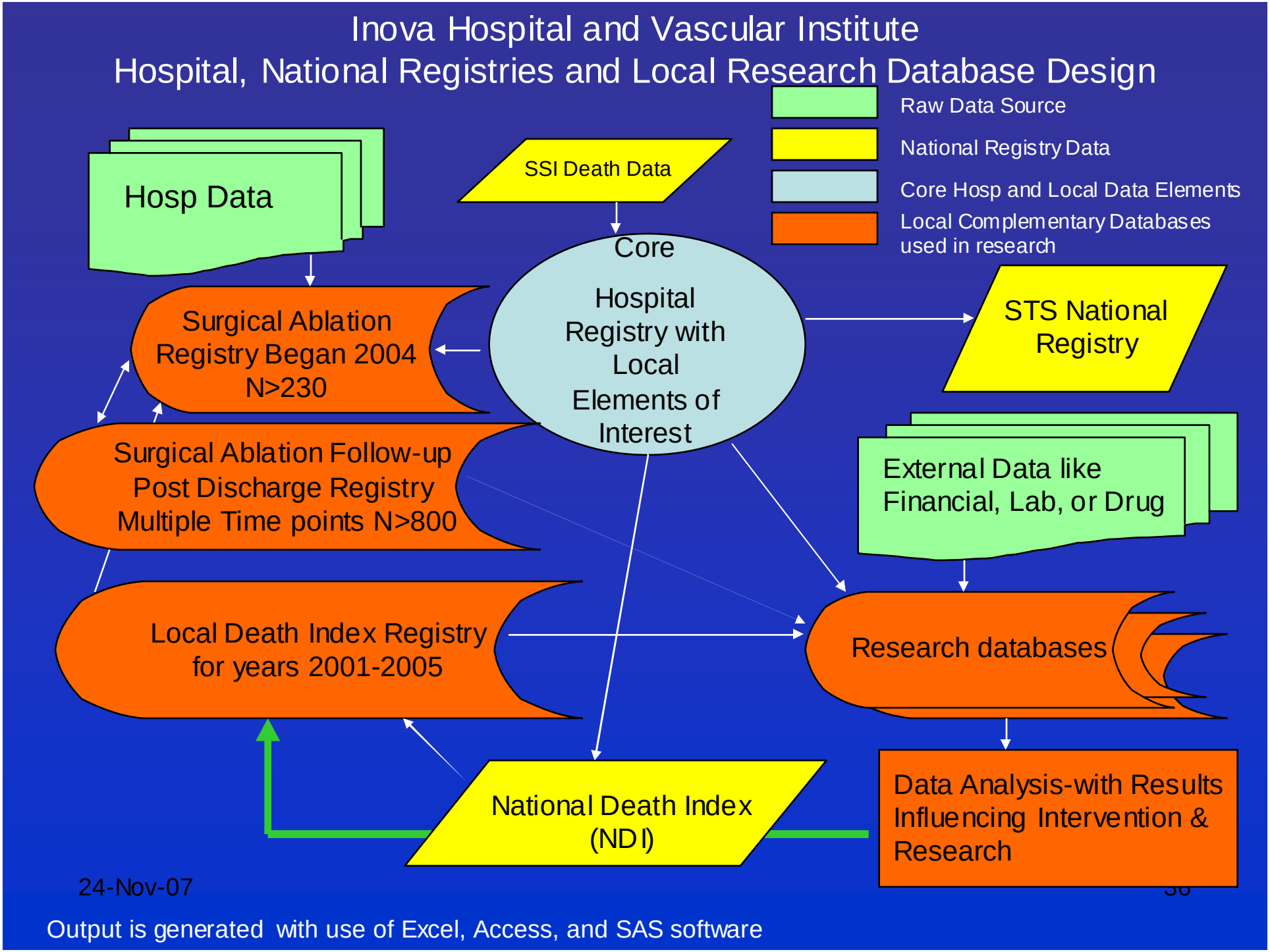
Hospital, National Registries and Local Research Database Design



24-Nov-07

Output is generated with use of Excel, Access, and SAS software

Example of Registry Database

- Allows for collection of pre-surgery data specific to this group of patients - history of afib with dates and treatments, history of embolic events, atrium measurements…
- Allows for SF-12 follow-up at specific time points and clinical follow-up as needed-repeated events
- Updated almost continuously
- Merged with core STS Registry data for analysis

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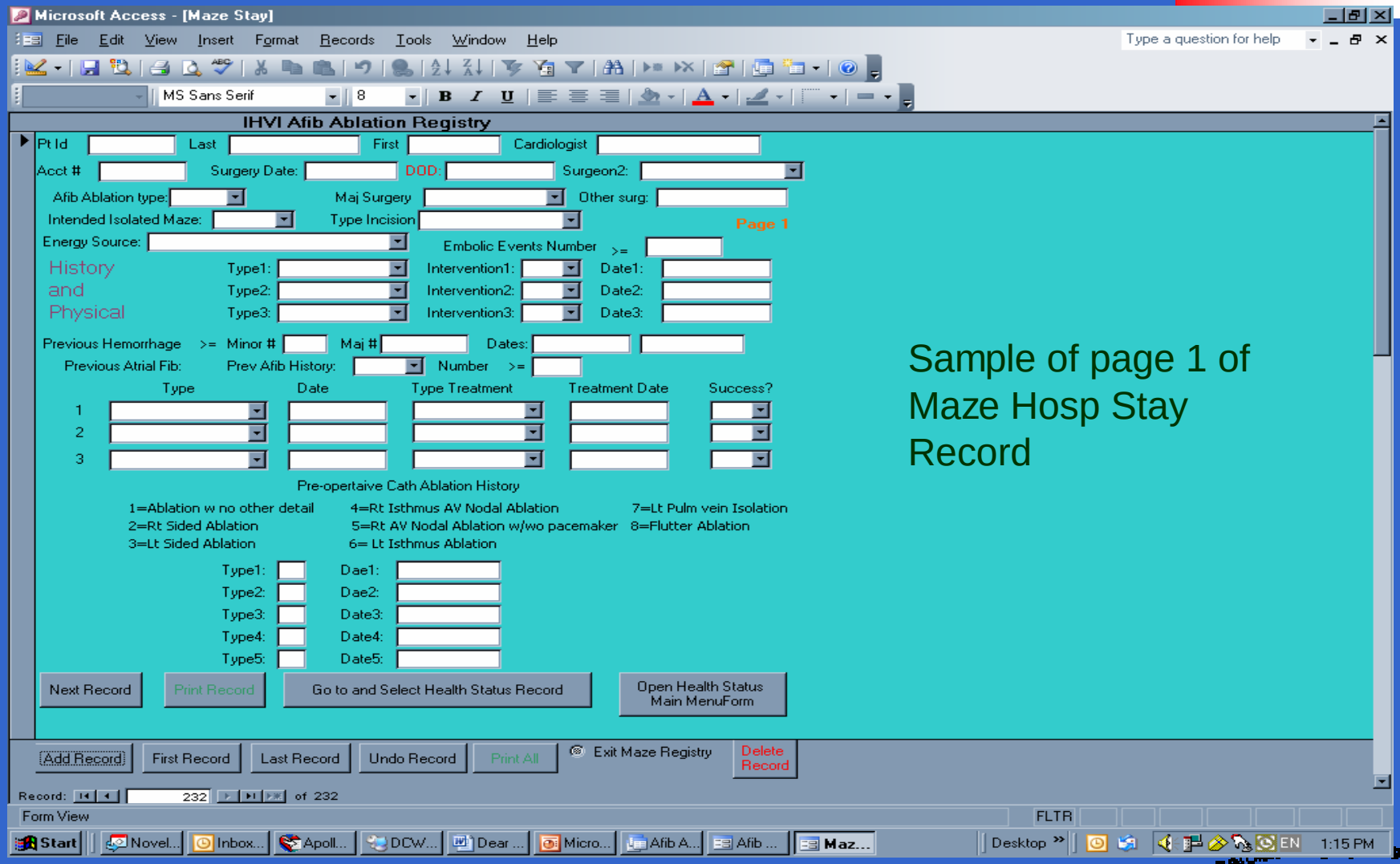

Sample of page 1 of Maze Hosp Stay Record

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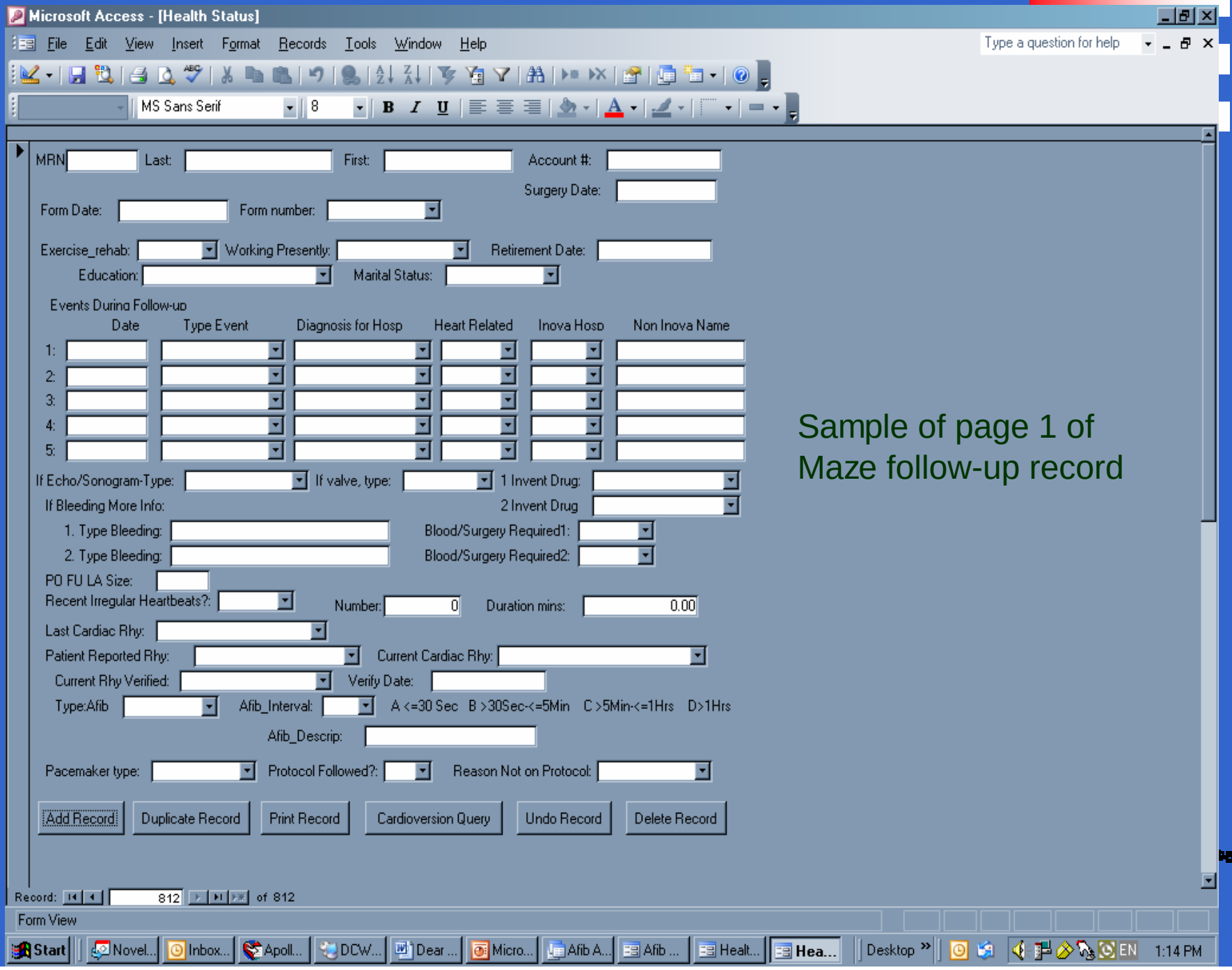

Sample of page 1 of Maze follow-up record

Post Surgical Ablation Patient Follow-Up

Post Surgical Ablation Patient Follow-Up

	D/C	3 Mon	6 Mon	9 Mon	12 Mon	18 Mon	24 Mon	Yearly Thereafter
Patient Self-Report For Follow-Up From Previous Time Point								
Health-Related Quality of Life		✓	✓		✓		✓	✓
Cardiac Procedure		✓	✓	✓	✓	✓	✓	✓
Hospital Admission		✓	✓	✓	✓	✓	✓	✓
Infection		✓	✓	✓	✓	✓	✓	✓
Stroke		✓	✓	✓	✓	✓	✓	✓
Bleeding		✓	✓	✓	✓	✓	✓	✓
Atrial Fibrillation/Arrhythmia		✓	✓	✓	✓	✓	✓	✓
Patient Self-Report on Current Date of Follow-Up								
Current Cardiac Rhythm		✓	✓	✓	✓	✓	✓	✓
Current Atrial Fibrillation Medications		✓	✓	✓	✓	✓	✓	✓
Nurse Coordinator Activities								
Reconciliation of Missing Data		✓	✓	✓	✓	✓	✓	✓
Verification of Cardiac Rhythm		✓	✓	✓	✓	✓	✓	✓
Protocol Status		✓	✓	✓	✓	✓	✓	✓
Other Clinical Follow-Up		As information becomes available, which are outside the standard time points, they are listed as "Follow-Up" - Most recent F/U can then be extracted.						

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Using Clinical Data: Challenges, Implementation, and Benefits

Presented By:
Linda L. Henry, PhD, RN

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Using Clinical Data: Challenges, Implementation, and Benefits

Clinically Based Information Can Be Important

Things to Think About:

- Settings where data is to be collected
- Treatments can make a difference in the measured outcomes
- If you are a medical professional are you obligated to treat
- Other

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Using Clinical Data: Challenges, Implementation, and Benefits

Data Collection

- What clinical data would be relevant to help explain your findings?
- What data is easily obtainable and amenable to data collection?
- How will you verify the correctness of your data?
- What are you going to do with abnormal findings?

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Using Clinical Data: Challenges, Implementation, and Benefits

Clinical Interventions

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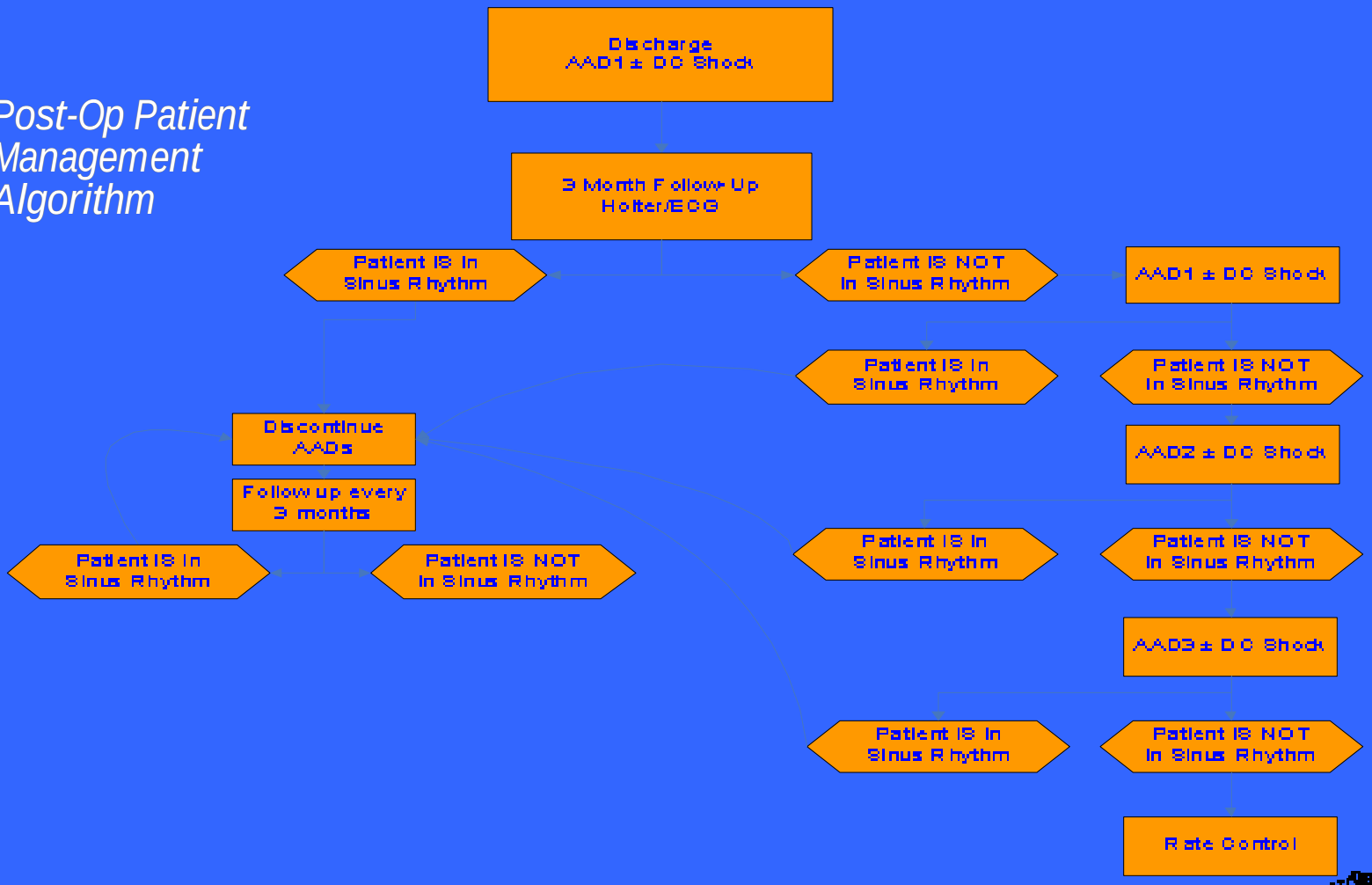
Using Clinical Data: Challenges, Implementation, and Benefits

Post-Op Patient Management Algorithm



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Using Clinical Data: Challenges, Implementation, and Benefits

What Does This Mean to You

- Communication with other care providers
- Other means of educating patients
- Assisting care givers with treatment protocol

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Preparing for and Reporting Study Results

Scott D Barnett, PhD

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3 Steps to Consider

1. **Designing Your Research Question**
   - **Prep Work**

2. **Analyzing Your Data**
   - **Statistics**

3. **Reporting Your Data**
   - **Writing**

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Designing Your Research Question

Getting Started 1

1. Start thinking about your final report
2. Is this for internal or external reporting?
3. Have you written a protocol yet?
4. Have all co-workers/authors/participants been decided on?
   - Never underestimate the grief surrounding authorship issues
5. Assume every accepted abstract/poster will become a manuscript

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Getting Started 2

- Have you started the IRB process?
- Will bias or confounding be an issue?
- Do you have all needed data?
- If no, how will you collect new data and how will you store your data?
  - Laptop? Desk? File cabinet?
- Will you need another department's data/help (e.g. financial data)?
  - Anticipate headaches!!

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Analyzing Your Data

Statistics 1

- Questions to ask when before your analysis:
  - How many timepoints?
  - Do you care about confounding?
  - Is the interpretation of the results or are the actual results more important?
  - If you use modeling techniques, are you modeling for association or prediction?

Statistics 2

- Is your study qualitative or quantitative?
- Have you named your primary endpoint?
  - Is it categorical, continuous?
  - Is time involved? Is it a rate?
    - Answers to these questions dictate the choice of statistical test.
      - "The data drive the test not the other way around."

Statistics 3

Continuous data

- 1 sample?
  - i.e., testing your value vs. theoretical value?
- 2 sample?
  - i.e., male vs. female; CCU vs. Step-down?
- Regression?
  - i.e., control for potential confounders
- Trend analysis?
  - i.e., money, time, predict future events

Statistics 4

Categorical data

- Simple 2*2 tables?
- Complex 2*n tables?
- Simple association between variables?
- Diagnostic study?
  - Is there a gold std? Is it readily available?
  - Binomial outcome (yes/no; died/lived, etc.)

Statistics 5

- Most common statistical tests for QOL studies:
  - Students' t-test
  - 1 or 2-way ANOVA
  - Paired t-tests
  - ANCOVA

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Statistics 6

- Most common tests for longitudinal studies:
  - Students' t-test
  - ANOVA
  - Logistic regression
  - Cox modeling
  - Kaplan-Meier

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Statistics 7

- Sample Size and Power
  - Power is the probability of rejecting the null hypothesis given the null hypothesis is correct. (getting it right)
    - H_o: drug A has no effect
    - H_a: drug A is superior
  - Null hypothesis is straw man to knock down or disprove.

Statistics 8

- Type 1 Error (α, usually 0.05):
  - P(rejecting null | null is correct)
- Type II Error (β, usually 0.20):
  - P(accepting null | null is false)
- Power = 1 – β; Power = 1 - 0.20=0.80:
  - Industry standard for power is 80%

Statistics 9

For Sample size calculations:

1. We need:
   - Power = 80% or β = 20%
   - α = 5%
   - What else?? Treatment effect
     - From literature; a guess; intuition; anywhere as long as it's defensible
   - Standard deviation

Statistics 10

- Reality often dictates that you cannot get enough subjects to perform an adequately powered study
- So…..how many can you get?
- Should you open it up to other institutions?
- Should you Broaden or Narrow your study question?

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Statistics 11

Open study up to other institutions:

- Con -
  - More paperwork, potential new IRB, more contracts, new egos to handle, increased authorship responsibilities and drama
- Pro -
  - More data, more collaboration, more prestige

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Statistics 12

Broaden or narrow your research idea

- **Con –**
  - Go too narrow: underpowered, get negative reviews upon submission, project turns out badly
- **Pro –**
  - narrow (refined) idea can help increase power, sympathetic reviewers, identify sub groups of importance, may generate two publications

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Statistics 13

The only possible reasons to observe a research finding:

1. **Chance**
2. **Bias**
3. **Confounding**
4. **An effect really exists**

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Reporting Your Data

Graphing 101

- Specialized graphing software is a great tool but costly
- Excel is a pretty good tool
- Time: always on the x-axis
- Deltas: always on the y-axis
- Simplicity is always better
- Use color to highlight importance
- Don't forget titles and legends

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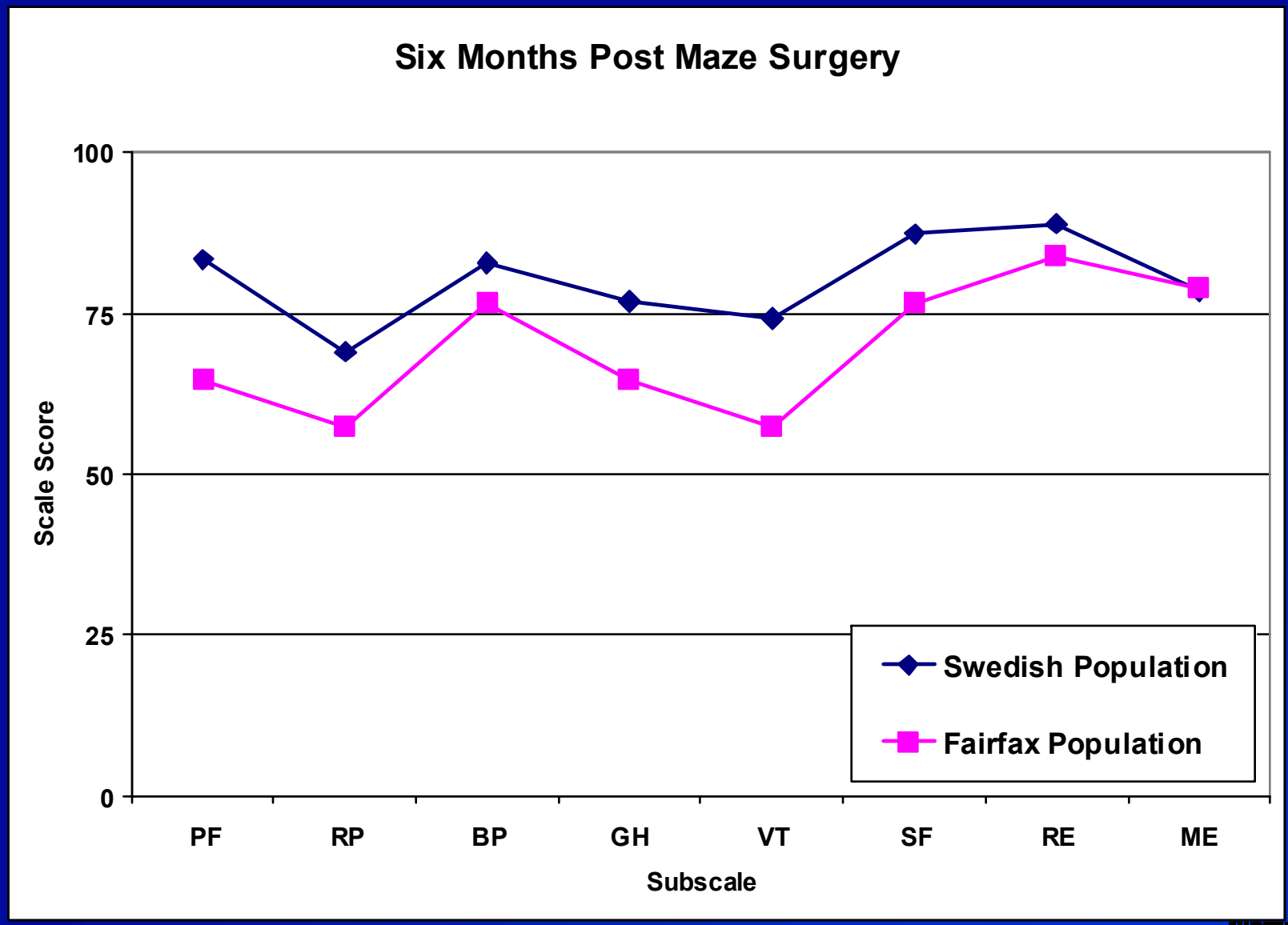
Graph Examples



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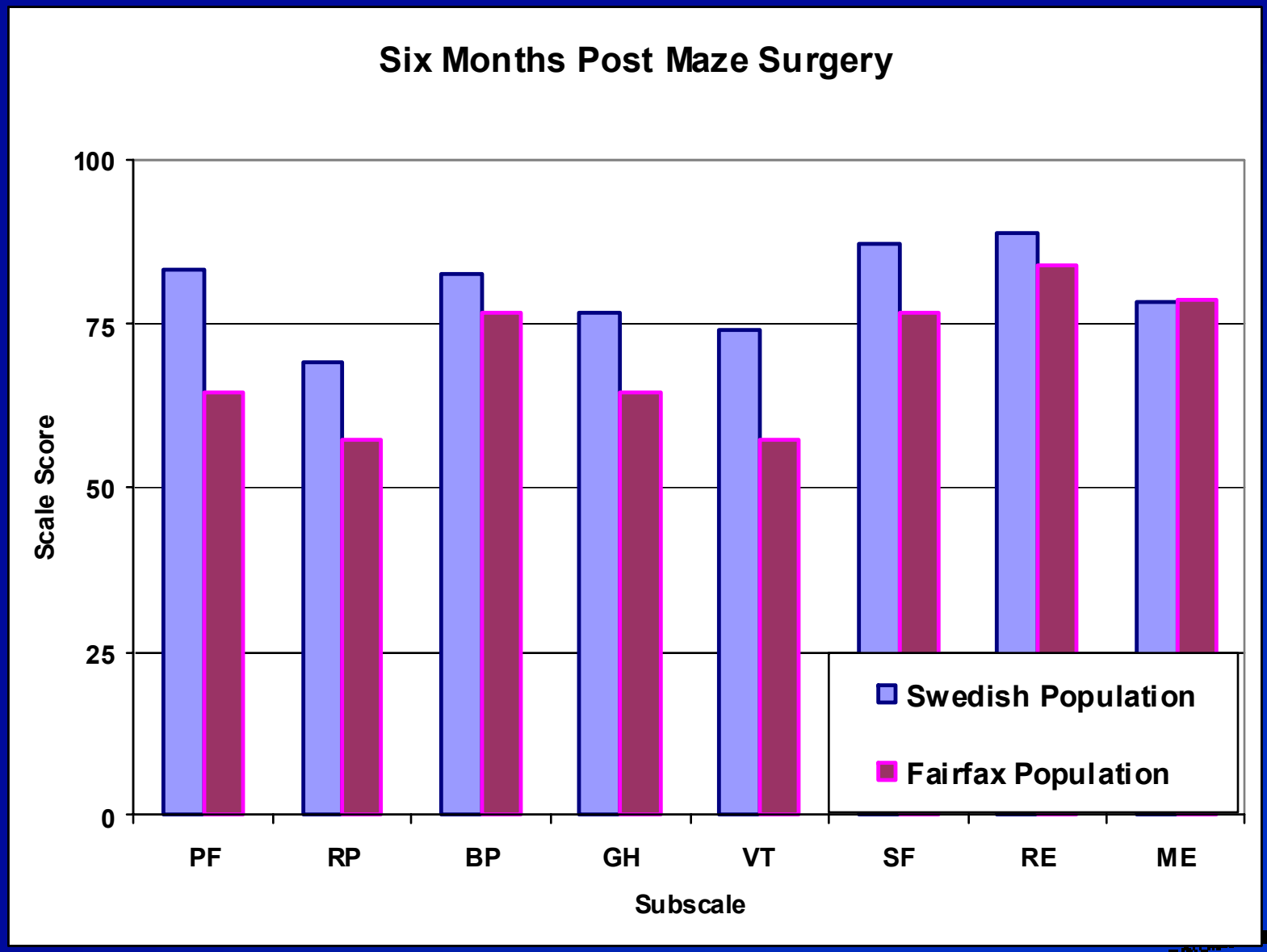

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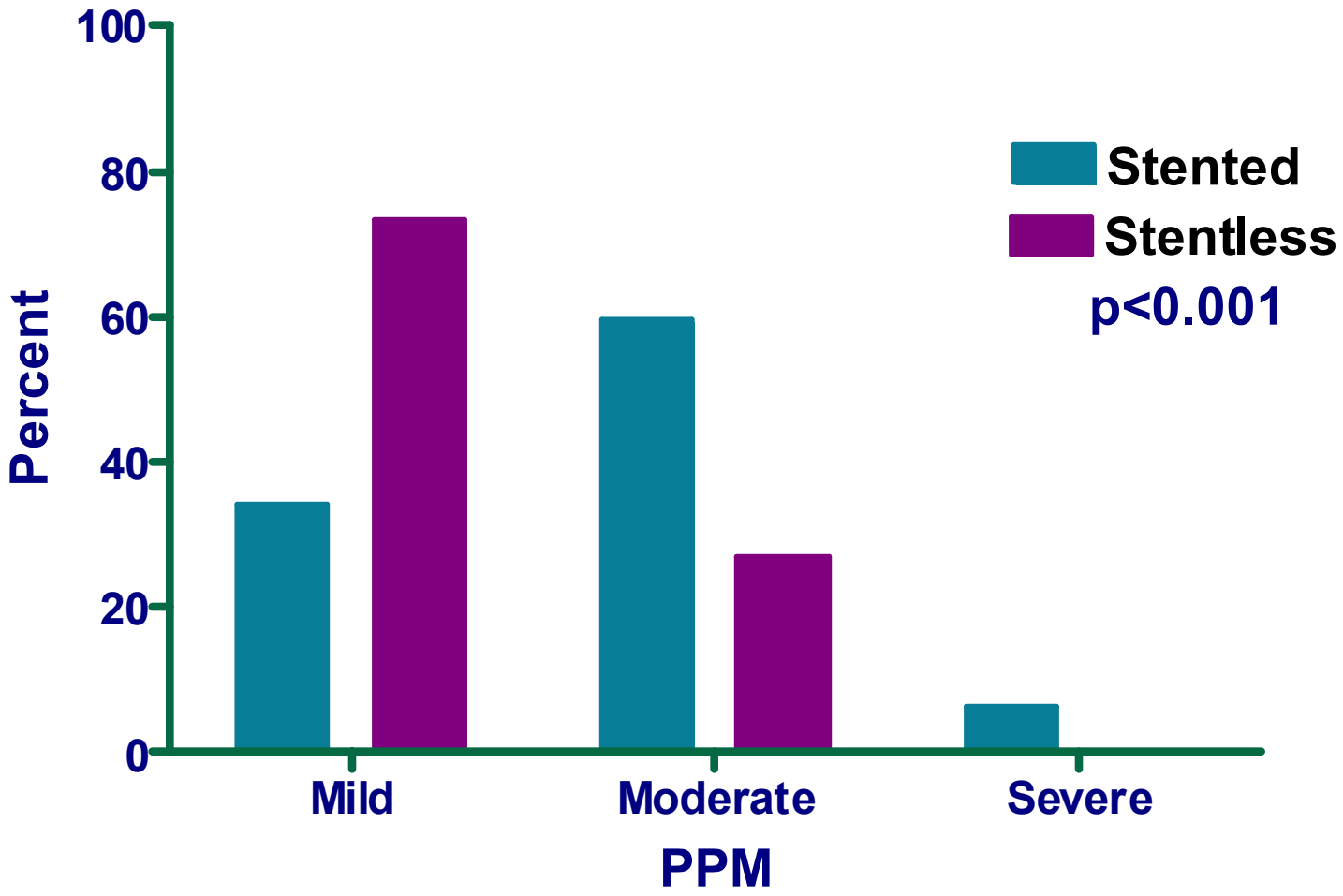

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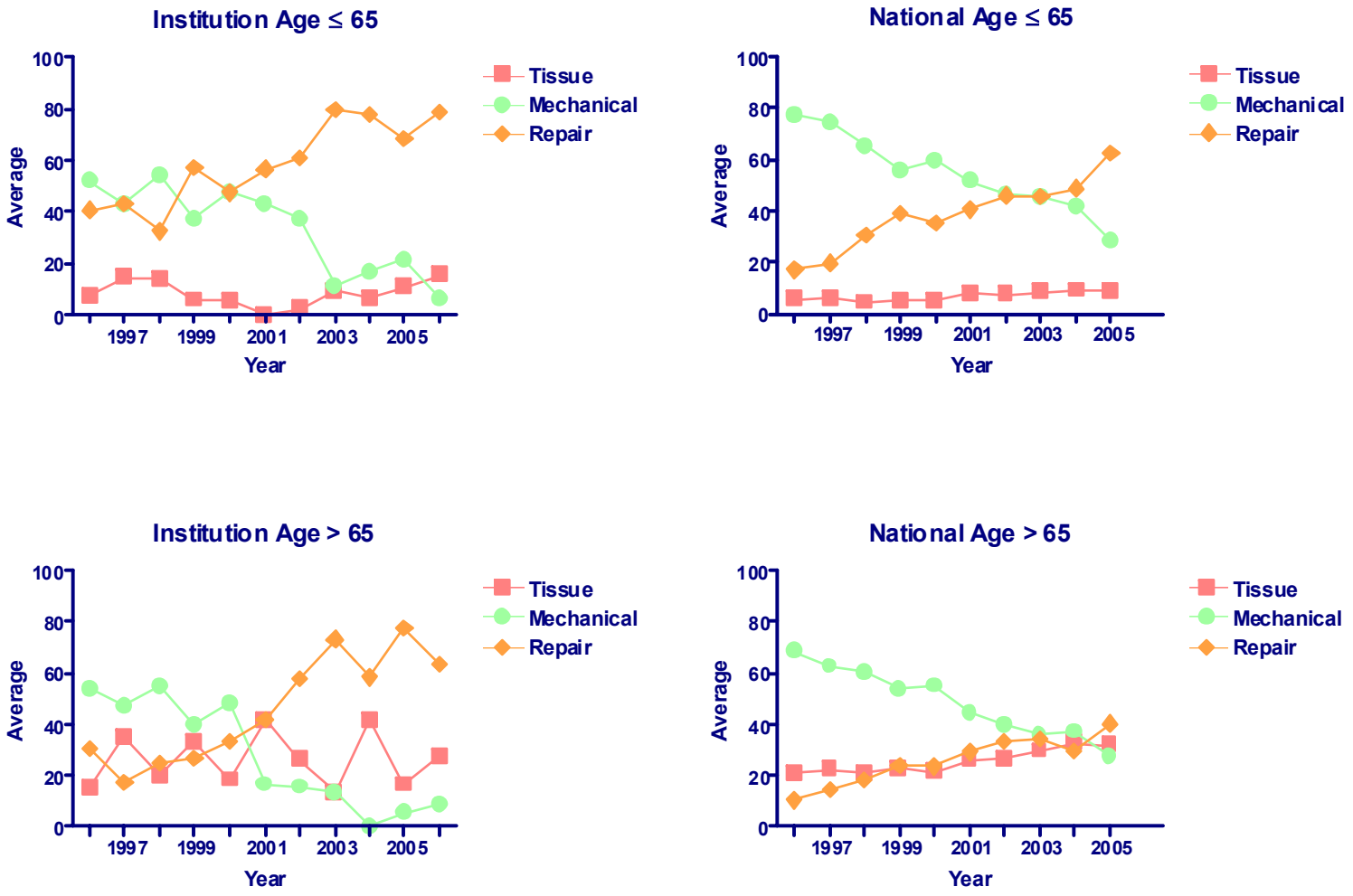
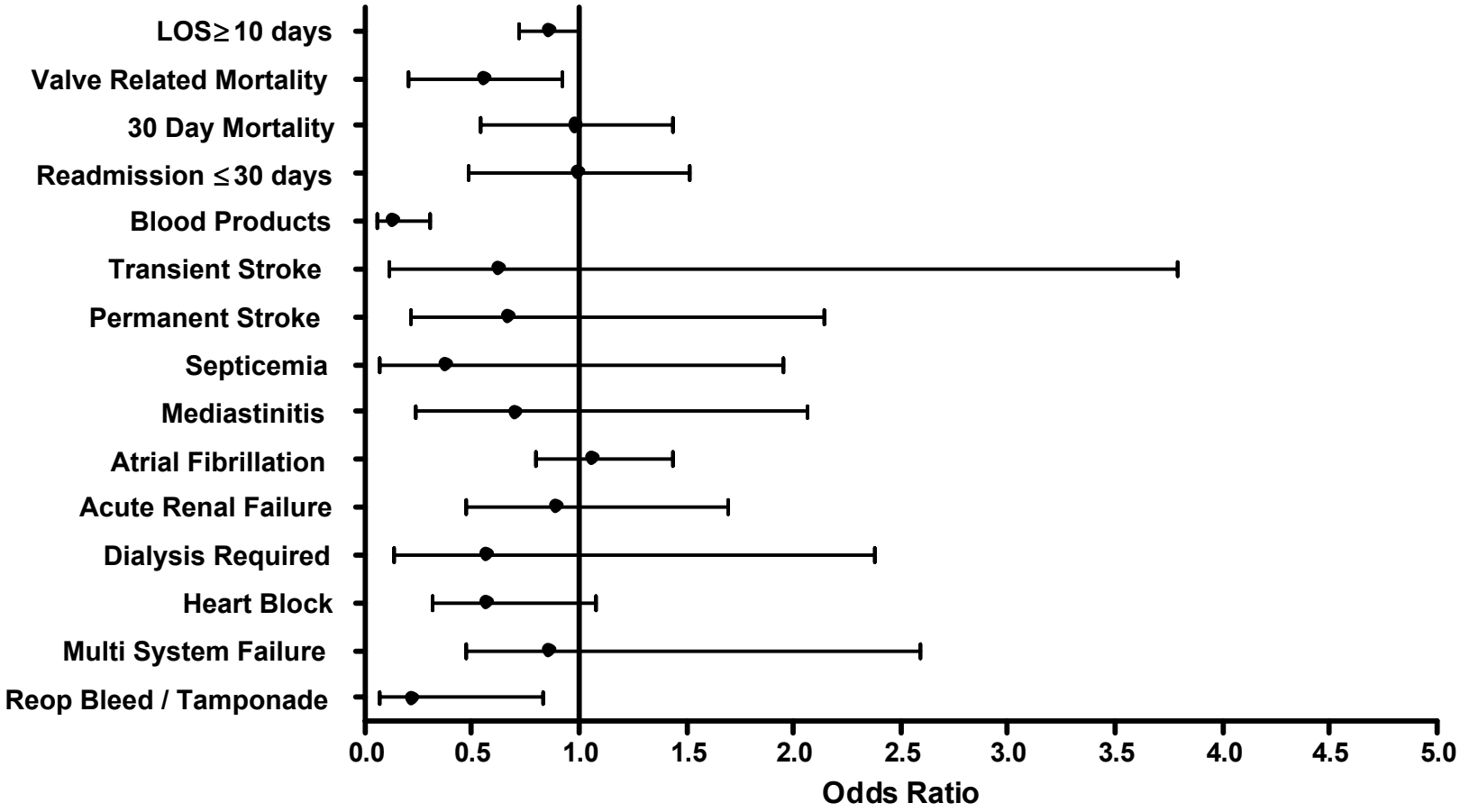
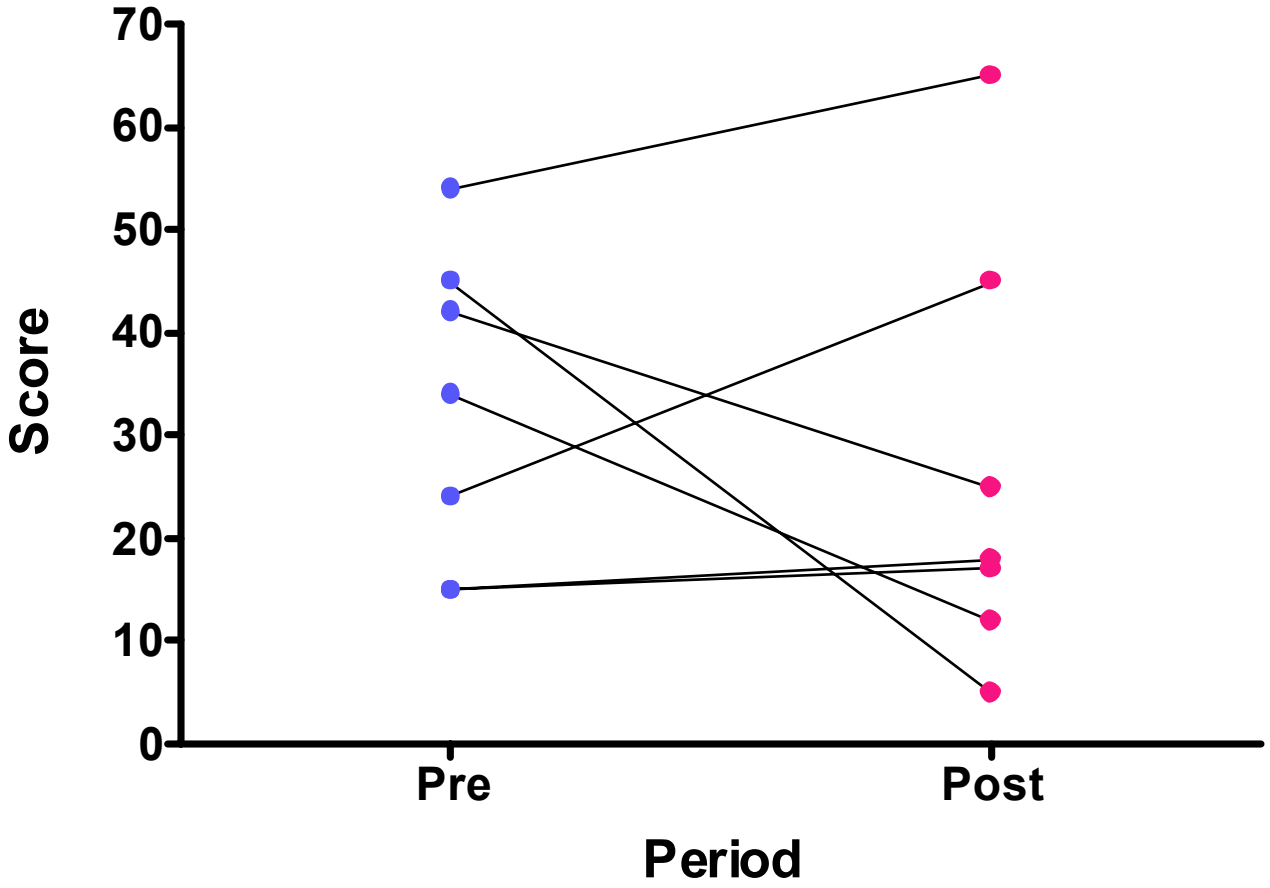
Figure 3. Annual Implantation Rates by Valve Type and Age Group





Full Root is referent group

Scores Before and After Intervention



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Writing 1

- **Writing is formulaic (learn it!)**
  - **Learn the W's**
    - **What's the problem?**
    - **What's been done?**
    - **What are you going to do?**
    - **What did you find?**
    - **What does it mean?**
    - **Where are you going to go from here?**

Writing 2

- Anticipate reviewer questions!
- Know your audience!
  - Are you writing for a specific journal? Institution? Peers?
- Seek and embrace criticism!!
- Authorship
  - Probably best to know before project starts

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Writing 3

- Housekeeping
  1. Keep a book of publications and posters
  2. Be prepared to generate progress reports
  3. In our business, a CV is expected too exceed 1 page
  4. Always be prepared to sell yourself or your department to administration!!

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Summary

- Have a plan
- Anticipate criticism of your plan
- Embrace that criticism
- Be able to defend your plan
- Write concisely
- Highlight your strengths / weaknesses

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Thank You

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