Monitoring Data Completeness of Participant Data Entry

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Overview

- Background Information

- Design of Data Management System

- Monitoring Data Completeness

- Examples

- Lessons Learned

Study of Novel Approaches to Prevention (SNAP)

- SNAP is three armed multi-center RCT designed to test whether behavioral interventions can prevent weight gain in young adults

- Randomized 599 adults

- Eligibility criteria

  - 18-35 years old

  - BMI 21-30 kg/m^2

  - Must have regular access to Internet

Study of Novel Approaches to Prevention (SNAP)

- Online participant data entry completed at baseline, 4 months and annually thereafter

- 19 or more forms completed at each visit

  - Over 400 questions

- Participants have 8 week visit window to complete forms

- All cohorts have completed through year 2 visits

  - 6 (of 11) cohorts have completed or currently completing 3 year visits

Design of Participant Website

- Participant website designed for simplicity and convenience

- Visit windows control participant data entry

- Form navigation is simple

  - Names are user friendly

  - Grouped into sections with similar topics

  - Estimated time for completion provided

Questionnaires	Estimated time for completion	Date Entered
SECTION 1: *Questions about myself and my family*	**16 - 26 minutes**	
Demographics	2 - 5 minutes	*CLICK TO ENTER*
Contact Information	7 - 10 minutes	*CLICK TO ENTER*
Life Events	3 - 5 minutes	*CLICK TO ENTER*
Weight History of Friends and Family	1 - 2 minutes	*CLICK TO ENTER*
Perception of Program	3 - 4 minutes	*CLICK TO ENTER*
SECTION 2: *Questions about my mood and behavior*	**11 - 15 minutes**	
Eating Inventory	5 - 6 minutes	*CLICK TO ENTER*
TSRQ	2 - 3 minutes	*CLICK TO ENTER*
PSS	1 - 2 minutes	*CLICK TO ENTER*
SECTION 3: *Questions about my diet*	**35 - 40 minutes**	
BLOCK	35 - 40 minutes	*CLICK TO ENTER*
SECTION 4: *Questions about my health and health behaviors*	**11 - 18 minutes**	
Health Behaviors	2 - 3 minutes	*CLICK TO ENTER*
Medication Use	1 - 2 minutes	*CLICK TO ENTER*
Audit	1 - 2 minutes	*CLICK TO ENTER*
Weight History	3 - 4 minutes	*CLICK TO ENTER*
Smoking and Tobacco Behaviors	2 - 3 minutes	*CLICK TO ENTER*
Quality of Life Questionnaire	1 - 2 minutes	*CLICK TO ENTER*
SECTION 5: *Questions about my lifestyle*	**18 - 26 minutes**	
EDA	4 - 5 minutes	*CLICK TO ENTER*
Weight Management Strategies	4 - 6 minutes	*CLICK TO ENTER*
Self-Weighing Questionnaire	3 - 5 minutes	*CLICK TO ENTER*
Sedentary Behaviors	3 - 4 minutes	*CLICK TO ENTER*
Sleep Patterns	1 - 2 minutes	*CLICK TO ENTER*
Physical Activity Neighborhood Environment	3 - 4 minutes	*CLICK TO ENTER*

SNAP

Monitoring Data Completeness: Participant Level

- User friendly forms with minimal checks
  - Warnings if questions are not answered
  - Error messages only if answers required to determine safety alert values
- Use of "Not Applicable"
- Participants outside of window complete paper forms and these are entered by staff

Warning and Error Messages

ERROR - 2. Second question must be answered
ERROR - 3. Third question must be answered
WARNING - 4a. Question should be answered
WARNING - 4b. Question should be answered

Unable to save form; please correct error(s)!

SNAP EDA Questionnaire

PID: **10036**
ACROSTIC: **ARLMAH**
VISIT CODE: **4MO**

DATE FORM COMPLETED: 05/05/2014
{mm/dd/yyyy}

ADMINISTRATION TYPE: Self-administered (Paper) ▼

1. During the past 6 months, did you ever eat what most people, like your friends, would think was a **really big** amount of food?   Yes ▼

   → If No,   Skip to Question 5

   Did you ever eat a **really big** amount of food within a short time (2 hours or less)?   Yes ▼

   → If No,   Skip to Question 5

2. When you ate a **really big** amount of food, did you ever feel that you could not stop eating? Did you feel that you could not control what or how much you were eating?   ▼

3. During the past 6 months, how often did you eat a **really big** amount of food with the feeling that your eating was out of control?
   There may have been some weeks when you did not eat this way at all. And some weeks you may have eaten like this a lot. But, in general, how often did this happen?
   ▼

4. When you ate a really big amount of food and you could not control your eating, did you:
   a) Eat very fast?   ▼
   b) Eat until your stomach hurt or you felt sick in your stomach?   ▼

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Monitoring Data Completeness: Clinic Level

- Prior to clinic visit
    - Review to see if forms completed and number of warnings
    - Participants normally have completed all or none of the forms
    - E-mail and phone reminders
- Participants are not compensated until forms are complete

Study Forms   *Next Participant*

Back to Eligibility Summary

PID: ▮▮▮▮▮
NAME: ▮▮▮▮▮▮

	Participant Info
	Eligibility
	Pre-Screening
	Telephone Screening
	Orientation
	SV1
	SV2
	4 Month
	1 Year
	2 Year
	3 Year
	4 Year
	Un-Scheduled

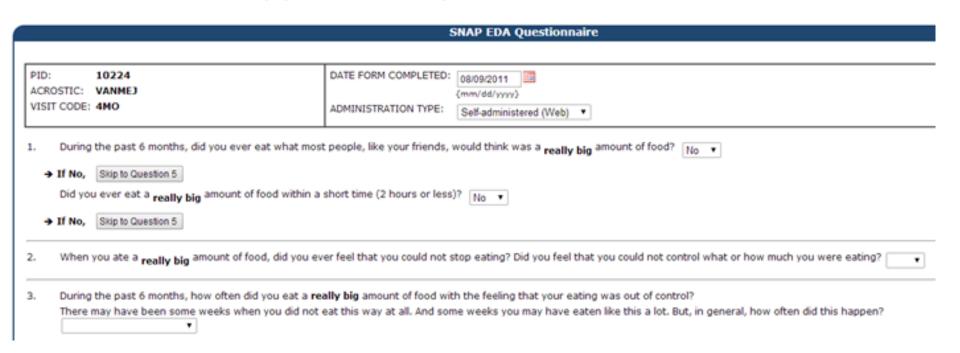| FORM	DATE ENTERED	NUMBER OF WARNINGS
STAFF-ENTERED FORMS		
Physical Measurements	03/29/2011	0
Exercise Habits	03/29/2011	0
Impedance	03/29/2011	0
MYSELF AND MY FAMILY		
Demographics	03/21/2011	1
Contact Information	03/28/2011	0
Life Events	03/21/2011	0
Weight History of Friends and Family	03/21/2011	0
Perception of Program	03/21/2011	0
MY MOOD AND BEHAVIOR		
Eating Inventory	03/21/2011	0
TSRQ	03/21/2011	0
PSS (Perceived Stress Scale)	03/21/2011	0
MY HEALTH AND HEALTH BEHAVIORS		
Health Behaviors	03/21/2011	0
Medication Use	03/28/2011	0
Audit	03/21/2011	0
Weight History	03/21/2011	0
Smoking and Tobacco Behaviors	03/21/2011	0
Quality of Life	03/21/2011	0
MY LIFESTYLE		
EDA (Eating Disorder Assessment)	03/28/2011	0
Weight Management Strategies	03/28/2011	0
Self-Weighing	03/21/2011	0
Sedentary Behaviors	03/21/2011	0
Sleep Patterns	03/21/2011	0
Physical Activity Neighborhood Environment	03/21/2011	0

SNAP

Monitoring Data Completeness: Coordinating Center Level

- Dynamic SAS reports for Form Completion and Item Completion

- Form completion rates
  - Missing rates range from 0.0% to 6.7%*
  - Fairly uniform missing rate for forms

- Item completeness
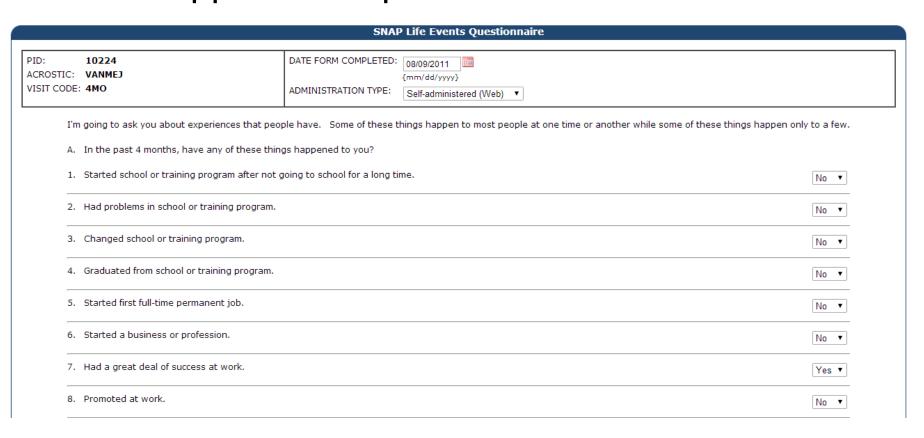 - Missing rates range from 0.0% to 16.65%

*excludes year 3 visits

Example:
Eating Disorder Assessment

- Scoring of this form leads to safety alert
- Error and warning messages
- No "Not Applicable" options

SNAP EDA Questionnaire

PID:	10224	DATE FORM COMPLETED: 08/09/2011
ACROSTIC:	VANMEJ	(mm/dd/yyyy)
VISIT CODE:	4MO	ADMINISTRATION TYPE: Self-administered (Web) ▾

1. During the past 6 months, did you ever eat what most people, like your friends, would think was a **really big** amount of food? No ▾

→ **If No,** Skip to Question 5

 Did you ever eat a **really big** amount of food within a short time (2 hours or less)? No ▾

→ **If No,** Skip to Question 5

2. When you ate a **really big** amount of food, did you ever feel that you could not stop eating? Did you feel that you could not control what or how much you were eating? ▾

3. During the past 6 months, how often did you eat a **really big** amount of food with the feeling that your eating was out of control?
 There may have been some weeks when you did not eat this way at all. And some weeks you may have eaten like this a lot. But, in general, how often did this happen?
 ▾

Life Events

- "Not Applicable" options

SNAP Life Events Questionnaire

PID: **10224**	DATE FORM COMPLETED: 08/09/2011
ACROSTIC: **VANMEJ**	{mm/dd/yyyy}
VISIT CODE: **4MO**	ADMINISTRATION TYPE: Self-administered (Web) ▾

I'm going to ask you about experiences that people have. Some of these things happen to most people at one time or another while some of these things happen only to a few.

A. In the past 4 months, have any of these things happened to you?

1. Started school or training program after not going to school for a long time. — No ▾

2. Had problems in school or training program. — No ▾

3. Changed school or training program. — No ▾

4. Graduated from school or training program. — No ▾

5. Started first full-time permanent job. — No ▾

6. Started a business or profession. — No ▾

7. Had a great deal of success at work. — Yes ▾

8. Promoted at work. — No ▾

Life Events

- Missing rates very low
  - At baseline, highest % of missing item was 0.12 (3 people)

12. Had troubles with your boss.
  - 0.12% left blank

- N/A selected for several questions – open for interpretation:

2. Had problems in school or training program.
  - 8.88% indicated N/A

27. Went on welfare.
  - 0.69% indicated N/A

Health Behaviors: Alcohol (BRFSS)

- Misinterpretation and Inconsistencies

. During the past 30 days, how many days did you have at least one drink of any alcoholic beverage?   10

. One drink is equivalent to a 12-ounce beer, a 5-ounce glass of wine, or a drink with one shot of liquor. During the past 30 days, on the days when you drank, about how man drinks did you drink on the average?

14

. Considering all types of alcoholic beverages, how many times during the past 30 days did you have 4 or more drinks on one occasion? (5 or more for men)   0

- Participant reports drinking 10 out of 30 days
- On average, participant reports drinking 14 drinks on those days
- Indicates 0 times they had 4 or more drinks on the 10 days they drank

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Smoking and Tobacco

- Skip Patterns

- At baseline, determined 16.65% of fields were being left blank

- Reordered questions and skip patterns

Visit	Total # items missing
Baseline	16.65%
4 month	5.21%
1 year	1.38%
2 year	1.07%
3 year	0.96%

Lessons Learned

- Decreases both staff and participant burden

- Clinic visit times are reduced

- Use error and warning messages only when appropriate

- Review for misinterpretations and inconsistencies

  - Revise forms as necessary

  - Add extra manual steps of review

- Skip Patterns

  - Navigate participants directly through website

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Lessons Learned

- Not Applicable Options
  - Ensures participants are answering questions
  - Only use when appropriate (scoring)
  - Rephrase when possible
    - Open to participant's interpretation
- For out-of-window visits, allow late data entry by participants

Acknowledgements

- Wake Forest – Coordinating Center
  - Mark Espeland, PhD
  - Wei Lang, PhD
  - Judy Bahnson
  - Leah Griffin
  - Rebecca Neiberg
  - Katelyn Garcia
  - Mark King
  - Kathy Lane
  - Mary Hontz
  - Patty Davis
  - Julia Robertson

- Providence Clinic
  - Rena Wing, PhD
  - Erica Ferguson
- UNC Clinic
  - Deb Tate, PhD
  - Karen Erickson
- SNAP Research Group
- This study is funded by the NHLBI, U01HL090875

Questions?