

Optimizing Study Management Using



A secure web application for building and managing surveys and databases

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???Research Lunch Forum???

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Presentation Outline

REDCap Overview and OUHSC History

Scenarios Favoring REDCap

Reports for Project Management

Reports for Outcomes

Overall Goals

Accessing REDCap at OUHSC

Security Practices and Policies

Citing REDCap in grants/IRB/manuscripts

REDCap overview (<http://project-redcap.org/>)

- Secure web application for building and managing surveys and databases.
 - Developed by informatics core at Vanderbilt with support from NCRR and NIH.
 - Designed for academic biomedical researchers.
- Provides:
 - A centralized, back-end storage component.
 - Tools to create an interactive front-end html GUI.
 - An API to import & export data.
 - Example templates.
 - Instructional videos for training.
 - User-group network of institutional researchers.
 - Also included: built-in project calendar, scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.
- It can reduce
 - Developing a lot of new software applications.
 - Anxieties related to security of home-grown software.

REDCap Software Features

Availability - Software available at no cost for REDCap partners.

Secure and web-based - Input data or build online survey anywhere in the world over secure web connection with authentication and data logging.

Multi-site access - REDCap databases/surveys can be used by researchers from multiple sites and institutions.

OUHSC Becomes REDCap Partner

- MIECHV grant (DBP) requests REDCap (Nov. 2011)
 - IT installs “DBP” REDCap instance, ver.4 (Jan. 2012)
- New DBP projects move to REDCap (2012-2013)
- Campus REDCap interest rises (2012-2013)
 - IT installs “Enterprise” REDCap instance, ver.5 (Mar. 2013)
 - IT installs “Development box” instance, ver.5 (Apr. 2013)
- Governance body requested (Mar. 2013)
 - Governance body formed (Jun. 2013)
- Funding for REDCap admin requested (Apr. 2013)
 - College of Medicine agrees to fund Dev box and Enterprise instance (Jun. 2013)
- **REDCap freely available to all**



Motivation: MIECHV Collaboration

1. The 4 statisticians on the project.
sharing software development.
2. The 20+ people on the project (1/3 off-site).
exchanging participant-level data.
3. The 3 partnering organizations. (OSDH, WIC, OHCA)
-receiving their subject-level & agency-level data.
-distributing results –fresh & frequently.
4. Academics in different areas. (particularly at OUHSC)
exchanging tools and workflows.
5. Researchers in other states pursuing similar goals.
publishing ideas and replicating previous work.

REDCap Software Highlights

Built-in project Calendar

The screenshot shows a monthly calendar view for April 2013. Events are color-coded and include descriptions such as "Initial Interview", "Two-day Follow-up", "Four-day Follow-up", and "Six-day Follow-up". Some events have multiple entries, indicating recurring or follow-up appointments.

Built-in Export Formats

This screenshot displays a list of data export formats for different statistical software:

- Microsoft Excel:** Instructions: Download and save all 3 files on the right to a common location. First, double-click on the "Pathway Mapper (.bat)" file, which will run quickly and invisibly. (If you are not using a Windows operating system, such as Mac or Linux, please see the Additional Instructions.) Now double-click on the ".csv" file, which will open Excel. When the file is loaded and displayed, choose Run->All from the top menu options. This will run the script that will automatically read in all data and manipulate data fields with labels, option values, etc.
- SPSS Statistical Analysis Software:** Instructions: Double-click on all 3 files on the right to a common location. First, double-click on the "Pathway Mapper (.bat)" file, which will run quickly and invisibly. (If you are not using a Windows operating system, such as Mac or Linux, please see the Additional Instructions.) Now double-click on the ".sav" file, which will open SPSS. When the file is loaded and displayed, choose Run->All from the top menu options. This action will launch the script that will automatically read in all data and manipulate data fields with labels, option values, etc.
- SAS Statistical Software:** Instructions: Download and save all 3 files on the right to a common location. First, double-click on the "Pathway Mapper (.bat)" file, which will run quickly and invisibly. (If you are not using a Windows operating system, such as Mac or Linux, please see the Additional Instructions.) Now double-click on the ".sas" file, which will open SAS. When the file is loaded and displayed, choose Run->All from the top menu options. This action will launch the script that will automatically read in all data and manipulate data fields with labels, option values, etc.
- R Statistical Software:** Instructions: Use command read.csv('filename') to read in data file.
- STATA Analysis and Statistical Software:** Instructions: Download both files to common location and double-click on *.dta file. The script will run a do script that will automatically read in all data and manipulate data fields with labels, option values, etc.

Scheduling Module (Define Events)

	Event #	Days Offset	Offset Range Min / Max	Event Name	Unique event name (auto-generated)
<input type="button" value="Add new event"/>	1	0	-0/+0	Initial Interview	initial_interview_arm_1
<input type="button" value="Add new event"/>	2	2	-0/+0	Two-day Follow-up	twoday_followup_arm_1
<input type="button" value="Add new event"/>	3	4	-0/+0	Four-day Follow-up	fourday_followup_arm_1
<input type="button" value="Add new event"/>	4	6	-0/+0	Six-day Follow-up	sixday_followup_arm_1
<input type="button" value="Add new event"/>		Days	-0 +0		Descriptive name for this event
		<input type="button" value="Convert from other units"/>			

Arm name: Arm 1 Rename Arm 1

(Assign Instruments)

Data Collection Instrument	Events			
	Initial Interview (1)	Two-day Follow-up (2)	Four-day Follow-up (3)	Six-day Follow-up (4)
	Survey	✓	✓	✓

(Schedule Participant)

Add new Participant ID: OR

Start Date:

Projected Schedule for "2" (NOTE: The dates below have NOT yet been scheduled)

The projected schedule below was automatically generated for Participant ID "2" based on your pre-defined Events. You may change the value of any dates generated below simply by clicking inside the date box and selecting a new date. Any dates generated below that fall on weekends will be listed in red. Click the Create Schedule button to finalize this schedule, which will then be added to the Calendar.

Time (optional)	Date / Day of Week	Event Name
<input type="text" value="X"/>	04/18/2013 Thursday	Initial Interview
<input type="text" value="X"/>	04/20/2013 Saturday	Two-day Follow-up
<input type="text" value="X"/>	04/22/2013 Monday	Four-day Follow-up
<input type="text" value="X"/>	04/24/2013 Wednesday	Six-day Follow-up

NOTE: Clicking the Create Schedule button will additionally add "2" as a new Participant ID.

REDCap Project Types

<https://redcap1.mayo.edu/redcap/index.php?action=training>

1. Traditional Database

classic model

2. Parent-Child Linking

linking together multiple databases

3. Operations

use case for non-study/non-trial

4. Longitudinal Database

multi-use forms with time points

REDCap Front-End Data Entry

- You have 2 options
 - Survey-based data entry
 - “Prettier” interface
 - Public and private audience options
 - Email tracking system
 - Form-based data entry
 - One-stop shop for data entry, scheduling, and data management
 - Familiar interface, resembles most form-based database software (e.g., MS Access)

Brief REDCap Demo

- How to design a REDCap project
 - Online demonstrations
 - <http://www.project-redcap.org/videos.php>
 - Templates and demos inside each REDCap instance
 - REDCap google group FAQ
- Survey project demo
- Form project demo (cross-sectional and longitudinal)
- If time permits
 - REDCap project for managing all research projects
 - Quality improvement operational database
 - Relational database tricks

Example: Survey-based Data Entry

- Login to DBP REDCap (all instances use OUHSC username and password authentication)
- Go to My Projects and select DataAnalytics Core Demo: Survey
 - Click “Open Survey” button
 - Click “Invite Participants” link, then “Open public survey”
 - Notice url
 - Click “Invite Participants”, then “Add participants”
 - Add email address then click “Send Survey Invitations”

Example: Survey-based Data Entry

[REDCap] Your survey link for forwarding to participants - Message (HTML)

File Message Adobe PDF

Ignore Delete Reply Forward All More Team E-mail Done Move Rules OneNote Mark Unread Categorize Follow Up Translate Find Related Select Zoom

Delete Respond Quick Steps Move Actions Tags Editing

From: Bard, David E. (HSC)
To: Bard, David E. (HSC)
Cc:
Subject: [REDCap] Your survey link for forwarding to participants

Sent: Tue 6/11/2013 9:54 AM

[This message was automatically generated by REDCap]

You may open the survey in your web browser by clicking the link below:
[REDCap Demo Survey](#)

If the link above does not work, try copying the link below into your web browser:
<http://miechvprojects.ouhsc.edu/redcap/surveys/?s=nYxhle>

Click on a photo to see social network updates and email messages from this person.



Example Form-based Data Entry

Editing existing Study ID c

Event Name: **Event 1**

Study ID c
(To rename this record, modify the value immediately below.)

Study ID (H) c

TANF
 Self
 WIC
 Medicaid
 Other

Referral Source

Has this individual taken the interview? (H) Yes
(H) No [reset value](#)

Which data collector? (H) Geneva
(H) Nicole
(H) La Chanda
(H) dc4
(H) dc5
(H) dc6 [reset value](#)

Was this participant referred by someone? (H) Yes
(H) No [reset value](#)

If yes, enter the participant id of the person who made the referral. (H) []

Are the consent forms scanned? (H) Yes
(H) No [reset value](#)

This section of the survey is to be filled out by the data collector. The following questions are about the individual who is participating in this survey. Provide as much detail as possible when completing this section of the survey.

Social Security # (H) []

Medicaid # (H) []

First Name (H) []

Last Name (H) []

Nickname (H) []

Alternate name (H) []

Date of Birth (H) [] 31 Today M-D-Y

Gender (H) []

Thomas' Data Entry Demonstration

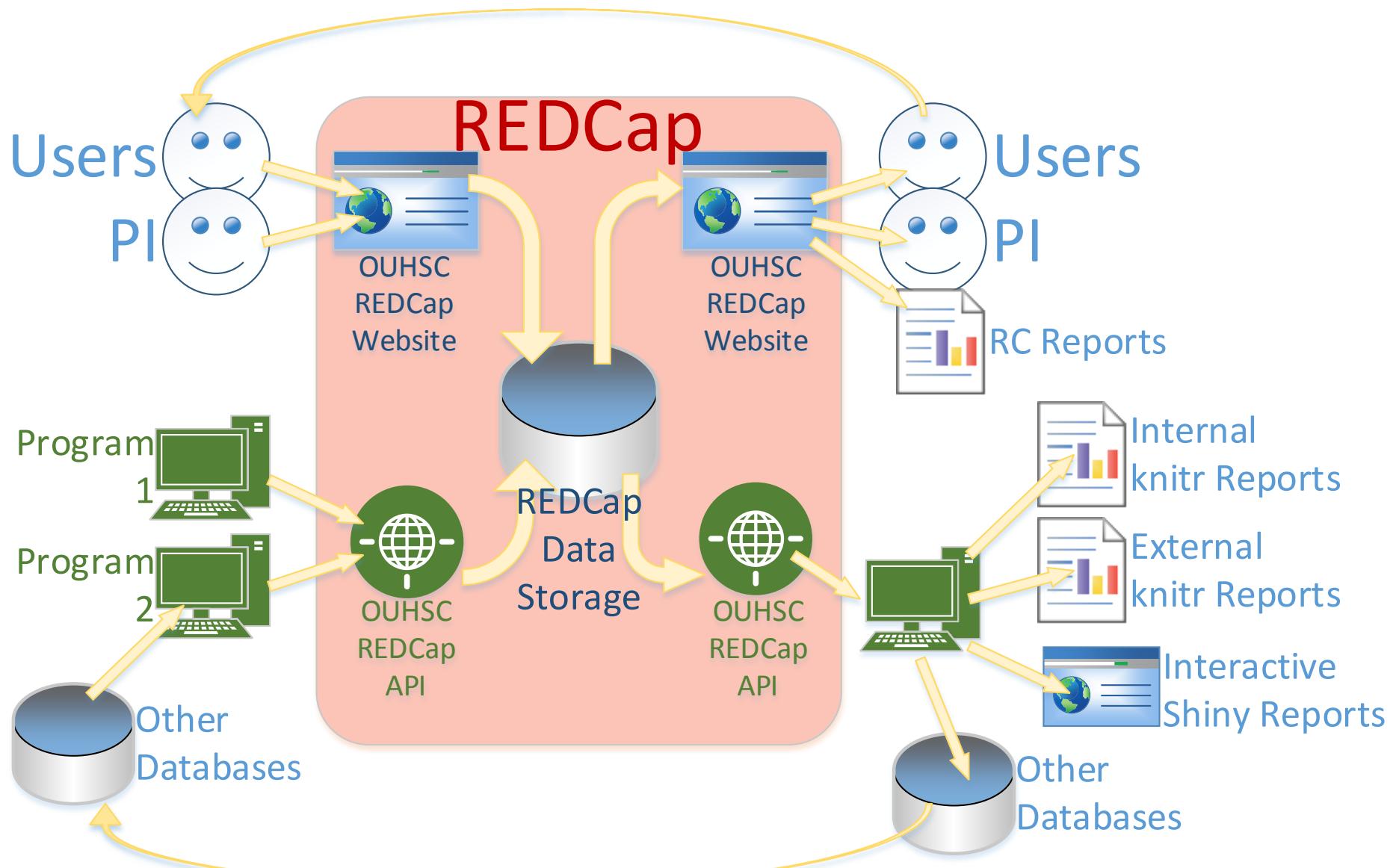
1. Go to <https://zzzzzzzz.ouhsc.edu/>
2. Login
3. Select project “testing123”
4. Enter some more test data
5. Create a calendar entry

(Note: the exact address has been changed for security purposes.)

Data Dictionary Demos

- Can create an entire project by uploading pre-existing data dictionary .csv file
 - Click “My Projects” and select ‘DATAnalytics Core Demo: Data Dictionary Upload’
 - Click “Upload Data Dictionary” button and select dictionary file
- Change existing field using data dictionary
 - Click “Project Setup” button, then “Upload Data Dictionary”
 - Select new dictionary file and “Commit Changes”
- Add new fields using data dictionary
 - Same as change existing fields

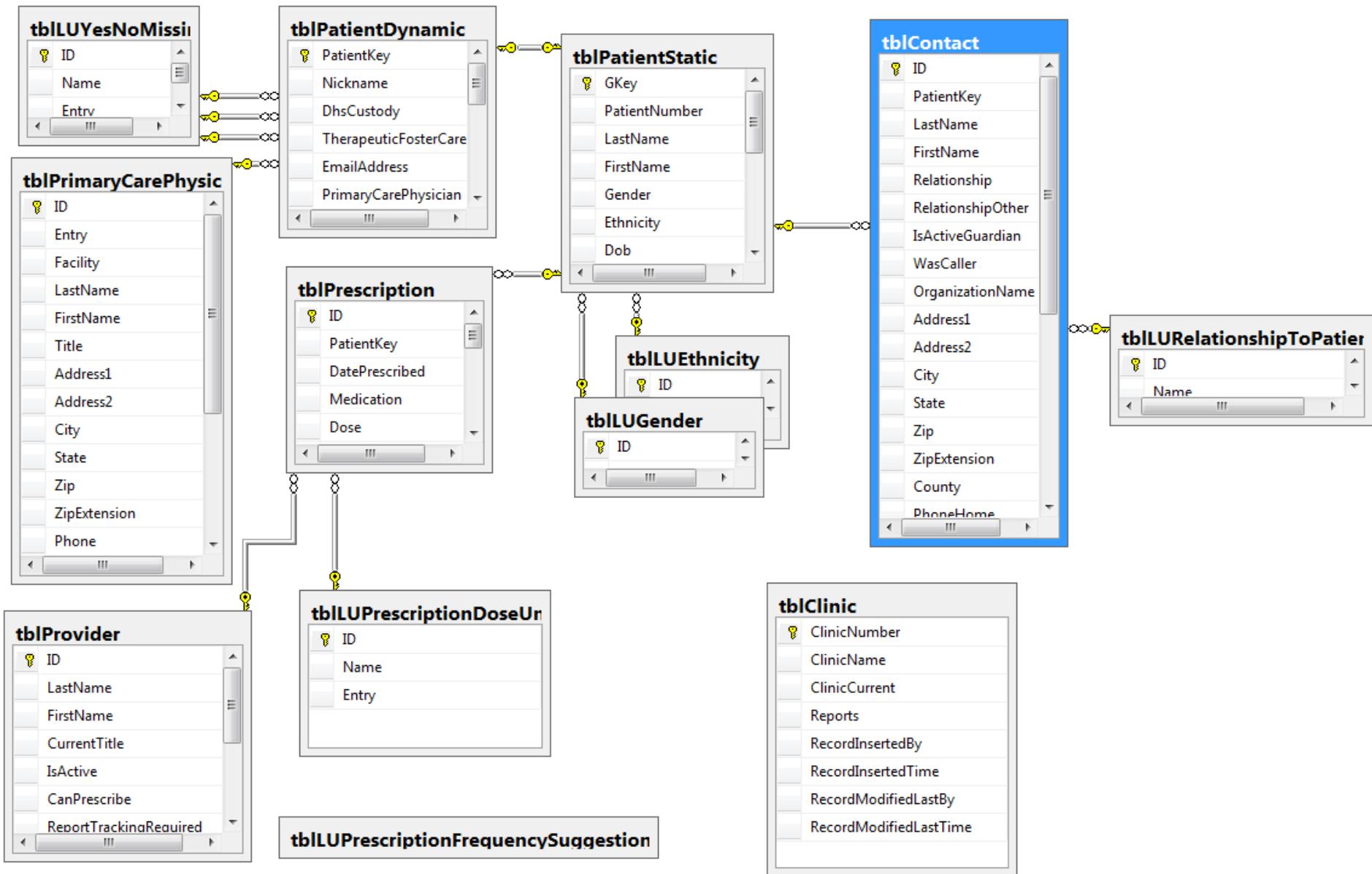
Possible REDCap Workflows



Scenarios Favoring REDCap

- Project requires a centralized data store, but multiple locations for data entry.
 - Avoid syncing different locations manually.
- You want a flexible, universal framework to create consistent data systems for multiple clinical projects (research and possibly operations).
 - Reduces your development time & your staff's training time.
 - Reduces writing new text for grant proposals and IRB?
- Project has a relatively flat data structure.
 - Typically accommodates 2 or 3 levels well, but is clumsy beyond that. County, Practice, Provider, Patient, Time, Family.

Scenario NOT favoring REDCap



Scenarios Favoring REDCap

- No professional software developer on the project
 - There's nothing magical about REDCap; it accommodates the designs and needs of many clinical projects.
 - To develop a comparable system from scratch, you'd need experience with several technologies.
- There are lots of dimensions and trade-offs when designing clinical research, and REDCap is **close to the sweet spot** for most designs.
- Candidate for replacing Access, Survey Monkey, Excel.

Project Management with REDCap

While the original intent of the development of REDCap was to provide researchers with a secure web application for research, a REDCap project can be designed to simultaneously aid in project management and productivity monitoring.

Productivity Monitoring

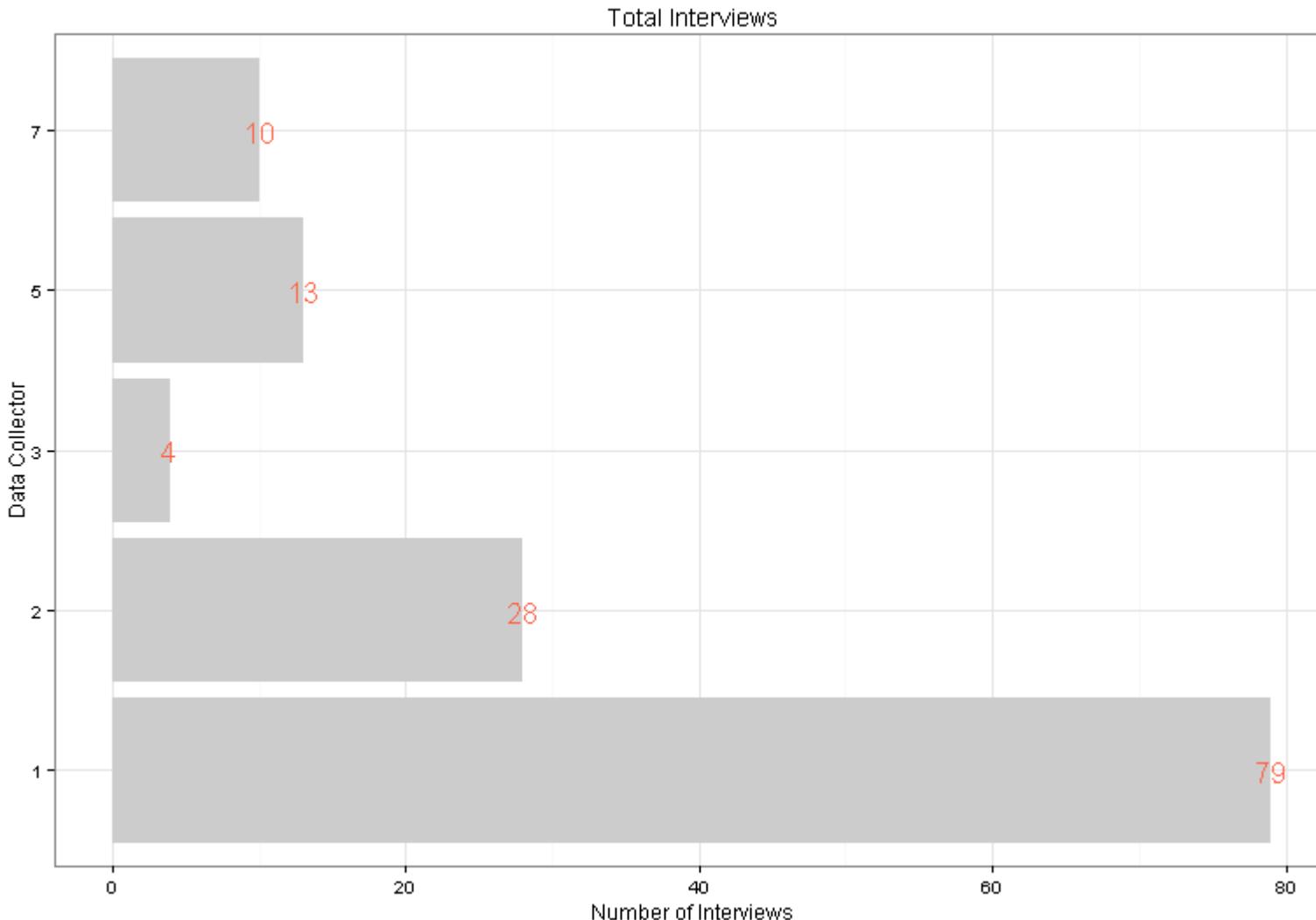
What do you want to monitor?

Productivity indicators can be incorporated in the original design phase of a REDCap project, or added to an existing project.

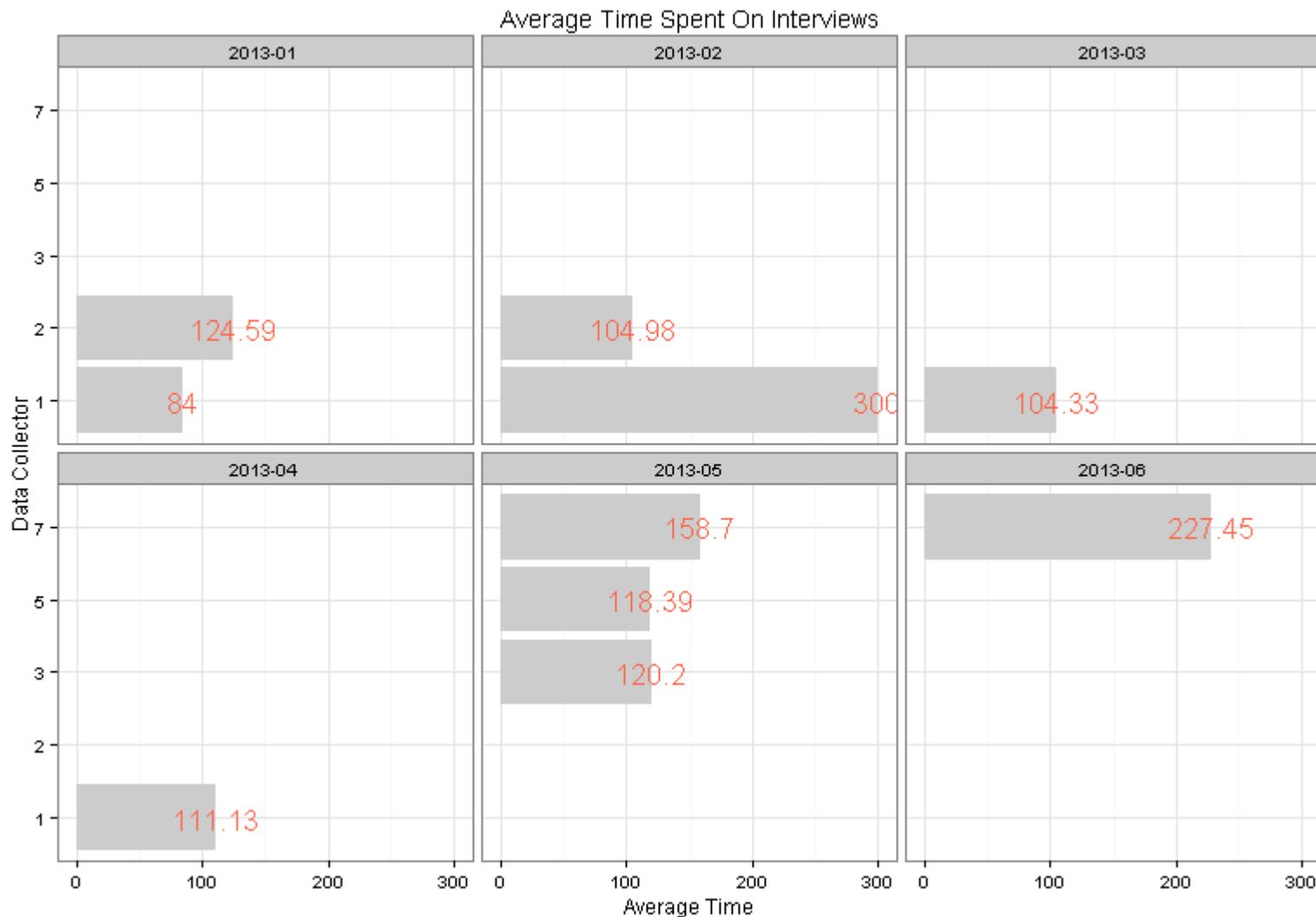
MIECHV Project Productivity Indicators

- Community Survey Recruitment
 - Total recruitment calls made
 - Time spent on recruitment calls
 - Average time per recruiting call
 - Number of recruits who agreed to participate
 - Percent of recruits who agreed to participate
- Community Surveying
 - Total interviews completed
 - Time spent conducting interviews
 - Average time per interview

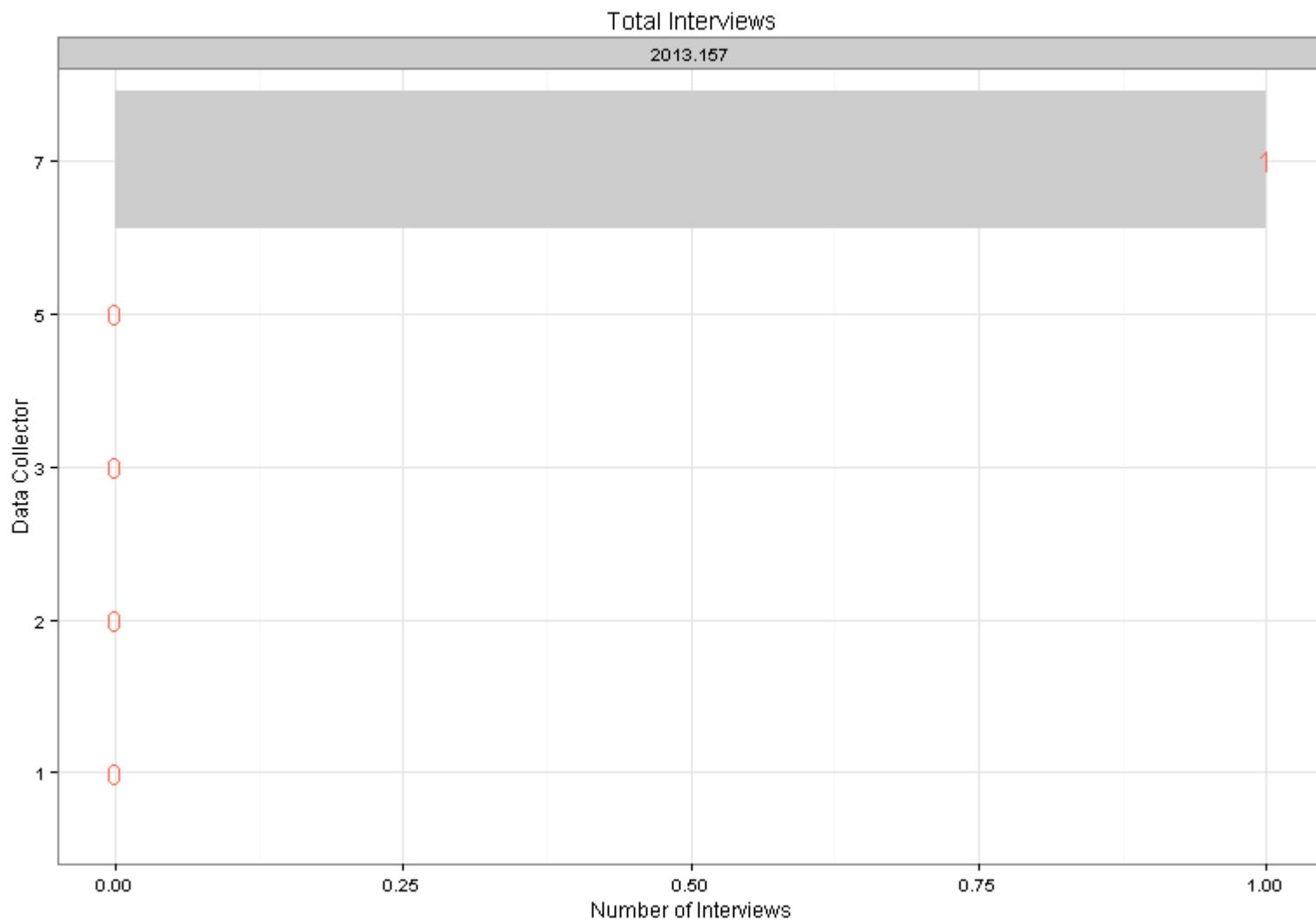
Example Report (Project Aggregate)



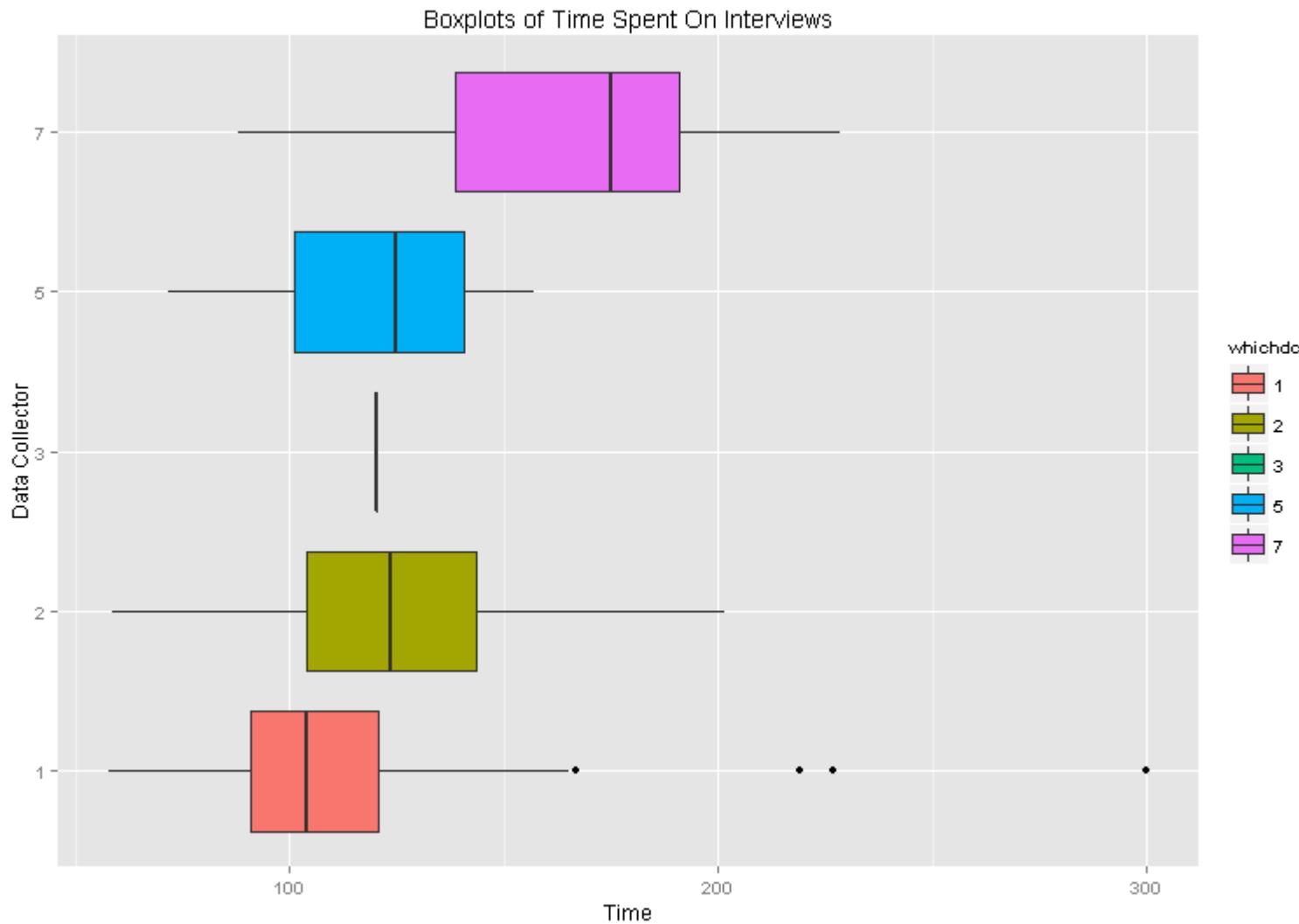
Example Report (6 Month History)



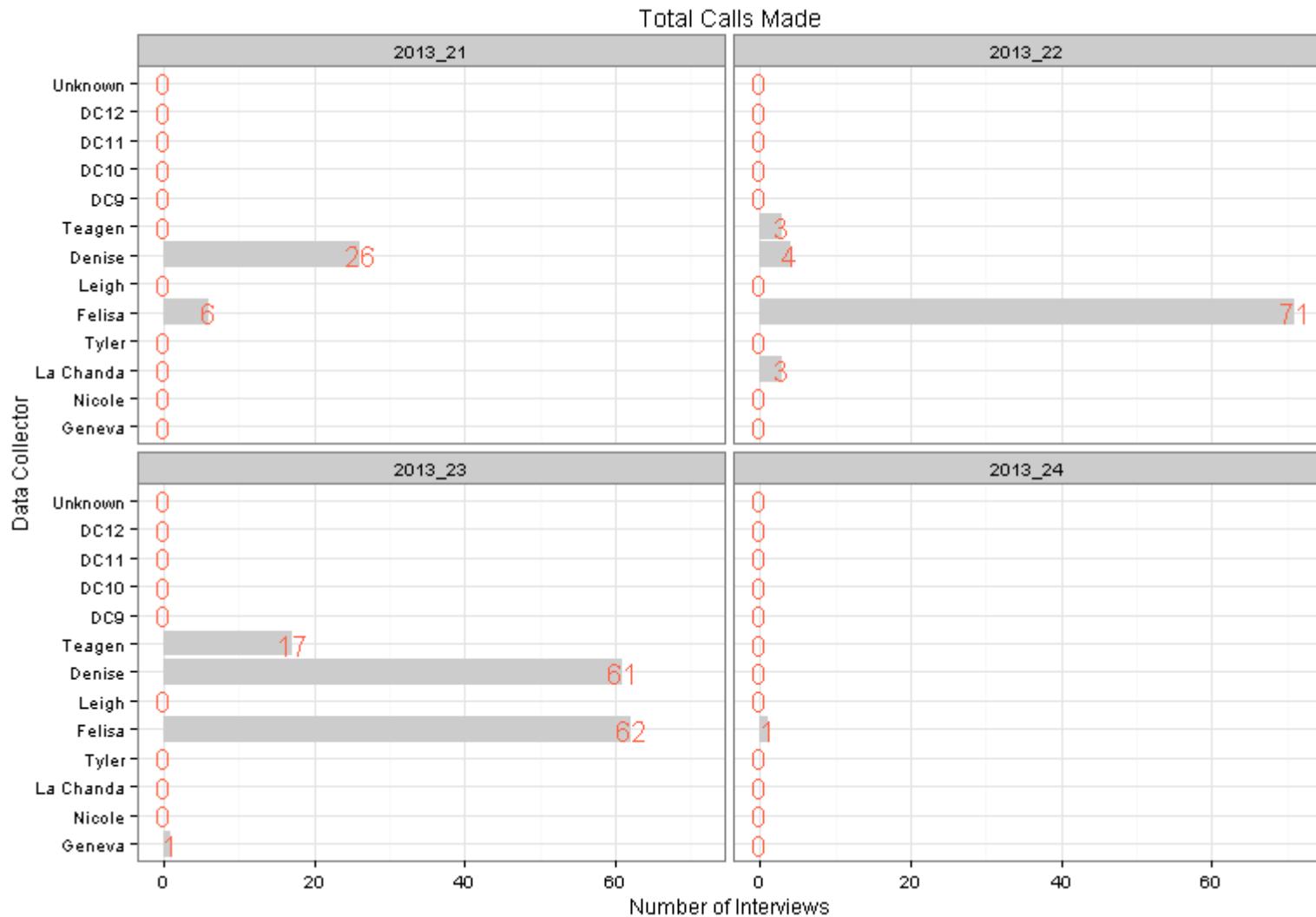
Example Report (7 Day History)



Example Report (Project Aggregate)



Example Report (4 Week History)



REDCap Advantages

- Flexibility:
 - Productivity indicators established by project team
 - Reporting methods determined by project needs
 - All aspects are customizable
 - Current and historical reports
- Automated:
 - Not necessary to compile data
 - Real-time data availability

Reports for Outcomes: within REDCap

Accommodates basic
descriptives & graphs,
but not much more.

Number of results returned: 3

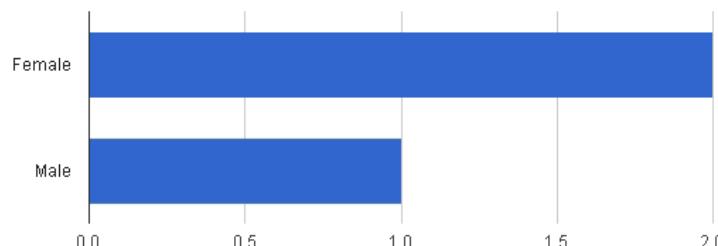
Total number of records queried: 12 ('records' =

PresentationDemo	
Ethnicity (ethnicity)	Gender (sex)
Non-Hispanic (1)	Female (0)
Hispanic (2)	Female (0)
Non-Hispanic (1)	Male (1)

Gender: [Refresh Plot](#) | [View as Bar Chart](#) ▾

Total (N)	Missing	Unique
3	9 (75%)	2

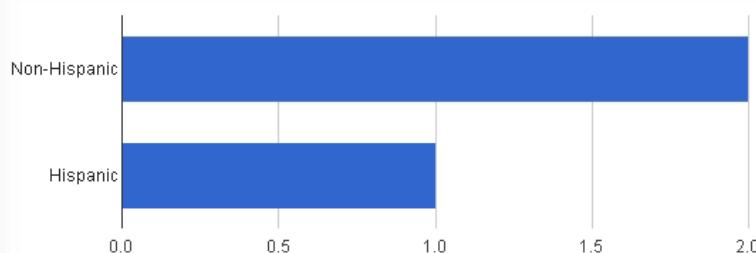
Counts/frequency: Female (2, 66.7%), Male (1, 33.3%)



Ethnicity : [Refresh Plot](#) | [View as Bar Chart](#) ▾

Total (N)	Missing	Unique
3	9 (75%)	2

Counts/frequency: Non-Hispanic (2, 66.7%), Hispanic (1, 33.3%)



Reports for Outcomes: External to REDCap

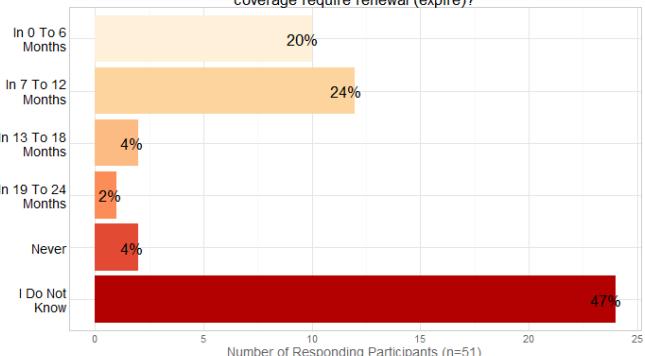
- Use automation to present results in a coherent document.
- Eliminate the need to repeatedly copy & paste:
 - Multiple descriptives, graphs, and model results.
 - Updated results after more data trickles in.
- Internal vs. External Audiences

Reports for Outcomes: Examples

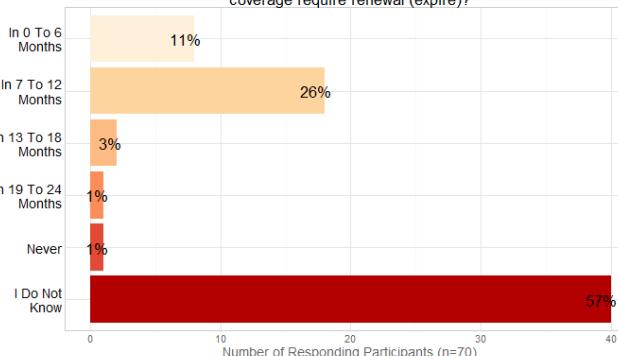
- Descriptives & graphs for internal audiences.
- Tables for external audiences.
- Text and Graphs for external audiences.
- Optionally hosted online.
<https://github.com/OuhscCcanMiechvEvaluation/MReporting/blob/master/OhcaReports/OhcaReport1/OhcaReport1.md>

Quick for Internal Audiences

When does your (not your child's) Medicaid/SoonerCare coverage require renewal (expire)?



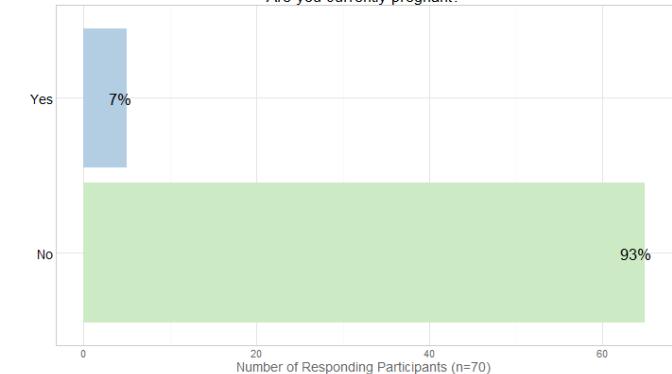
When does your child's Medicaid/SoonerCare coverage require renewal (expire)?



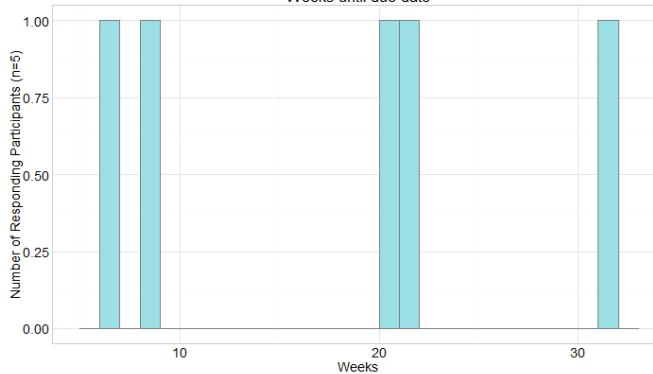
Section B: Pregnancy

Current and Previous Pregnancy

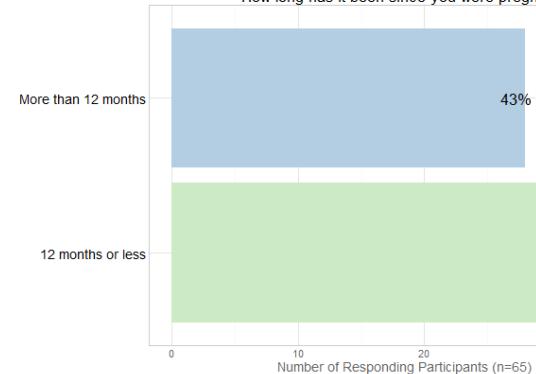
Are you currently pregnant?



Weeks until due date

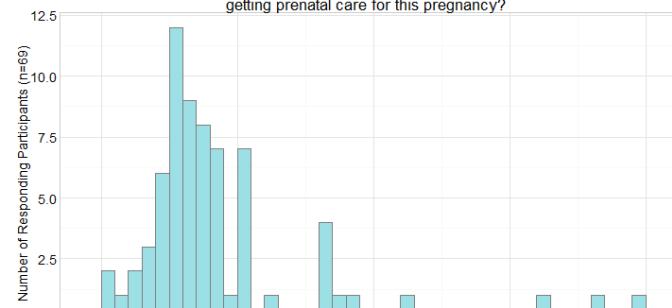


How long has it been since you were pregnant?

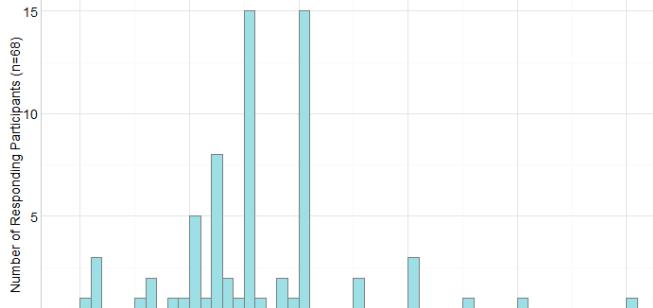


Prenatal Care and Education

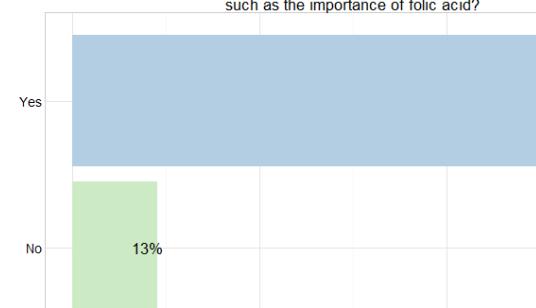
How many weeks pregnant were you when you began getting prenatal care for this pregnancy?



How many prenatal care visits did you have during your pregnancy?



Have you received education on pre-pregnancy/in-between pregnancies such as the importance of folic acid?



Text and Graphs for External Audiences

Draft of C1 Activity Level Report

OUHSC External MIECHV Evaluation Team
David Bard, Will Beasley, & Thomas Wilson

March 21, 2013

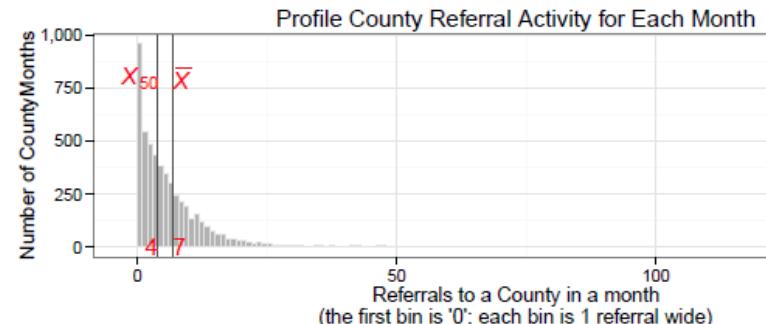
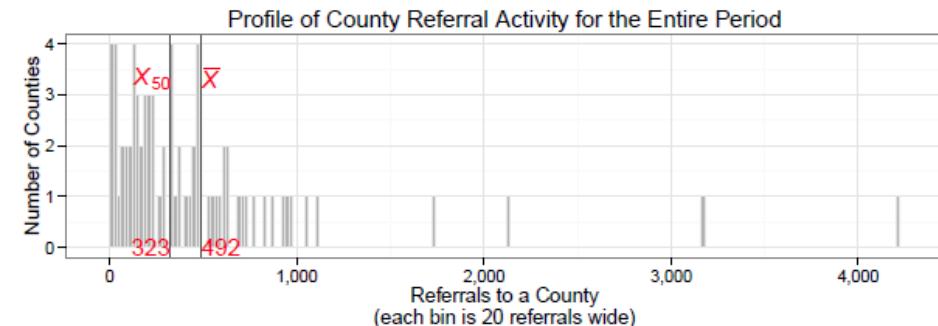
Note: This is a draft, and does not represent the official results. One next step is to address potential redundant records, which we believe represent fewer than 10% of the existing records. A second step is to account for the referrals that come from a county without an established health department or C1 program. Currently the analysis considers all referrals equivalently, which biases down the activity level so it appears that the performance is worse than it actually is.

This report contains information from 74 counties, 86 clinics, 33,170 parents, 36,379 referrals, 5,936 enrollments, 641 recorded graduations, and 2,826 recorded nongraduations. It summarizes C1 referrals between January 02, 2007 and November 29, 2012. The 3 referrals received by the central OSDH office (i.e., ID #99) have been excluded.

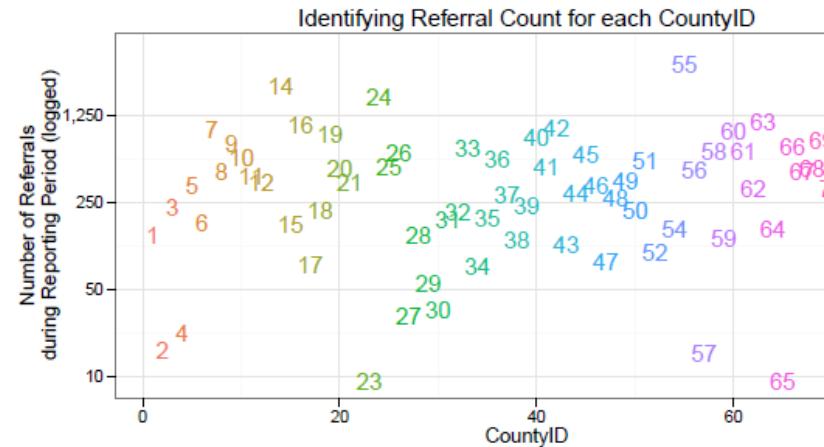
1 Referrals

The first histogram looks at the number of referrals received by the different *counties* during the reporting period. The second histogram looks at the number of referrals received by the different *county months* during the reporting period. Notice the median and mean are annotated each with a darker vertical gray line; the median is on the left, the mean is on the right.

There are many months where a county received few referrals. Several sources of these zeros have been identified, and we are deciding how to most accurately represent them in various contexts. For instance, when analyzing the cost-effectiveness of C1, an understaffed county should be treated differently than an adequately staffed county. We soon will incorporate a county's operational dates and its specific funding and staffing levels.



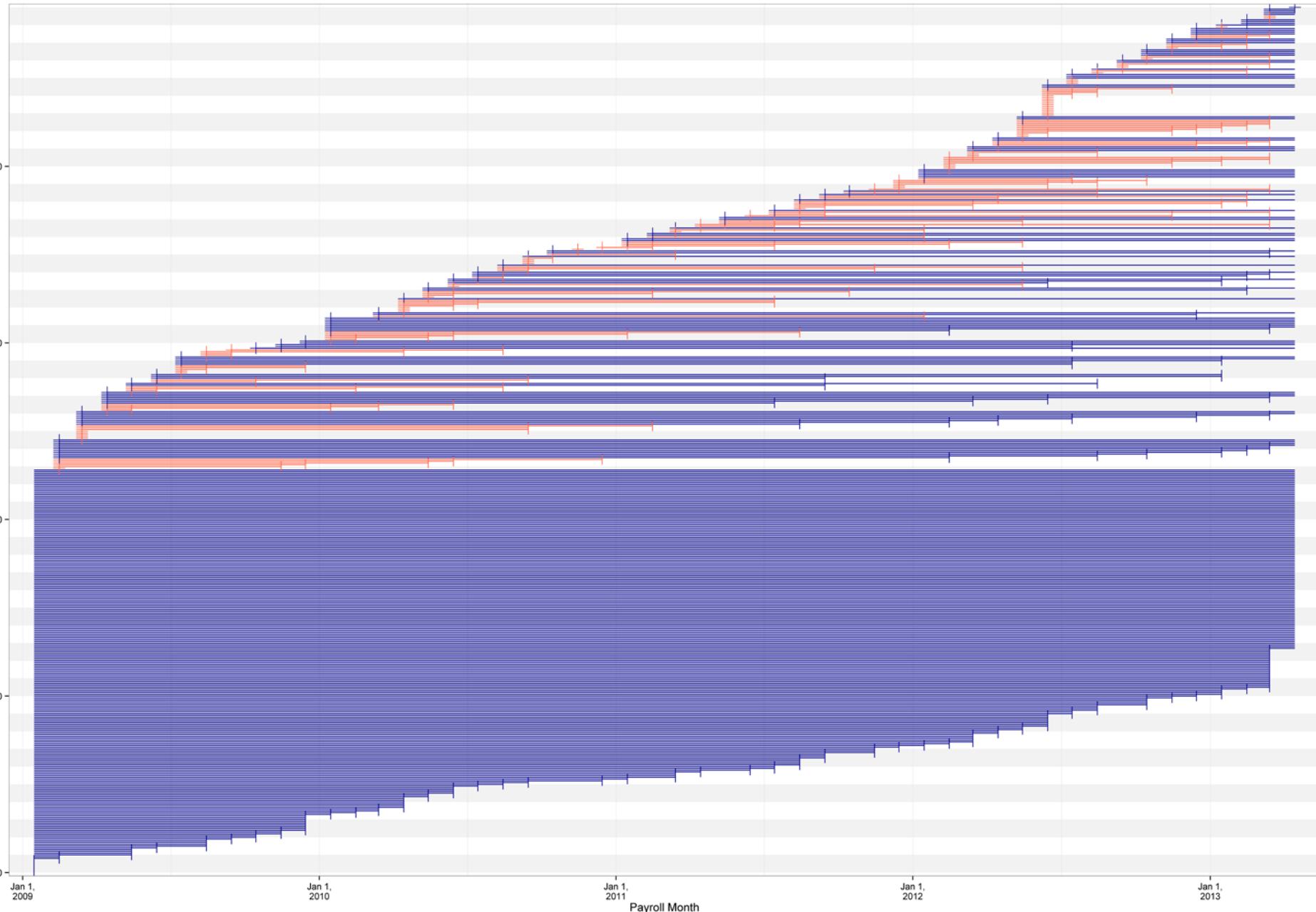
This scatterplot is atypical, because the horizontal is not a real quantitative dimension, it is the value of the county. The information is redundantly displayed by the numbers in the scatterplot. Notice the vertical is logged. Smaller counties will not be bunched together. This plot can serve as a legend for the subsequent line graphs. The county names corresponding to the scatterplot corresponds to its color in the subsequent line graphs. The county names corresponding are decoded in the long table at the end of this document.



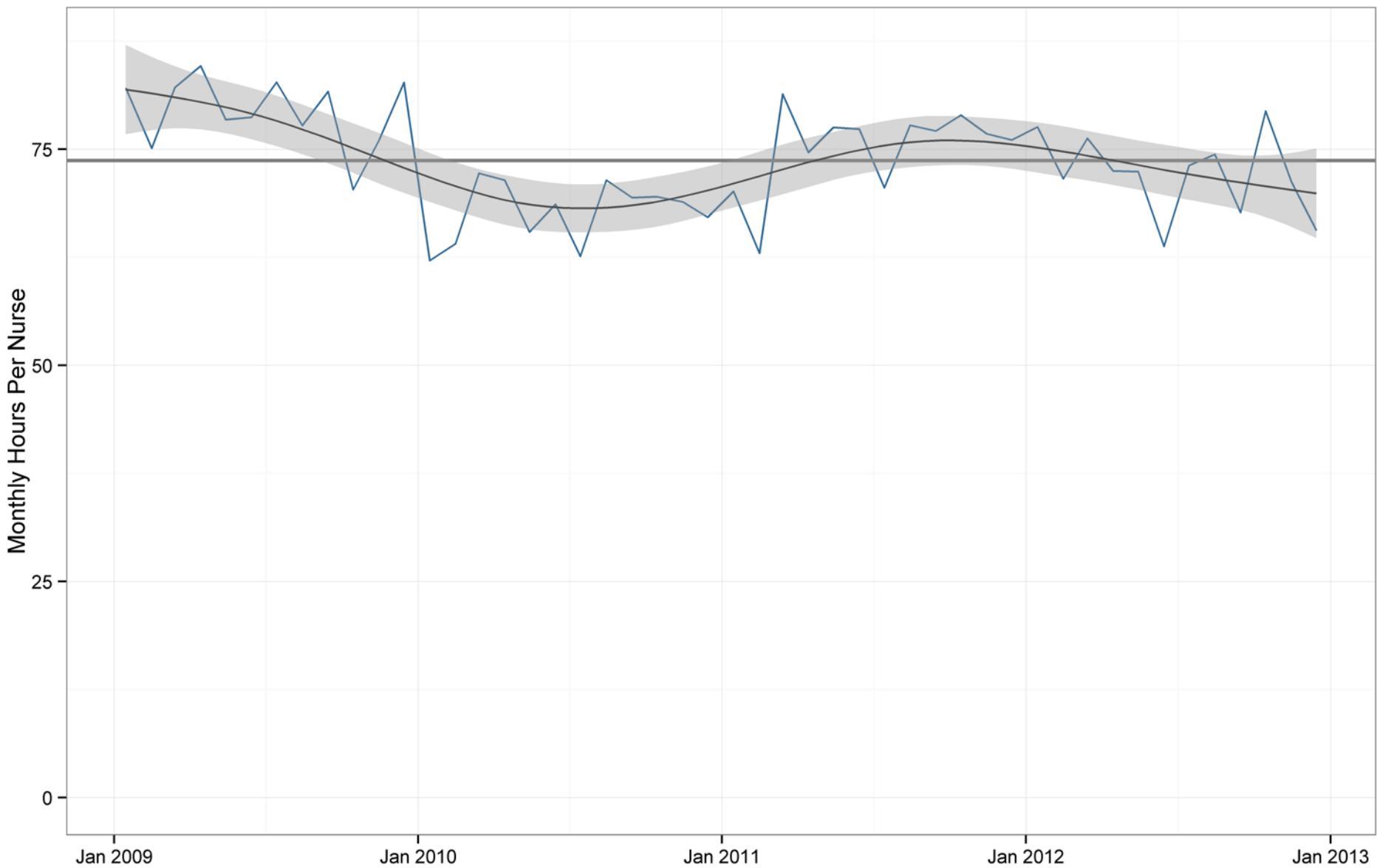
The next two graphs show the number of referrals received over time, by county. Each county has a unique color. The numbers on the points denote a month's 25%, 50% and 75% counts of referrals to a county. For instance, when the middle of a box is 10, then 50% of the counties received 7 referrals or fewer.

The gray lines appear again as the median (on bottom) and mean (on top). A curvy longitudinal line shows the state's trend during the reporting period. The two graphs are identical, except the second one zooms in on the first 20 county IDs.

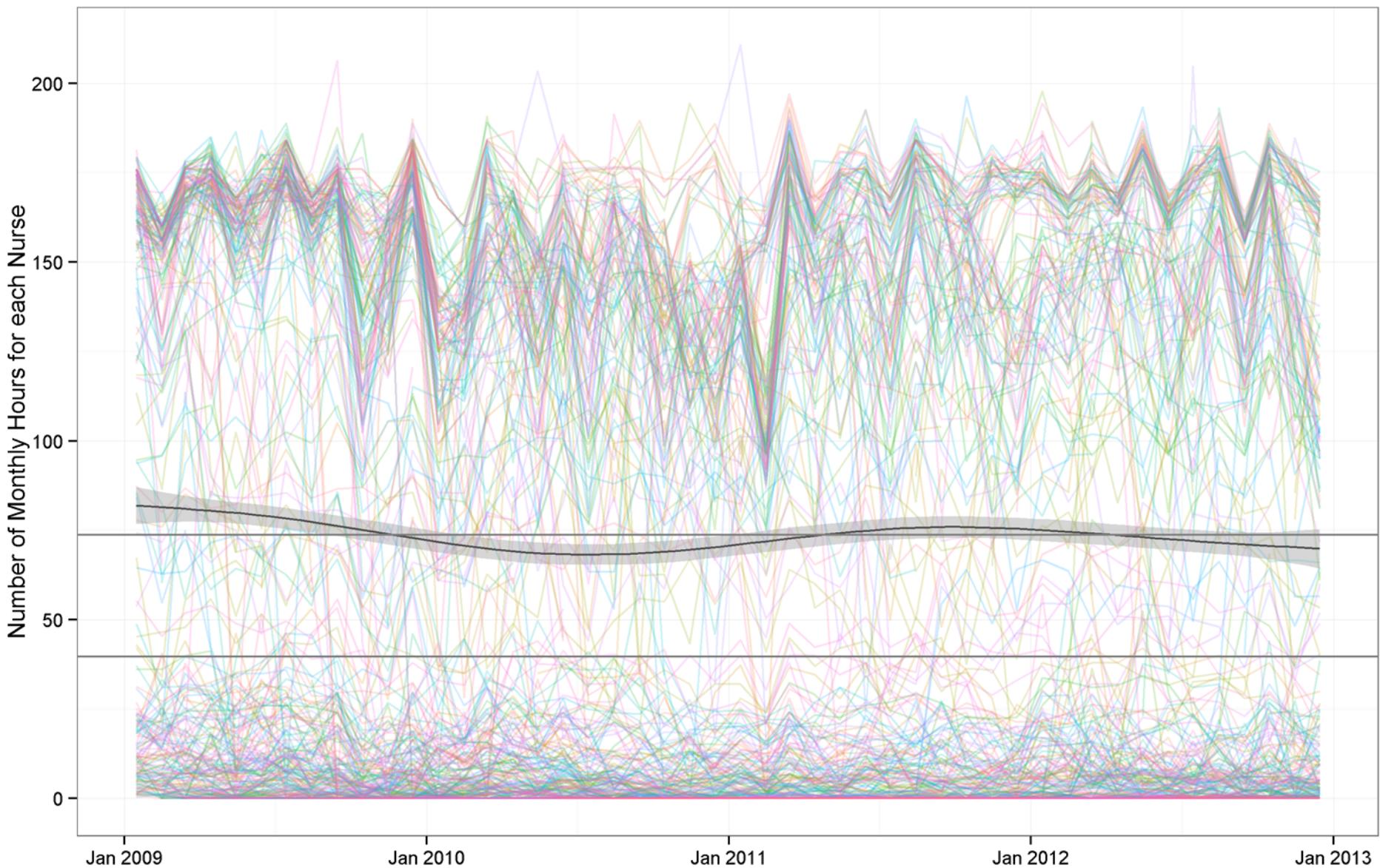
Text and Graphs for External Audiences



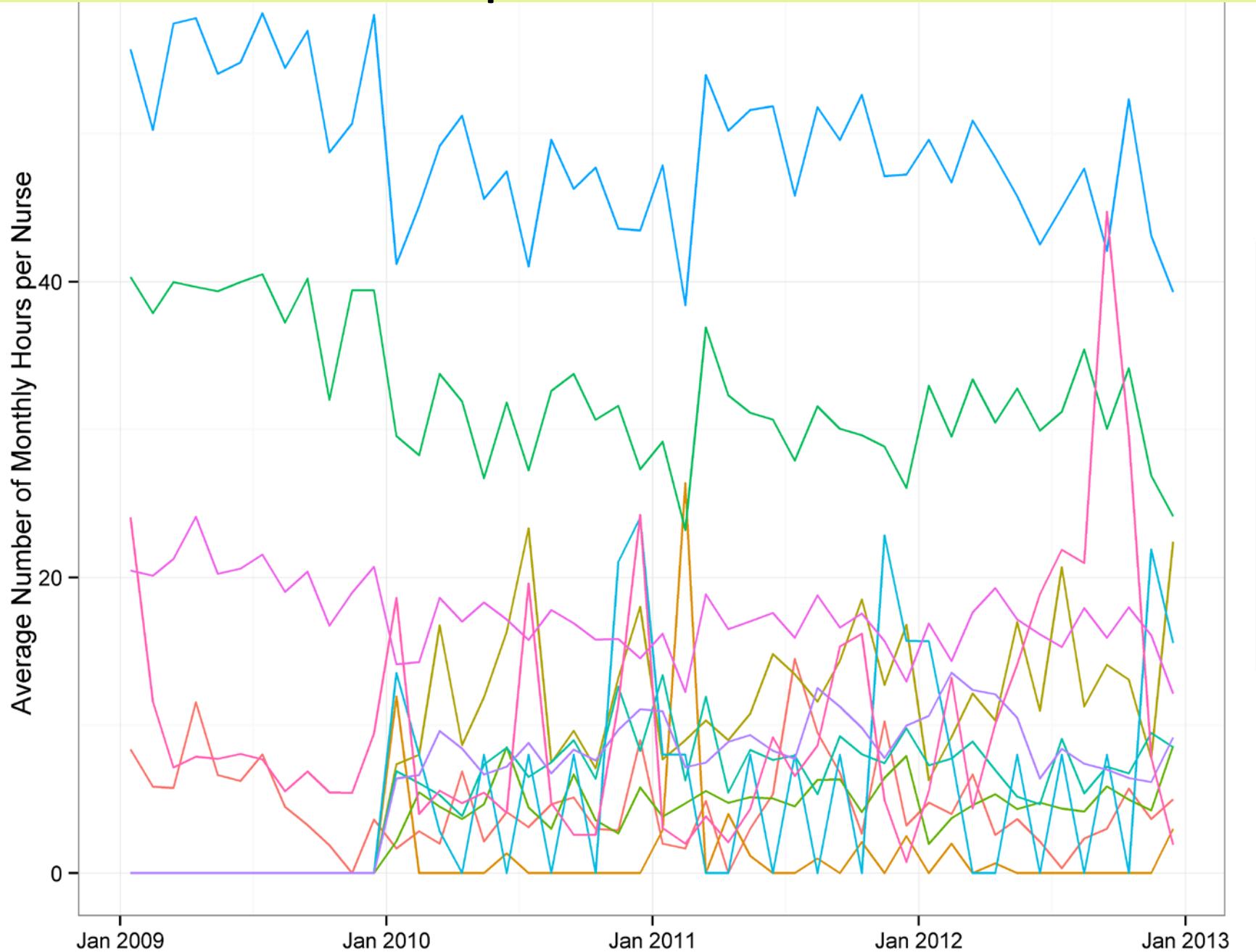
Text and Graphs for External Audiences



Text and Graphs for External Audiences



Text and Graphs for External Audiences



Tables for External Audiences

Comparison of Versions of Kinship Links Joe Rodger's BG Team

December 9, 2012

Outcome: HeightZGenderAge;
 RelationshipPath: Gen1Housemates [ID:1]; Newer Links Version: 53; Older Links Version: 52;
 Newer Links: R Excludes Gen1 R=0, .375, .75
 Older Links: After chaning 'R' to 'RFull'; Excludes Gen1 R=0
 R Groups specifically excluded: {}
 Drop pair if housemates are not confirmed in the same generation: FALSE

1 Ace - Comparison of *R* Variants

(See the final table for an explanation of the different *R* variants.)

<i>R</i> Variant	a_{new}^2	c_{new}^2	e_{new}^2	N_{new}	a_{old}^2	c_{old}^2	e_{old}^2	N_{old}
R	.90	.00	.10	3729	.90	.00	.10	3784
RFull	.50	.19	.31	4227	.50	.19	.31	4227
RExplicit	.78	.06	.16	3702	.78	.06	.16	3702
RImplicit2004	.75	.09	.16	2262	.75	.09	.16	2262

Table 1: Comparison of *R* Variants (by rows) and of Links Versions (left vs right side).

2 Subgroups – R

<i>R</i>	Included in SEM	N_{Pairs}	s_1^2	s_2^2	$s_{1,2}$	r	Determinant	PosDefinite
0.125	TRUE	88	0.91	0.95	0.15	0.16	0.8	TRUE
0.250	TRUE	238	1.01	1.14	0.26	0.24	1.1	TRUE
0.500	TRUE	3392	0.97	1.02	0.44	0.44	0.8	TRUE
1.000	TRUE	11	0.29	0.61	0.37	0.89	0.0	TRUE

Table 2: R – Newer Version of Links

<i>R</i>	Included in SEM	N_{Pairs}	s_1^2	s_2^2	$s_{1,2}$	r	Determinant	PosDefinite
0.125	TRUE	88	0.91	0.95	0.15	0.16	0.8	TRUE
0.250	TRUE	238	1.01	1.14	0.26	0.24	1.1	TRUE
0.375	TRUE	45	1.00	1.18	0.48	0.44	1.0	TRUE
0.500	TRUE	3392	0.97	1.02	0.44	0.44	0.8	TRUE
0.750	TRUE	10	0.78	0.76	0.55	0.71	0.3	TRUE
1.000	TRUE	11	0.29	0.61	0.37	0.89	0.0	TRUE

Table 3: R – Older Version of Links

3 Subgroups – RFull

RFull	Included in SEM	N_{Pairs}	s_1^2	s_2^2	$s_{1,2}$	r	Determinant	PosDefinite
0.000	TRUE	443	0.93	0.82	0.23	0.26	0.7	TRUE
0.125	TRUE	88	0.91	0.95	0.15	0.16	0.8	TRUE
0.250	TRUE	238	1.01	1.14	0.26	0.24	1.1	TRUE
0.375	TRUE	45	1.00	1.18	0.48	0.44	1.0	TRUE
0.500	TRUE	3392	0.97	1.02	0.44	0.44	0.8	TRUE
0.750	TRUE	10	0.78	0.76	0.55	0.71	0.3	TRUE
1.000	TRUE	11	0.29	0.61	0.37	0.89	0.0	TRUE

Table 4: RFull – Newer Version of Links

RFull	Included in SEM	N_{Pairs}	s_1^2	s_2^2	$s_{1,2}$	r	Determinant	PosDefinite
0.000	TRUE	443	0.93	0.82	0.23	0.26	0.7	TRUE
0.125	TRUE	88	0.91	0.95	0.15	0.16	0.8	TRUE
0.250	TRUE	238	1.01	1.14	0.26	0.24	1.1	TRUE
0.375	TRUE	45	1.00	1.18	0.48	0.44	1.0	TRUE
0.500	TRUE	3392	0.97	1.02	0.44	0.44	0.8	TRUE
0.750	TRUE	10	0.78	0.76	0.55	0.71	0.3	TRUE
1.000	TRUE	11	0.29	0.61	0.37	0.89	0.0	TRUE

Table 5: RFull – Older Version of Links

4 Subgroups – RExplicit

RExplicit	Included in SEM	N_{Pairs}	s_1^2	s_2^2	$s_{1,2}$	r	Determinant	PosDefinite
0.250	TRUE	245	1.03	1.18	0.29	0.26	1.1	TRUE
0.375	TRUE	45	1.00	1.18	0.48	0.44	1.0	TRUE
0.500	TRUE	3412	0.96	1.01	0.44	0.44	0.8	TRUE

Table 6: RExplicit – Newer Version of Links

RExplicit	Included in SEM	N_{Pairs}	s_1^2	s_2^2	$s_{1,2}$	r	Determinant	PosDefinite
0.250	TRUE	245	1.03	1.18	0.29	0.26	1.1	TRUE
0.375	TRUE	45	1.00	1.18	0.48	0.44	1.0	TRUE
0.500	TRUE	3412	0.96	1.01	0.44	0.44	0.8	TRUE

Table 7: RExplicit – Older Version of Links

Quick for Internal Audiences

One-way General Linear Model

Predictor Variable:

▼

Show your score
 Show Summary

What is your gender?

▼

What is your age?



A horizontal slider with a blue arrowhead at the 40 mark. The scale has numerical labels 0, 40, and 100.

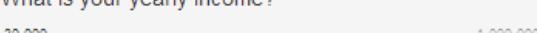
What is your marital status?

▼

How many children do you have?

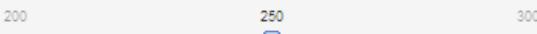
▲ ▼

What is your yearly income?



A horizontal slider with a blue arrowhead at the 30,000 mark. The scale has numerical labels 30,000 and 1,000,000.

What is your Development Score ?

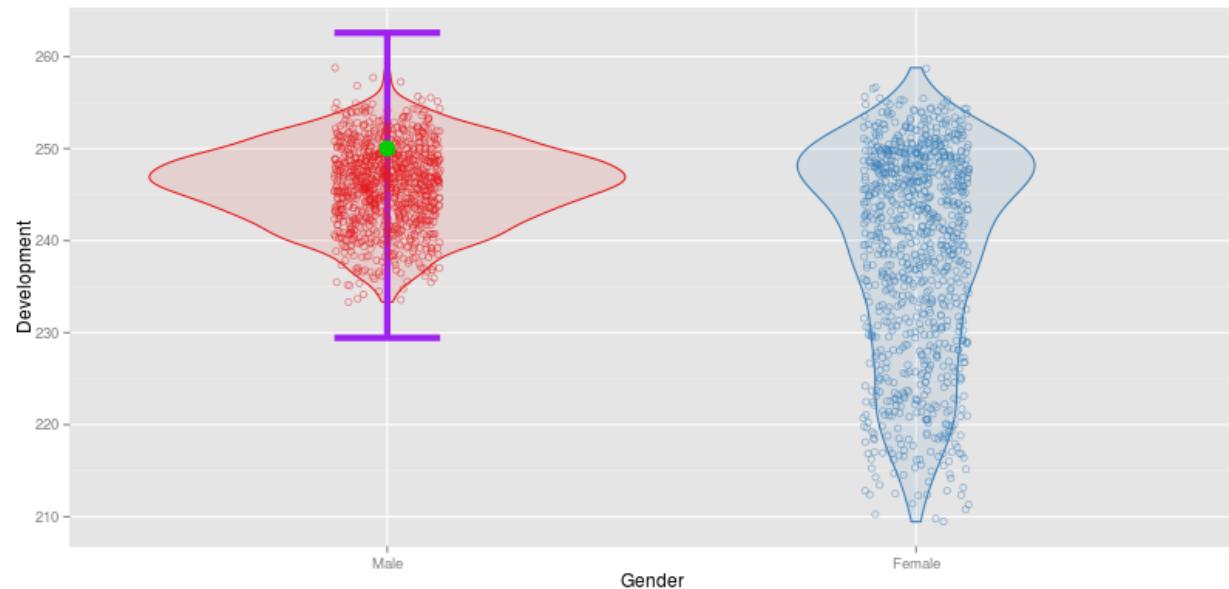


A horizontal slider with a blue arrowhead at the 250 mark. The scale has numerical labels 200, 250, and 300.

Predictor Variable: Gender

Dataset: /home/wibeasley/ShinyApps/Oneway/Data/FakeData.csv

Sample Scores



Most patients with your value of Gender fall between 229 and 263 points on the Development scale.

Subset of data:

Number of rows to display:

6

	SubjectID	Development	Gender	Age	MaritalStatus	ChildCount	Income	AgeGroup
1	1	247.24	Female	44.47	Unmarried	1	11508.09	[40,50)

Quick for Internal Audiences

One-way General Linear Model

Predictor Variable:

Age

Show your score
 Show Summary

What is your gender?

Male

What is your age?

0 30 100

What is your marital status?

Unmarried

How many children do you have?

3

What is your yearly income?

0 279,000 1,000,000

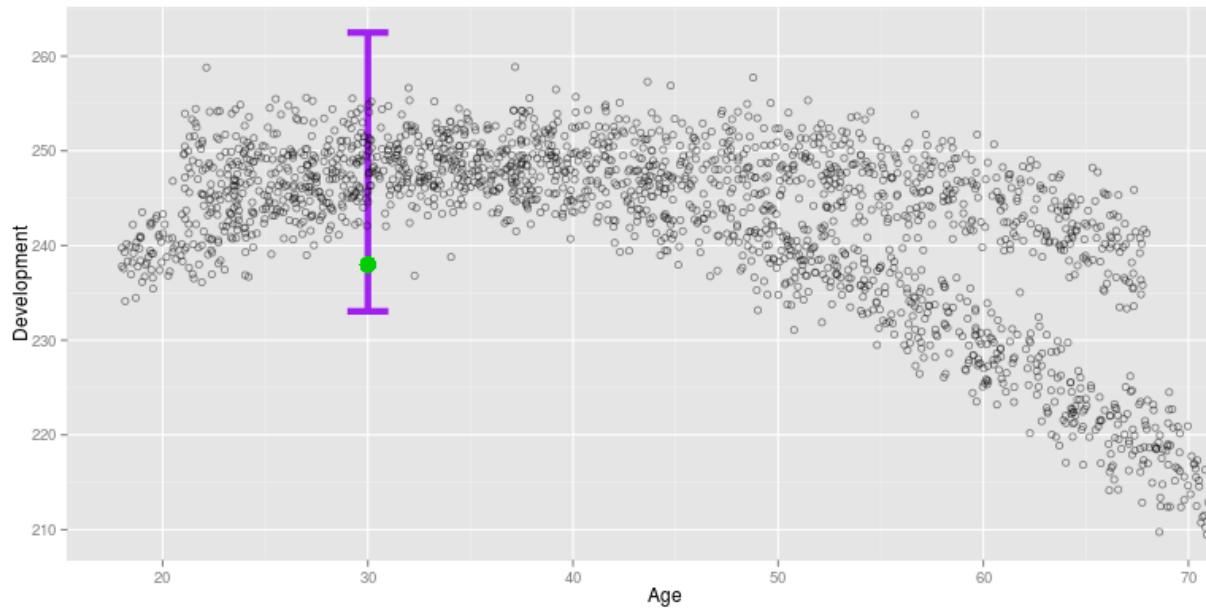
What is your Development Score ?

200 238 300

Predictor Variable: Age

Dataset: /home/wibeasley/ShinyApps/Oneway/Data/FakeData.csv

Sample Scores



Most patients with your value of Age fall between 233 and 262 points on the Development scale.

Subset of data:

Number of rows to display:

6

SubjectID	Development	Gender	Age	MaritalStatus	ChildCount	Income	AgeGroup
1	1	247.24	Female	44.47	Unmarried	1 11508.09	[40,50)

Goals

- Reproducible research.
 - Facilitates scientific replication.
 - Disseminates techniques to other subfields.
 - Promotes cumulative research.
- Literate programming.
 - Evaluated programs need fresh & frequent feedback.
- Collaborative Development.

Collaboration among

1. The 4 statisticians on the project.
sharing software development.
2. The 20 people on the project.
exchanging participant-level data.
3. The 3 partnering organizations. (OSDH, WIC, OHCA)
-receiving their subject-level & agency-level data.
-distributing our results –fresh & frequently.
4. Academics in different areas. (particularly at OUHSC)
exchanging tools and workflows.
5. Researchers in other states pursuing similar goals.
publishing ideas and replicating previous work.

Accessing OUHSC REDCap

- OUHSC REDCap website:

<https://miechvprojects.ouhsc.edu/redcap/BBMC/redcap.html>

- [REDCap Overview](#)
- [Access to REDCap](#)
- [REDCap Login](#)
- [Licensing](#)
- [Compliance](#)
- [Policy](#)
- [Training and Learning Resources \(Basic\)](#)
- [Training and Learning Resources \(Advanced\)](#)
- [Getting Help](#)
- [For More Information](#)

Intro to Security Concepts

- College of Medicine has devised a REDCap governance body to oversee data security concerns
 - In a nut-shell, looking to see if investigators and staff have proper IRB clearances for storing PHI on REDCap.
 - Will provide general advice on secure best practices
 - To gain access to REDCap, you must have seal of approval of this governance body
 - Please visit REDCap website to initiate request and review security policies and procedures under Compliance links
<https://miechvprojects.ouhsc.edu/redcap/BBMC/redcap.html>
 - After request is initiated, the REDCap Appropriate Use Policy must be reviewed and the REDCap Data Use Agreement must be signed (BBMC will circulate after request is made)
<https://miechvprojects.ouhsc.edu/redcap>

Underlying Security Concepts Part 1

- Principle of least privilege: expose as little as possible.
 - Limit the number of team members.
 - Limit the amount of data (consider rows & columns).
 - Obfuscate values and remove unnecessary PHI in derivative datasets.
- Redundant layers of protection.
 - A single point of failure shouldn't be enough to breach PHI security.

Underlying Security Concepts Part 2

- Simplify when possible.
 - Store data in only one or two places. (REDCap & SQL Server)
 - Easier to identify & manage than a bunch of PHI CSVs scattered across a dozen folders, with versions.
 - Manipulate your data programmatically, not manually.
 - Windows AD account controls everything, indirectly or directly. (VPN, Odyssey, file server, SQL Server, & REDCap)
- Lock out team members where possible.

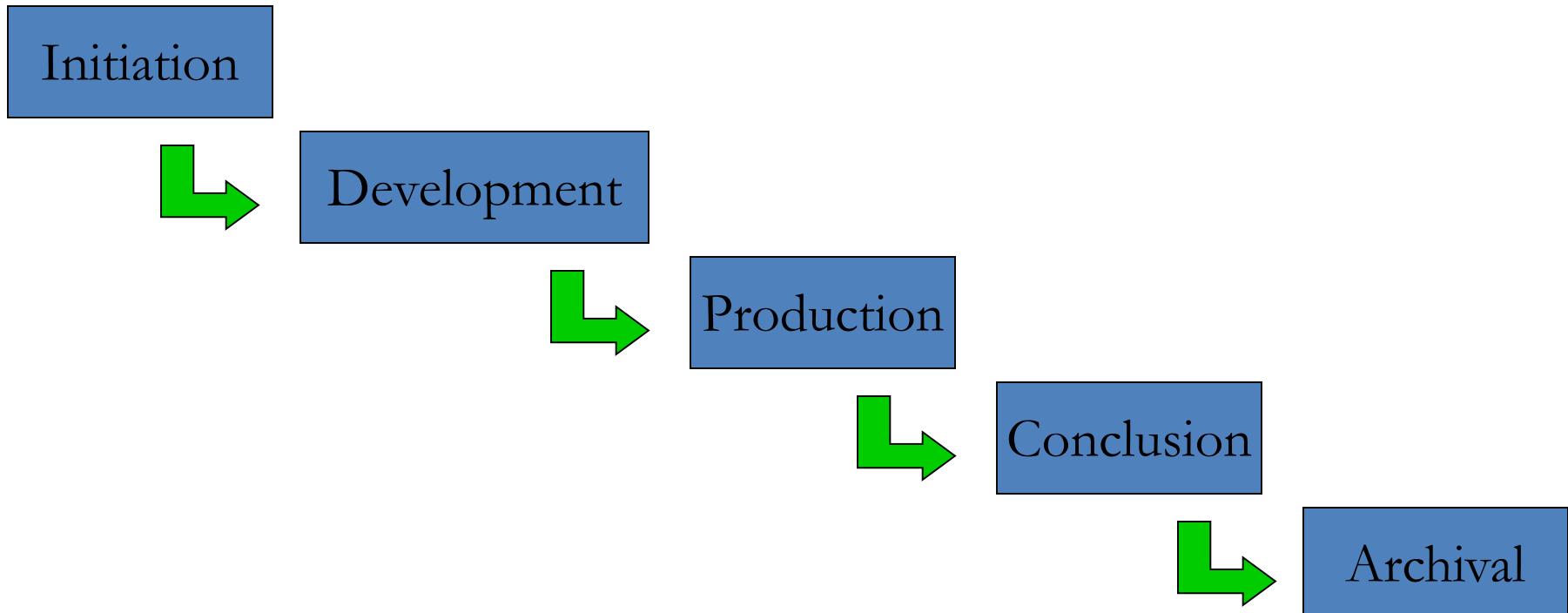
It's not that you don't trust them with a lot of unnecessary data, it's that you don't trust their ex-boyfriend and their coffee shop hacker.

The design of the project is as follows:

- Simplify when possible.
 - Store data in only two houses. (REDCap & SQL Server)
 - Easier to identify & manage than a bunch of PHI CSVs scattered across a dozen folders, with versions.
 - Manipulate your data programmatically, not manually.
 - Windows AD account controls everything, indirectly or directly. (VPN, Odyssey, file server, SQL Server, & REDCap)
- Lock out team members where possible.
It's not that you don't trust them with a lot of unnecessary data, it's that you don't trust their ex-boyfriend and their coffee shop hacker.

SOPs and Documenting Projects in REDCap

- Standard Operating Procedures (SOPs)
 - The different phases considered in the development of a project are aligned with REDCap:



SOPs and Documenting Projects in REDCap

- The major actions regulated and documented are:
 - Request a new project
 - Project definition
 - Letter of collaboration and agreement
 - Validation testing
 - User account request
 - Training log
 - Change Project definition
 - Platform transfer specifications
 - Data sharing
 - Database closure
 - Decommissioning

The design of the project is as follows:

Project Life-Cycle

Data Entry: Event Grid

The grid below displays the form-by-form progress of data events. You may click on the colored buttons to access the navigating to the [Define My Events](#) page.

or one particular Participant ID for all defined wish, you may modify the events below by

Phases

Participant ID: (1)

Data Collection Instrument	Events				
	Initiation (1)	Development (2)	Production (3)	Completion (4)	Archival (5)
Request a new project	●				
Project Definition	●				
Letter of Collaboration & Agreement	●				
Validation Testing		●	●		
Request REDCap User Accounts		● mcarroll ● kjacobs ● lcarroll ● jsimkin ●		●	
Training Log		● Dr. Matt Carroll ●		●	
Change Project Definition				●	
Platform Transfer Specifications				●	
Data Sharing			●	●	
Database Closure				●	
Decommissioning					●

Actions

SOPs and Project Development

Editing existing Participant ID 5 (Project Acronym IBD)

Event Name: Development

Participant ID 5

Following the authorization of the requirements definition, the implementation phase can begin. During this phase, if CRSU is in charge of the implementation phase, the required project deliverables will be configured and tested by CRSU. If CRSU is not in charge of this phase, it is the sole responsibility of the project team to establish the appropriate process to assure the implementation of the study follows their own requirements.

Precise implementation detail will be project-specific and software-specific. It may require additional documentation.

Examples of typical tasks are:

- Study Configuration
- Study Events Definition
- Data Collection Form Implementation
- Data Completion Guidelines

The authorization of this form indicates that user acceptance testing has been completed to the approver's satisfaction and that the specified project components are ready to be deployed in a production environment.

During implementation, CRSU personnel will test the project implementation by following a documented test plan. The precise form of testing will reflect the specifications made in the Project Initiation Form. Evidence of such testing will be documented in the project file.

Instructions

Documentation

Functionality	CRSU Tester	Date	Outcome
Study Configuration	Ashley	17-04-2012 31 Today D-M-Y	Pass
Site Configuration	Ashley	17-04-2012 31 Today D-M-Y	Pass
User / Respondent Configuration	Ashley	18-04-2012 31 Today D-M-Y	Pass
Form / Event Implementation / Configuration	Ashley	18-04-2012 31 Today D-M-Y	Pass

SOPs and Training

SOP

Attached is relevant SOP.

Attachment: [CFRI SOP Study and Project EDC Training.doc](#) (0.09 MB)

Training Session Information

Date of Training Session: 13-02-2012

Name of Trainer: Ashley McKerrow

Type of Training Session: In person Webinar

Software:
Only Specify if not using REDCap

Attendee Information

Name of Attendee: Dr. Matt Carroll

Documenting
Training

Training Categories- Select all categories attendee was trained in

Training Categories	Select all the apply
Project Set-Up and Design	<input checked="" type="checkbox"/>
Data Entry	<input checked="" type="checkbox"/>
Data Management	<input checked="" type="checkbox"/>
New Features	<input checked="" type="checkbox"/>
Re-Training	<input type="checkbox"/>

SOPs and Training

Version control



STANDARD OPERATING PROCEDURE: CRSU TRAINING PLAN FOR CRI SUPPORTED PROJECTS

SOP Number:	1.04.02
Version Number:	1.0
Department/System:	CRSU
Supersedes:	N/A
Effective Date:	DD-MMM-2012
Number of pages including cover:	5

Approval:

Name: Victor Espinosa	Title: Manager, CRSU
Signature:	Date:

Name: Stuart Turvey	Title: Director, Clinical Research Studies
Signature:	Date:

SOPs and Training

Purpose

Responsibilities

Scope

Definitions

1. PURPOSE

- 1.1 To identify the standard procedure for user training on CRI CRSU supported EDC and web-based applications for surveys, studies and other research related management projects conducted at the CRI.
- 1.2 With support from the CRSU, project teams will be able to develop and manage their projects independently. After completing all of the training categories, the project administrator will understand the general features of CRSU Platform pertaining to their project and the CRSU policies for hosting a project. They will therefore be accountable for making sure all users have the ability to successfully perform their assigned participation within the lifecycle of a CRSU based project.

2. SCOPE

- 2.1 This procedure applies to CRSU trainers, assigned Project Administrators and additional identified study teams members using CRI EDC and web-based applications.

3. RESPONSIBILITIES

- 3.1 CRSU Trainer is responsible for booking and scheduling, conduct of training sessions, certification, documentation of training activities, release authorization and production of annual training report.
- 3.2 Project Administrator is responsible for making training appointments, determining team members requiring training and evaluating whether training objectives have been met. When training task is delegated to the Project Administrator to part of his/her team and/or other sites, is also responsible for booking and scheduling and conduct of training sessions.
- 3.3 CRSU Manager is responsible to review annual training report.

4. RELATED SOPS/DOCUMENTS

- 4.1 CRSU Training Plan
- 4.2 Training Logs

5. DEFINITION

Training Log: a training log will be created for each CRSU supported project, and will be designed as a CRSU Platform project instrument. The log will keep track of each user account training in a project and other training details; hence all CRSU Data Management platform (CRSU Platform) users will be included in a project log. Project logs will be updated by the CRSU for all users who participate in a training session hosted by CRSU. The project administrator will be responsible for documenting on their project's training log for all training that was NOT performed by CRSU. This includes training performed by the project administrator or other users, self-trained users and users who opted out of training. The project administrator is accountable to making sure all users on their project are sufficiently trained; hence, negating this responsibility from the CRSU.

SOPs and Training

(types of training)

Procedure

6. PROCEDURE

- 6.1 Upon receiving an approved request for a new project, the project is created in the CRSU Platform by the CRSU. The project's project administrator is contacted to discuss training options and scheduling. This can occur during discussions about setting up the study or via email after the study has been set-up in the CRSU Platform. The project administrator will be invited to scheduled weekly onsite sessions or choose to request a time, which the CRSU will try to accommodate. If they are not available to attend an on-site session, either a phone or online training session will be scheduled (see below for eligibility and details).
- 6.2 A general training session will include all categories; however this will be tailored to the attendees. Training session can also be divided by categories, for example set-up and design may be combined with management. Once the project is designed, a training session on data entry can be completed.
- 6.3 CRSU Platform users can attend several training sessions if necessary. As they are hosted weekly, they will be able to come to any on-site session.

6.4 Types of trainings:

6.4.1 Onsite Training

The CRSU hosts one on-site training session per week on alternating days and scheduling is subjective to client request. The project administrator will attend and can be accompanied by other team members as necessary.

During general on-site training, any combination of the training categories will be covered. The categories presented depend on the type of project, ability of users and timeline for the project. To maximize the training session all categories can be covered in one session. Project management is only covered if a project administrator is present.

For special request, extra time is added to the end of a general session to cover features/applications not covered in regular training.

If the on-site session is broken into categories, the project administrator will be responsible for contacting the CRSU to schedule a session for the remaining categories. If other full general sessions are also occurring, the team will have the option to attend the part of the session that applies to them. For example if the users have been trained in designing and only require data entry, they can attend the data entry portion of the full training session. This will only occur if the CRSU has several training sessions available. Otherwise, sessions will be scheduled according to user requests.

6.4.2 Online training

In most cases, online training will be applicable to multi-center projects, where centers are off-site. This session will generally occur in combination with the project administrator, as they will need to answer project-specific questions. Typically, the CRSU will train the onsite project administrators and they will be responsible for training other team members. All the details will be in the training log, with the CRSU completing the log for users who attended the session. The format of the session will be the same as onsite training, however the session should occur in one session.

Citing REDCap in Grants/IRB

- How should I describe REDCap in grant or IRB applications?
 - Data for this study will be entered into REDCap, a database software system developed by Vanderbilt University for electronic collection and management of research and clinical trial data. REDCap uses a MySQL database via secure web interface with data checks used during data entry to ensure data quality. REDCap includes a complete suite of features to support HIPAA and FERPA compliance, including a full audit trail, user-based privileges, and integration with the institutional LDAP server. REDCap also enables automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus), simultaneous multi-user and multi-site access, full control over individual-level data access permissions, and remote survey and form-based data capture methods. REDCap technical support is provided by the Biomedical and Behavioral Methodology Core of the Department of Pediatrics, College of Medicine. The MySQL database and the web server will both be housed on secure servers operated by the University of Oklahoma Health Sciences Center Information Technology. The servers are in a physically secure data center on campus and are backed up nightly, with backups stored in accordance with the OUHSC IT schedule of daily, weekly, and monthly tape retentions of 1 month, 3 months, and 6 months, respectively. Weekly backup tapes are stored offsite. The OUHSC IT servers provide a stable, secure, well-maintained high-capacity data storage environment, and both REDCap and MySQL are widely-used, powerful, reliable, well-supported systems. Access to the study's data in REDCap will be restricted to the members of the study team by username and password.

Citing REDCap in Manuscripts

- How should I cite REDCap in study manuscripts?
 - Study data were collected and managed using REDCap electronic data capture tools hosted at the University of Oklahoma Health Sciences Center.¹ REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

¹ Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr; 42(2): 377-81. Link to article:
<http://dx.doi.org/10.1016/j.jbi.2008.08.010>

Comments or Questions???

THANK YOU!

Feature

REDCap

Qualtrics

Feature	REDCap	Qualtrics
Data Dictionary	Y	?
Data Import	Y	n
Data Export & Summaries	Y	Y
E-mail survey	Only using a survey form, not a data collection form.	Y
Copy other surveys	Y	n
Survey templates	n	Y
Branching logic	Branching logic for individual Qs.	Branching for individual Qs and for groups of Qs.
Audio capabilities	Done via html	?
Expiration capabilities: (eg, 1 week to respond)	n	Y
Spell check	n	Y
API	Y	n
Free to academic institutions	Y	n?
Offline data capture	Currently, there is not an official REDCap offline data capture component. However, CCAN has created an "in-house" off-line version of REDCap that is currently in use.	

Our exposure to Qualtrics is limited.
Please don't interpret this as the authoritative guide.