The PCH Project

Long Term Follow-Up of Patients with Primary Congenital Hypothyroidism by Primary Care Providers

- Collecting Long-Term Follow-Up Data at Primary Care Settings using REDCap

- Ning Rosenthal, MD, PhD, Project P.I.
- Emily Bezar, M.A., Study Manager

Genetic Disease Screening Program
California Department of Public Health
Outline

- Overview of the PCH Project
- Long-term follow-up data collection process
- REDCap data collection interface and our experience
- Limitations and suggestions
1. Overview of the PCH project
Primary Congenital Hypothyroidism (PCH) is the most common screened disorder and affects 1 in 1,706 live births in California (CA).

Most children with PCH need lifelong treatment.

Delayed or inappropriate treatment may cause severe neurocognitive disabilities.

Primary care providers (PCPs) have unique advantages in caring for patients with PCH.

Little is known about the role of PCPs in PCH-related care.
1.1 Background (cont.)

- **The PCH Project**: a three-year grant funded by the Health Resources and Services Administration (HRSA) from August 1\textsuperscript{st}, 2013 through July 31\textsuperscript{st}, 2016

- **Participating states**: California and Hawaii

- **Target populations**: PCPs and patients with PCH
**Research Team**

Ning Rosenthal, M.D., Ph.D.
Principal Investigator
Genetic Disease Screening Program, CDPH

Co-Investigators:

Lisa Feuchtbaum, Dr.PH, MPH
Genetic Disease Screening Program, CDPH

Laura Jelliffe-Pawlowski, Ph.D
Genetic Disease Screening Program, CDPH

Sylvia Mann Au, M.S., CGC
Hawaii Department of Health, Genetic Section

Laura Bachrach, M.D.
Professor of Pediatrics
Division of Endocrinology
Stanford University Medical Center

**Study Manager:**

Emily Bezar, M.A.
Genetic Disease Screening Program, CDPH

**Advisory Committee**

Swati Banerjee, M.D.
Division of Pediatric Endocrinology,
Children's Hospital Central California

Mitchell E. Geffner, M.D.
Chief, Center for Endocrinology, Diabetes and Metabolism, Children’s Hospital Los Angeles

Michael Gottschalk, M.D., Ph.D.
Chief, Pediatric Endocrinology,
UCSD/Rady Children’s Hospital

Mary Rutherford, M.D.
Pediatrician, Children’s Hospital,
Oakland, CA

Stuart K. Shapira, M.D., Ph.D.
Chief Science Officer
National Center on Birth Defects and Developmental Disabilities (NCBDDDD),
CDC, Atlanta
1.2 Study Objectives

1) **Assess** the willingness and capability of PCPs to provide long-term care for patients with PCH and their needs for PCH-related continuing medical education

2) **Evaluate** the current case management patterns and clinical outcomes

3) **Assess** PCPs’ willingness to obtain informed consent and provide data to the PCH long-term follow-up (LTFU) database

4) **Investigate** the practicality of providing real time LTFU data by PCPs and identify barriers incurred

5) **Improve** PCPs’ knowledge on PCH and increase their capability of providing care for patients with PCH
1.3 Study Methods

- **Provider-Based Cross-Sectional Survey (CSS)**
  - Objectives 1–3, completed
  - All PCPs who were listed as contact doctor for ≥1 patients with PCH during 2009–2013 in California and Hawaii (N=823)

- **Two-Year Long-Term Follow-Up Data Collection**
  - Objective 4, in progress
  - Respondents to the CSS who indicated interest in LTFU

- **Post Follow-Up Survey**
  - Objective 4, to be implemented
  - PCPs who participated in the LTFU data collection

- **Continuing Medical Education about PCH**
  - Objective 5, in progress
2. LTFU Data Collection Process Overview
2.1 LTFU Study Process and Timeline

**Enrollment**
- **PCP Enrollment:** 5/5/14 – 6/30/14
- **Patient Informed Consent Process:** 6/2/14 – 9/30/14

**Data Collection** (1/1/14–12/31/15)
- **Training:** 6/4/14 – 6/30/14
- **Database went Live:** 6/16/14
- **Retrospective data collection**
- **Prospective data collection**

**Ongoing data quality monitoring by project staff:** Monthly Check-ins
2.2 LTFU Invitation Response Rate as of 9/8/14

Total PCPs invited: 124

- Total responded: 41
  - Enrolled PCPs: 19
  - Tentative: 3
  - No: 19

- Not yet responded: 83
  - Enrolled Patients: 27
  - (Confirmed enrollment is pending parent ICF signatures)

Signed ICF forms received: 19

Continuing enrollment efforts August/Sept 2014:

- Made approx. 42 phone calls to selected non-responders
- Email and phone reminders to enrolled PCPs to complete the informed consent process
2.4 Data Collection Forms

- **Patient enrollment form**
  - Obtain informed consent from guardians and informed assent from patients of 7 years or older
  - Complete the enrollment form before the first Follow-Up Visit Form is initiated
  - Contents include:
    - Demographics (DOB, Sex, Race/Ethnicity, Insurance....)
    - Informed Consent/Assent Forms
    - PCH treatment history
    - Diagnostic testing
    - Comorbid conditions
### Event Name: Patient Enrollment

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<thead>
<tr>
<th>Study Site ID</th>
<th>NRosenthal_pt1</th>
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</thead>
<tbody>
<tr>
<td>Patient ID</td>
<td>jobr10</td>
</tr>
<tr>
<td>Patient's first name</td>
<td>John</td>
</tr>
<tr>
<td>Date of patient enrollment</td>
<td>[ ] 31 [ ] Today</td>
</tr>
</tbody>
</table>

#### Informed Consent Form

- **Has the Informed Consent Form been signed by the patient's parent or legal guardian?**
  - [ ] Yes
  - [ ] No
- **If the patient is between 7 and 17 years old, has he or she signed the Informed Assent Form?**
  - [ ] Yes
  - [ ] No
  - [ ] Not applicable, patient is less than 7 years old

#### Patient Enrollment Information

- **Patient's date of birth (mm/dd/yyyy)**
  - [ ] 31 |
  - [ ] Today | M-D-Y
- **Patient's sex**
  - Male
  - Female
- **Mother's first name**
  - 
- **How was the patient identified?**
  - Newborn screening program
  - Clinically
Patient follow-up visit form

- One follow-up visit form needs to be completed for each patient visit regardless of the reason for the visit
- Forms can be revisited and edited anytime
- Forms need to be completed within 30 days of the visit
- Form contents include:
  
  patient information, follow-up status, physical measurements, developmental assessment, laboratory tests, treatment, clinical symptoms, care coordination, ER visits and hospitalization
## Follow-up Visit Form (Draft)

**Event Name:** Follow-up Visit #1

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<thead>
<tr>
<th>Study Site ID</th>
<th>NRosenthal_pt1</th>
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</thead>
<tbody>
<tr>
<td>Patient ID</td>
<td></td>
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</tbody>
</table>

**Patient Information**

- **Did the patient’s address change since his/her last visit to your practice?**
  - [ ] Yes
  - [ ] No
  - [ ] Don’t know
- **Did the patient’s telephone number change since his/her last visit to your practice?**
  - [ ] Yes
  - [ ] No
  - [ ] Don’t know
- **Did the patient’s primary medical insurance change since his/her last visit to your practice?**
  - [ ] Yes
  - [ ] No
  - [ ] Don’t know
- **Did the patient’s PCH diagnosis change since his/her last visit to your practice?**
  - [ ] Yes
  - [ ] No
  - [ ] Don’t know

**Patient’s Follow-Up Status**

- [ ] Active: patient currently being seen at this practice
- [ ] Transferred: patient transferred to another practice
- [ ] Lost to follow-up
- [ ] Moved out of state
- [ ] Refused follow-up
- [ ] Follow-up not deemed necessary
- [ ] Patient deceased

**Since the last visit to your practice, has the caregiver (e.g., parent) missed any scheduled appointments?**

- [ ] Yes
- [ ] No
- [ ] Don’t know

**Physical Measurements**
Laboratory results form

- One Lab Results form is associated with each Visit Form.
- If lab tests were ordered for PCH-related conditions by the participating doctor or by another specialist during the follow-up period, a lab form needs to be filled out
- Form contents include:
  - Thyroid-stimulating hormone (TSH) Test
  - Free thyroxine (free T4) test
  - Total thyroxine (T4) test
  - Other lab test
### Lab Results Form (Draft)

**Editing existing Study Site ID NRosenthal_pt1 (Patient ID jobr10)**

**Event Name:** Follow-up Visit #1

<table>
<thead>
<tr>
<th>Study Site ID</th>
<th>NRosenthal_pt1</th>
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</table>

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<tr>
<th>Patient ID</th>
<th>must provide value</th>
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</table>

<table>
<thead>
<tr>
<th>Patient’s first name</th>
<th>must provide value</th>
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</table>

Tests ordered at this office visit, or since the patient’s last visit

<table>
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<tr>
<th>Test Description</th>
<th>Yes</th>
<th>No</th>
<th>Don’t know</th>
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<tbody>
<tr>
<td>Thyroid-stimulating hormone (TSH) test</td>
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<tr>
<td>Free thyroxine (free T4) test</td>
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<tr>
<td>Total thyroxine (T4) test</td>
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<tr>
<td>Other lab test</td>
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</table>

Lab Test Document Uploads

(Note: You are not required to upload the original copies of lab reports. If you choose to do so, please make sure to complete the preceding lab results section first.)

Would you like to upload lab report copies here?

<table>
<thead>
<tr>
<th>Would you like to upload lab report copies here?</th>
<th>Yes</th>
<th>No</th>
</tr>
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</table>

Form Status

Complete?

<table>
<thead>
<tr>
<th>Complete?</th>
<th>Incomplete</th>
</tr>
</thead>
</table>
3. REDCap and Our Experience
### 3.1 Why REDCap?

<table>
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<tr>
<th>REDCap</th>
<th>Screening Information System</th>
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</thead>
<tbody>
<tr>
<td>1. More user friendly and broadly platform-compatible</td>
<td>1. Less user friendly and only works with Internet Explorer</td>
</tr>
<tr>
<td>2. Easy to create unique user profile and grant access right to ensure doctors only have access to their own patients</td>
<td>2. Can not limit the access right of users to only see their own patients</td>
</tr>
<tr>
<td>3. More cost-efficient</td>
<td>3. Very pricy</td>
</tr>
<tr>
<td>4. Non-technical staff can design and modify data collection forms with limited support</td>
<td>4. Professional technical staff are needed to create and modify data collection forms</td>
</tr>
</tbody>
</table>
3.2 REDCap features that we like

- User-friendly interface
3.2 REDCap features that we like

- Branching-logic function
  - Create compact, clean forms that expand when needed
3.2 REDCap features that we like

- **File repository:** Easy user access to important study documents
3.2 REDCap features that we like

- Easy navigation
  - Move between each patient’s forms on the Event Grid
  - Move between different patient records on the Record Status Dashboard
3.2 REDCap features that we like

- **Easy data monitoring**: Study manager can easily review users’ data-entry actions and conduct quality assurance.

![Logging](image)

This module lists all changes made to this project, including data exports, data changes, and the creation or deletion of users.

<table>
<thead>
<tr>
<th>Time / Date</th>
<th>Username</th>
<th>Action</th>
<th>List of Data Changes OR Fields Exported</th>
</tr>
</thead>
<tbody>
<tr>
<td>2:11pm 09/08/2014</td>
<td>emilyb</td>
<td>Updated Record 54_1209_JO (Visit 1)</td>
<td>Assign record to Data Access Group (redcap_data_access_group = '999')</td>
</tr>
<tr>
<td>2:11pm 09/08/2014</td>
<td>emilyb</td>
<td>Updated Record 54_1209_JO (Visit 1)</td>
<td>tsh_date = '2014-09-08', tsh_who = '1', tsh_status = '2', tsh_val = '34', tsh_unit = '1', tsh2_ordered = '2', freet4 = '1', freet4_date = '2014-09-01', freet4_who = '2', freet4_status = '1'</td>
</tr>
</tbody>
</table>
### 3.2 REDCap features that we like

**Data export:** Study data is quickly available in many formats

<table>
<thead>
<tr>
<th>Software</th>
<th>Download Syntax &amp; Data</th>
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</thead>
<tbody>
<tr>
<td><strong>Microsoft Excel</strong></td>
<td><img src="image" alt="Excel" /></td>
</tr>
<tr>
<td>You may download the survey results in CSV (comma-separated) format, which can be opened in Excel. You have the choice of downloading the data either with the full headers and answer labels or just with the answer codes (i.e. raw data).</td>
<td></td>
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<tr>
<td><strong>NOTE:</strong> If you are using a version of Microsoft Excel prior to Excel 2007, due to limitations the data will only be read to 255 columns when opened.</td>
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<tr>
<td><strong>SPSS Statistical Analysis Software</strong></td>
<td><img src="image" alt="SPSS" /></td>
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<tr>
<td>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 *.sps file, which will open SPSS. When the file is loaded and displayed, choose Run---&gt;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.</td>
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<tr>
<td><strong>Additional instructions</strong></td>
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<tr>
<td><strong>SAS Statistical Software</strong></td>
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<td>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 (or Run---&gt;Submit) 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.</td>
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<tr>
<td><strong>Additional instructions</strong></td>
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<tr>
<td><strong>R Statistical Software</strong></td>
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<tr>
<td>Instructions: Use command read.csv(‘filename’) to read in data file.</td>
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4. Limitations and suggestions
4.1 REDCap Limitations

- Difficult to shield end-user from a view into the design and development environment. Hard to protect participating doctors’ privacy.
4.1 REDCap Limitations

- Lack of flexibility for question design

Weight: _kilograms_

OR

_lbs_  _oz_
4.1 REDCap Limitations

- Does not allow dynamic allocation of different numbers of visit events per patient. The interface may appear cluttered and overwhelming for users who need to access fewer forms.

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<th>Patient ID</th>
<th>Enrollment Form</th>
<th>Follow-up Visit Form 1</th>
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<th>Follow-up Visit Form 3</th>
<th>Follow-up Visit Form 4</th>
<th>Follow-up Visit Form 5</th>
<th>Follow-up Visit Form 6</th>
<th>Follow-up Visit Form 7</th>
<th>Follow-up Visit Form 8</th>
<th>Lab Results Form 1</th>
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4.2 Suggestions for the future

- Provide more flexible questionnaire design to accommodate complicated clinical questions
- Add more features to address the needs of patient visit-based observational research
- We hope to utilize the additional tools for data analysis, reporting and sharing that are part of the LPDR
Acknowledgements

- The LPDR Team
  - Amy Brower
  - Jennifer Loutrel
  - Michael Watson
  - Irina Butler
  - Bruce Bowdish
- The PCH Project Research Team
- The PCH Project Advisory Committee
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