

Site Training

**The 39th Multicenter Airway Research
Collaboration (MARC-39) Study**



Study Leadership

Kohei Hasegawa, MD, MPH (PI)

Carlos Camargo, MD, DrPH (Co-I)

Project Coordination: Catalina Gimenez-Zapiola

Funded by a grant from Teva to MGH

Emergency Medicine Network

www.emnet-usa.org

Dept. of Emergency Medicine, MGH, Boston, MA



Outline of Presentation

1. Overview
2. Screening
3. ED interview
4. Chart review
5. Follow-up interview

Outline of Presentation

1. Overview
2. Screening
3. ED interview
4. Chart review
5. Follow-up interview

Aims

1. To determine the proportion of ED patients with acute asthma who report they ran-out of their short-acting beta-agonist (SABA) rescue inhaler before presenting to the ED
2. To examine the ED patients' technique in using their SABA inhalers

Aims (continued)

3. To examine the methods used by ED patients to identify how many doses remain in their SABA inhalers
4. To examine the association between ran-out status and acute asthma outcomes (relapse, readmission)

Significance

- Acute asthma – almost 2 million ED visits/year, representing a high-risk population
- Adult asthma patients in EDs in the late 1990s demonstrated that 30% ran-out of their SABA
- In 2003, FDA recommendation – a dose-counting mechanism be integrated into inhaler drug products
- The current status is unknown

Methods

- **Design:** Prospective observational study
 - Subjects will be evaluated and medically treated as usual
- **Setting:** BIDMC, BWH, and MGH
- **Participants:** Adults presenting to the ED with acute asthma (133 pts / sites)
- **Study period:** Oct 1, 2015 – Sep 31, 2016

Inclusion criteria

- 1) Acute asthma (the primary reason of ED visit)
 - Okay to have a concomitant dz (eg, COPD, PNA)
- 2) Adult patients aged 18-54 years
- 3) History of doctor-diagnosed asthma before the ED visit
- 4) Prescription of SABA inhaler before the ED visit
- 5) Willing to complete the ED interview + telephone follow-up
- 6) Ability to give informed consent

Exclusion Criteria

- 1) Previous participation in MARC-39
- 2) Inability to give informed consent
- 3) Altered mental status, intoxication, incarceration
- 4) Lack of permanent address (e.g., homeless)
- 5) Language barrier (i.e., non-English, non-Spanish speaking)

Spanish Speaking Participants

- All forms have been translated into Spanish and certified
- The translated forms are meant to be read to participants in Spanish, but data are recorded in English into REDCap
- Participants will indicate their preferred language for follow-up on site log

Data Entry: REDCap

Research Electronic Data Capture

Two REDCap databases

1.m39 Screening Database

- Screening questions (inclusion/exclusion criteria)
- After informed & consent, then

2.MARC-39 Database

- Interview questions,
- Chart Review Questions,
- Follow-up questions
- Other stuff (rarely used) – e.g., AE, deviations

Outline of Presentation

1. Overview
2. **Screening**
3. ED interview
4. Chart review
5. Follow-up interview

Screening Form

- Confirms patient's eligibility
- Screening Form ID # assigned by REDCap
- Ask ALL questions even if you discover that participant is ineligible → complete screening database

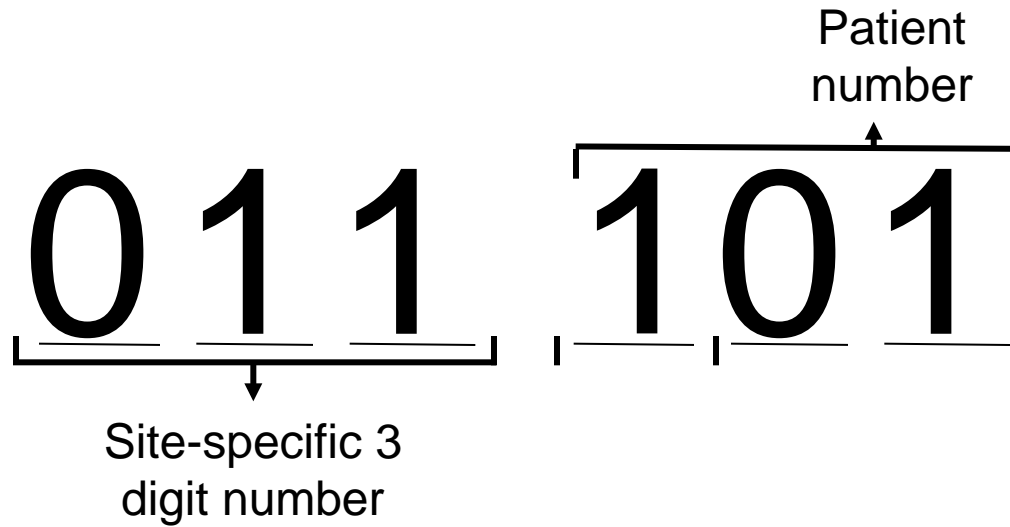
Informed Consent

- Should be done before any study procedures are performed
- Should be a thorough discussion of responsibilities
- Must consent to ED interview, chart review, AND follow-up interview

Study ID

- After Consent Form signed → answer the last question on Screening Form, which confirms enrollment
- Assign each enrolled participant a unique Study ID #
- Record the study ID # on Screening Form

Study ID#



After Screening & Informed Consent

Enrolled to the study – four parts:

1. ED patient interview (~20 mins)
2. ED chart review (5 mins)
3. Swabs/blood collection in the ED (**optional and explained later**)
4. Telephone interview in 2 weeks (<10 mins)

Outline of Presentation

1. Overview
2. Screening
3. **ED interview**
4. Chart review
5. Follow-up interview

Interview Items

1. Demographics
2. Past asthma history
3. Chronic asthma medications
4. SABA ran-out status
5. Methods to evaluate the doses of SABA
6. SABA inhalation technique
7. Contact information → Site log

Short-acting beta-agonist (SABA) inhalers

- AKA “quick relief” inhalers
- Not inhaled corticosteroids (ICS) or long-acting one (LABA)

MDI vs. DPI

ProAir HFA
Ventolin, Xopenex



ProAir RespiClick only in
the U.S.



How to Count?

- Track record (diary)
- “Shake” testing
- “Spray” testing
- Dose counter



Inhalation Technique (MDI)

<https://youtu.be/doppxjlq40w>

(a total of 38 seconds)

*If the patient does *not* carry his/her SABA inhaler, ask ED provider to prescribe an albuterol MDI in the ED (standard care)

Inhalation Technique (DPI)

<https://youtu.be/B0h8Wgt-46c?t=40s>

(Starts at 0:40 and ends at 1:55)

Administrative Items (not often)

Report to Teva

- **Self-reported** adverse events (other than asthma symptoms)
 - All serious events
 - Non-serious AND related to Teva SABA inhaler
- **Self-reported** complaints about Teva SABA inhaler
- Pregnancy AND Teva SABA inhaler

Teva SABA Inhalers

ProAir HFA (MDI)



ProAir RespiClick (DPI)



Contact Information

- Includes protected health information (PHI)
- Entered to **Site Log** (NOT to REDCap)
- Collect patient's zip code
 - Conversion to house-hold income

Site Log - Site Use Only

- Using the Excel sheet, enter patient PHI
 - e.g., name, date of birth, medical record number, home ZIP code
- Maintain the tracking form locally; do NOT send it to the EMNet Coordinating Center.

Median Household Income

- Estimated by ZIP code (=PHI)
 - ZIP code will be collected on the Chart Review Log
- Conversion table (ZIP code → Income) will be posted online

http://www.emnet-usa.org/MARC_39/M39.html

- Please call EMNet Coordinating Center if the patient's ZIP code is not on the table.

Outline of Presentation

1. Overview
2. Screening
3. ED interview
4. **Chart review**
5. Follow-up interview

Chart Review Items

- ED presentation (e.g., vital signs, peak flow)
 - If peak flow was not measured, ask ED provider to measure it (standard care)
- ED treatments
- ED disposition & discharge medications

Decision rules for conflicting results

Between providers within the ED visit

- Attending > resident > PA/NP > student

No vs. Not Documented/Unknown

- “NO” -- if, after review of all charts, the treatment was not consistently documented
 - e.g., there is the d/c medication list and an inhaled corticosteroid is not listed
- “Not documented/Unknown” -- if insufficient documentation was available to inform the variable
 - e.g., if the d/c medication list is missing, do not assume “No”

Practice Charts

- Abstractors will complete 2 practice charts
- If accuracy is less than 80% per chart, the individual will be retrained
- After confirming the accuracy $\geq 80\%$, study can be started.
- Online tools will be available
 - e.g., Manual of Procedures, ZIP-income table, FAQ

Practice Charts (continued)

- Practice charts will be posted online (password-secured).
 - http://www.emnet-usa.org/Marc_39/M39.htm
- Enter the data to REDCap (PRACTICE MARC-39 DATABASE)

Outline of Presentation

1. Overview
2. Screening
3. ED interview
4. Chart review
5. **Follow-up interview**

Procedures

- Quick chart review to check the ED dispo
- Telephone interview 2 weeks after the ED visit
 - Must be within 3 weeks
 - x 5 times over 3 days
- If patient refuses,
 - Ask for the reason(s)
 - Perform quick chart review at the site (e.g., re-ED visits, readmissions)

Measured Variables

- Relapse requiring ED visit/hospitalization
- Changes in treatment
- Symptoms

Questions?

Kohei Hasegawa, MD, MPH

khasegawa1@partners.org

617-726-5276

Catalina Gimenez-Zapiola

Cgimenez-zapiola@mgh.harvard.edu

617-726-5276



- REDCap (*Research Electronic Data Capture*) is a secure, web-based application designed exclusively to support data capture for research studies
- Initiated at Vanderbilt University and includes 775 active institutional partners (<http://project-redcap.org/>)

Features

- Can be used at bedside (no paper)
- Built-in branching logic to ensure proper sequence of questions
- Interviewer prompts helps flow of interviews

Features (continued)

- Validation/pop-up alerts to minimize data-entry errors
- Save forms as PDF and print as needed
- No need to transmit data to EMNet Coordinating Center

Getting Started

- Send completed Electronic Data Capture Use Agreement to EMNet
- Access granted by Partners (MGH)
- User groups enable you to only see your site's records
- Firefox or Chrome strongly recommended as browser
- Log in at <https://redcap.partners.org>

Getting Started (continued)



Log In



FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL
AND MASSACHUSETTS GENERAL HOSPITAL

Please log in with your user name and password. If you are having trouble logging in, please contact [Partners HealthCare EDC Support](#).

User name:

Password:

Log In

Welcome to REDCap!

REDCap is a secure, web-based application for building and managing online surveys and databases. Using REDCap's stream-lined process for rapidly developing projects, you may create and design projects using 1) the online

REDCap Features

Build online surveys and databases quickly and securely - Create and design your project rapidly using

Data Entry

- Select database from “My Projects”
- Use the left-hand toolbar to initiate data entry

Data Entry (continued)

You may view an existing record/response by selecting it from one of the drop-down lists below. The records are separated into each drop-down list according to their status for this particular data collection instrument. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: 181	
Incomplete Records (0)	-- select record --
Unverified Records (0)	-- select record --
Complete Records (181)	-- select record --
Enter a new or existing Study ID	<input type="text"/>

[Hide Unverified Records drop-down](#)

Data Search	
Choose a field to search (excludes multiple choice fields)	-- select search field --
Search query Begin typing to search the project data, then click an item in the list to navigate to that record.	<input type="text"/>

Data Entry (continued)

- Move between forms of the same record by clicking on the dot next to the form name or the form name; exit a record using “select other record”
- Use your mouse to move from field to field (Note: pressing “Enter” will save and kick you out of the form)
- Do not use the browser arrows to move back and forth between screens/forms

Data Entry (continued)

Data Collection

 Record Status Dashboard

 Add / Edit Records

Study ID **12540** (Justin Time)

[Select other record](#)

Data Collection Instruments:

- Intake Form
- Contact Form
- Intake Chart Review
- Maternal Pregnancy And Nutrition
- Specimen Enrollment Checklist
- Inpatient Form
- One Week Follow Up Form
- Protocol Deviation Report
- Protocol Deviation Report 2
- Protocol Deviation Report 3
- Adverse Event Form
- Adverse Event Form 2
- Adverse Event Form 3
- Readmission Intake Form
- Readmission - Intake Chart Review
- Readmission Inpatient Form
- Readmission Intake Form 2
- Readmission Intake Chart Review 2
- Readmission Inpatient Form 2
- Readmission Intake Form 3
- Readmission Intake Chart Review 3
- Readmission Inpatient Form 3
- Readmission Intake Form 4
- Readmission Intake Chart Review 4
- Readmission Inpatient Form 4

Data Collection Instruments:

Visit Form
Chart Review Form
Follow-Up Form
Specimen Collection Form
Specimen Adverse Event Form
Protocol Deviation Form

Data Entry (continued)

Interview date (H) 11-01-2012 ³¹ Today M-D-Y
* must provide value


Interview time (H) Nov 2012
* must provide value

Admission Date (H)
* must provide value

Admission Time: (H)
* must provide value

Please reinsert admission date and time in to this one field (for calculation purposes): (H)
* must provide value

Section A: General information



Interview date (H) 11-01-2012 ³¹ Today M-D-Y
* must provide value

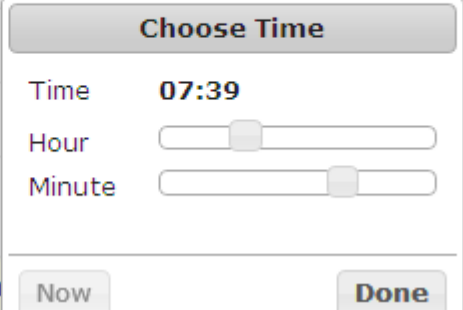
Interview time (H) 07:39 Now H:M
* must provide value

Admission Date (H)
* must provide value

Admission Time: (H)
* must provide value

Please reinsert admission date and time in to this one field (for calculation purposes): (H)
* must provide value

Section A: General information



Changing Responses

- “reset value”
- Response changes to questions with branching logic result in a pop-up box asking for confirmation of the change

Changing Responses

Over the past 24 hours, did he/she have a cough?
* must provide value

Yes
 No

Was the cough:
* must provide value

Mild (mostly gagging)
 Moderate (cough was significant, but did not wake child at night)
 Severe (cough that caused vomiting and/or woke your child at night)

The page at <https://redcap.partners.org> says:

? ERASE CURRENT VALUE OF THE FIELD "intake_cough" ?



The current field for which you just entered data requires that the field named "intake_cough" be hidden from view. However, that field already has a value, so its value might need to be reset back to a blank value.

Click OK to HIDE this field and ERASE its current value. Click CANCEL if you DO NOT wish to hide this field or erase its current value.

OK Cancel

Saving Records

Data Collection

 Record Status Dashboard
 Add / Edit Records

Study ID **12540** (Justin Time)
[Select other record](#)

Data Collection Instruments:

- Intake Form**
- Contact Form
- Intake Chart Review
- Maternal Pregnancy And Nutrition
- Specimen Enrollment Checklist
- Inpatient Form
- One Week Follow Up Form
- Protocol Deviation Report
- Protocol Deviation Report 2
- Protocol Deviation Report 3
- Adverse Event Form
- Adverse Event Form 2
- Adverse Event Form 3
- Readmission Intake Form
- Readmission - Intake Chart Review
- Readmission Inpatient Form
- Readmission Intake Form 2
- Readmission Intake Chart Review 2
- Readmission Inpatient Form 2
- Readmission Intake Form 3
- Readmission Intake Chart Review 3
- Readmission Inpatient Form 3
- Readmission Intake Form 4
- Readmission Intake Chart Review 4
- Readmission Inpatient Form 4

- **Incomplete** → no data entered
- **Unverified** → data entry partially complete
- **Complete** → data entry complete

Saving Records (continued)

- After saving a form, a pop-up box will appear if a response is missing in a required field
- Return to that field and enter a response

Saving Records (continued)

Contact Form

NOTE: Some fields are required!

Your data was successfully saved, but you did not provide a value for some fields that require a value. Please enter a value for the fields on this page that are listed below.

Provide a value for...

- Is it okay to leave a message about this study at this number?
- Do you have an email address we can use to contact you about this study?
- What is the best telephone number to reach him/her?
- Do you have another alternate contact you can share with us?
- Would you like test results sent to [child]'s primary care provider?

record to a Data Access Group?

Stu

Fir

* mu

Mid

Las

* mu

Suffix (e.g, Jr)

Does [child] have any nickname: Yes

Data Confirmation

- After completing blank fields, you are ready to save form as “complete”
- Before you save, initial that all fields left blank represent one of the following:
 - Unable to be answered
 - Refusals
 - Data not documented

Data Confirmation (continued)

Form Status	
Complete?	<input type="text" value="Complete"/>
<input type="button" value="Save Record"/>	
<input type="button" value="Save and Continue"/>	
<input type="button" value="Save and go to Next Form"/>	
<input type="button" value="-- Cancel --"/>	

Databases






1. m39 Screening Database

2. MARC-39 Database

Practice databases are available for use and are designated by “PRACTICE” in title

Databases (continued)

[Home](#)[My Projects](#)[Request New Project](#)[Training Resources](#)[Help & FAQ](#)[Send-It](#)

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. Newly created projects begin in **Development status**  as you begin to build and design them. When you are ready to begin entering real data in the project, you may move it to **Production status**  to designate the project as officially collecting data. When you are finished collecting data or if you wish to stop collection, the project may be set to **Inactive status** , although it may be brought back to Production status at any time when you are ready to begin collecting data again. Also listed is the project type, which designates if the project is in **classic**  or **longitudinal**  data collection format.

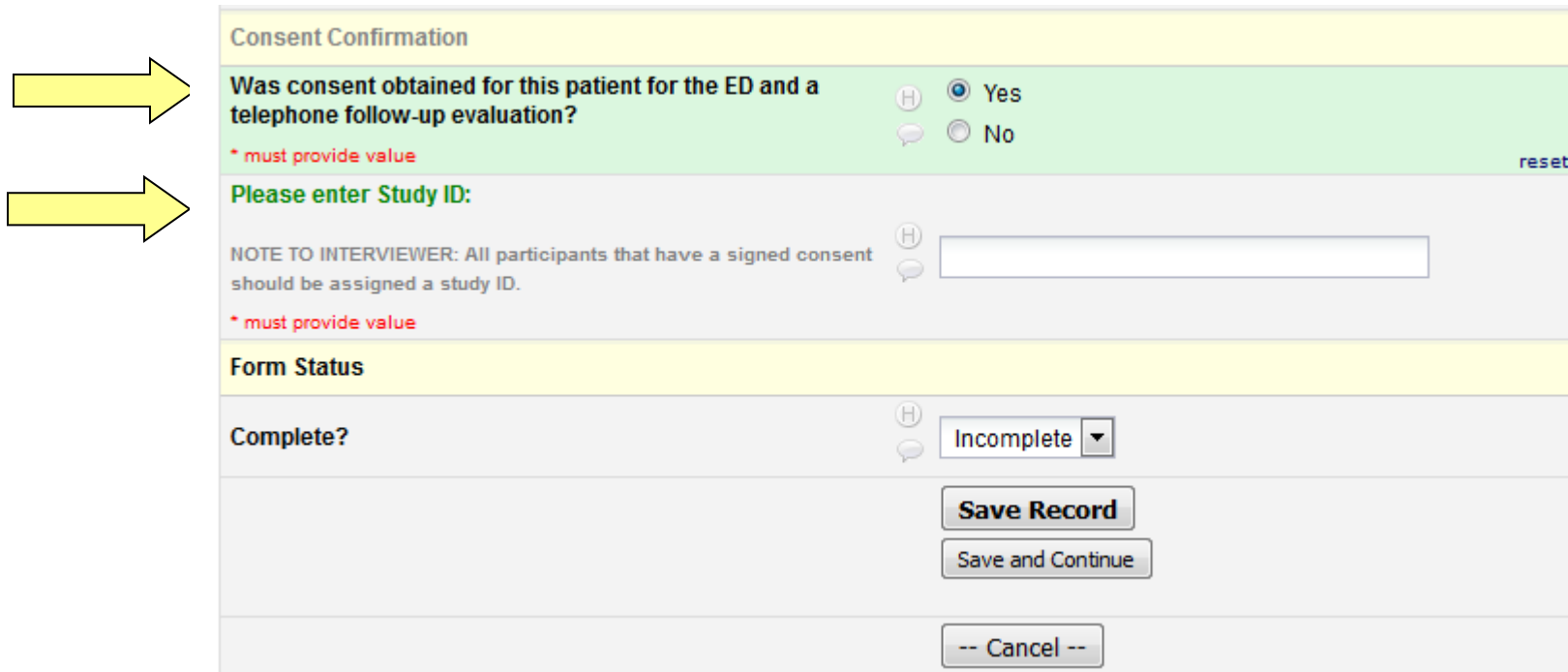
MARC-39 Database	2	450	6 forms		
m39 Screening Database	0	20	1 form		
PRACTICE MARC-39 Database	2	451	6 forms		

Screening Database

- Select Screening Form in left-hand tool bar
- Click “Add new record” button
- Screening ID # will automatically be assigned
- If editing record, select from the drop-down menus

Screening Database (continued)

If participant is enrolled, you must enter a study ID# at the bottom of the Screening Form



The screenshot shows a web-based screening form with the following sections:

- Consent Confirmation** (yellow header):
 - Question: "Was consent obtained for this patient for the ED and a telephone follow-up evaluation?"
 - Options: Yes, No
 - Red text: "* must provide value"
 - Link: "reset"
- Please enter Study ID:** (green text)
 - Note: "NOTE TO INTERVIEWER: All participants that have a signed consent should be assigned a study ID."
 - Red text: "* must provide value"
 - Input field: A text box for entering the study ID.
- Form Status** (yellow header):
 - Question: "Complete?"
 - Options: Incomplete (dropdown menu)
- Buttons:** "Save Record", "Save and Continue", and "-- Cancel --"

MARC-39 Database

Complete in order:

Data Collection Instruments:

Visit Form

Chart Review Form

Follow-Up Form

Specimen Collection Form

Specimen Adverse Event Form

Protocol Deviation Form

Warnings

Built-in warnings when information entered does not match information elsewhere in a participant's record

Confirm child's DOB <small>* must provide value</small>	<input type="text" value="11-17-2011"/>  Today M-D-Y <small>MM/DD/YYYY</small>
STOP: The date of birth you entered does not match the date of birth of the record you are working in. Please confirm that you are in the right record. (Data from Intake Form)	
Child's Name	
First Name (Q1) <small>* must provide value</small>	<input type="text" value="Justin"/>
Middle Initial (Q1)	<input type="text" value="-"/>
Last Name (Q1) <small>* must provide value</small>	<input type="text" value="Time"/>

Tips

- Save your work frequently!
 - Before you leave a form
 - Times out
- REDCap is case sensitive
- Use the comment section to record anything that does not fit into form

REDCap Downtime

- Partners or EMNet will communicate scheduled downtimes (e.g., for system upgrades)
- May be unanticipated downtime or other factors that prevent use of REDCap (e.g., problem with local internet connection)
- Use paper forms if REDCap is unavailable

REDCap Questions?

- Problems logging in?

Contact Partners HealthCare EDC Support

edcsupport@partners.org

- New user requests, other issues, or questions?

Catalina Gimenez-Zapiola

Cgimenez-zapiola@mgh.harvard.edu

617-726-5276