



Asthma Background and Objectives Summary

This study involves research about asthma in children, as well as the drugs that are commonly used to treat asthma. It is an observational—not interventional—study. This means that participating in this study will not change patients' treatment while they are at the hospital; we simply want to collect data on certain aspects of children's asthma and asthma treatment.

We will examine how well steroid asthma medications work in controlling symptoms in children from birth through 17 years old who have been diagnosed with asthma. These drugs are inhaled through the airway and work in the lungs. The length of time before the drug is broken down and made inactive within the lungs has been noted to vary from individual to individual. Breaking down the drug is controlled by enzymes in the lungs, with some working rapidly and some more slowly. We inherit the enzymes that break down these steroids. Some people's asthma gets better with inhaled steroid treatment; however, some people see little or no improvement in asthma symptoms with inhaled steroid treatment. We think that the type of enzymes you inherit may cause them to work better or worse.

This study will compare the forms of the enzymes present in children's lungs to how well they work to help control asthma. In other words, we hope to clarify which types of inhaled steroid medications work best on each specific enzyme. The thought is that down the line, with the information we get from this study we could hopefully be able to find out which enzymes someone has and then give them the medication which will work best for controlling their asthma. Ultimately, it is our hope that we can provide better treatment of asthma with this information.

We can study enzymes by taking saliva samples. The study involves swabbing the patient's cheek (or collecting a spit sample), as well as administering a brief survey to determine the severity of a child's asthma. The long term goal of this study is to significantly improve the therapy of asthmatic children. We will enroll approximately 1500 children. Note that children do not have to be currently seeking care for asthma or other respiratory symptoms in order to be eligible to participate.

For questions/assistance, please contact:

Chris Stockmann, CCRC
Phone (801) 585-0903
Pager (801) 339-6261

ASTHMA SEVERITY

Study Purpose: To identify genetic elements which may be involved in the response to asthma medication use in kids

CONSENT TALKING POINTS:

1. Introduce yourself
2. Purpose: We are conducting a research study to help improve the treatment of asthma in children
3. This study is looking at the cells in children's saliva to see how well they work in breaking down asthma medications (Beclomethesone) so they can be used in the lungs
4. This information will allow us to identify which medications work best in individual patients for controlling their asthma
5. Risks/Benefits: In the future we may have the ability to do this test and then prescribe a specific drug that we know will be helpful in reducing a particular child's asthma symptoms
6. Procedures: We would like to ask you/your child a few questions about his/her asthma
7. Additionally, we would like to collect a small amount of saliva from you/your child
8. Do you have any questions? Would you like to participate in the study?

ASTHMA SEVERITY

Contact: Chris Stockmann
801.339.6261 (pager)
801.631.9487 (cell)
Location: Emergency Dept.
Language(s): ENG and SPN

Inclusion: ≥ 2 years to < 18 years old with a diagnosis of asthma who are actively taking beclomethasone

Exclusion: None

1. •Identify all patients ≥ 2 and < 18 years
2. •Review the patient's chart for "asthma" and "Beclomethasone"
3. •Approach healthcare provider
4. •Approach and obtain consent from family (please give a copy to the family)
5. •Obtain saliva sample (record the date/time and study ID # [obtained from the thin white Asthma binder in the AcA office])
6. •Complete survey questions with family
7. •Log patient in Asthma Tracking Log
8. •Place labeled saliva sample in cupboard
9. •Drop completed folder in lockbox located in the AcA office

The Asthma Study

Bob Ward, MD

Director

Pediatric Pharmacology Program

Department of Pediatrics

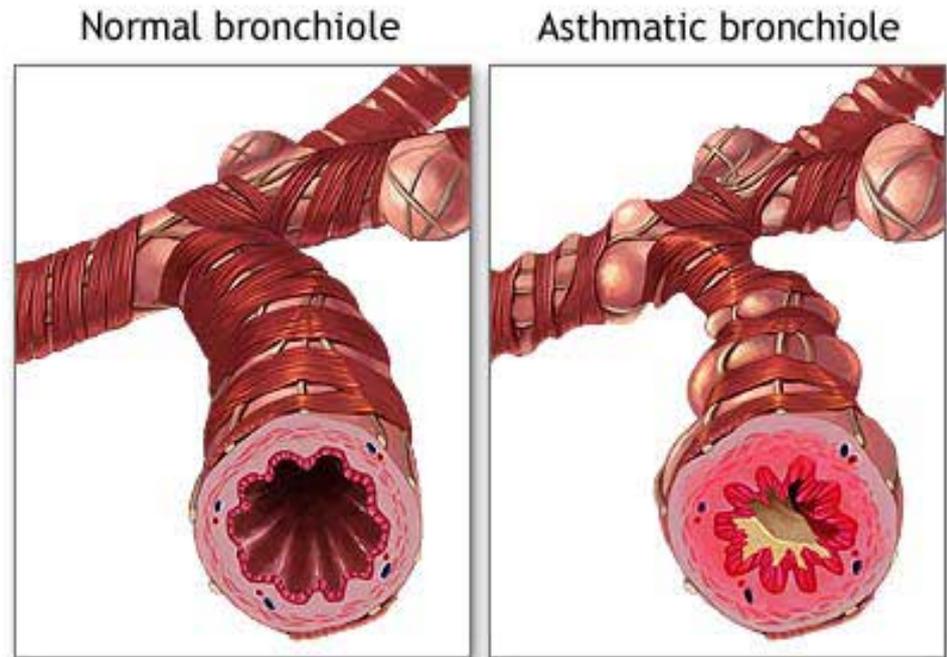
Chris Stockmann, CCRC

Study Coordinator

Department of Pediatrics

Study Background

- Asthma severity varies between kids
- First line therapy: “fast-acting” inhalers (e.g., albuterol)
- Second line therapy: inhaled steroids (e.g., flovent)



Study Background

- Enzymes in our lungs “break down” inhaled steroid medication so that we can use the medication to open airways and reduce inflammation (This is sort of similar to the way enzymes in our stomachs break down food so that we can absorb nutrients.)

- Everyone’s enzymes are not the same! There is some genetic variation

Hypothesis

- Because of each child's unique enzymatic make-up, a child's asthma will not respond equally well to all inhaled steroids
- It may be possible to “personalize” asthma treatment based on a child's genetics

Objective

- To compare asthma severity, inhaled steroid treatment, and genetic make-up of lung enzymes to determine if some medications are more effective than others for a given enzyme (or set of enzymes)
- To provide a personalized approach to inhaled steroid treatment of asthma in children

Inclusion

- All children 2-17 years old who have been diagnosed with asthma and actively taking beclomethasone

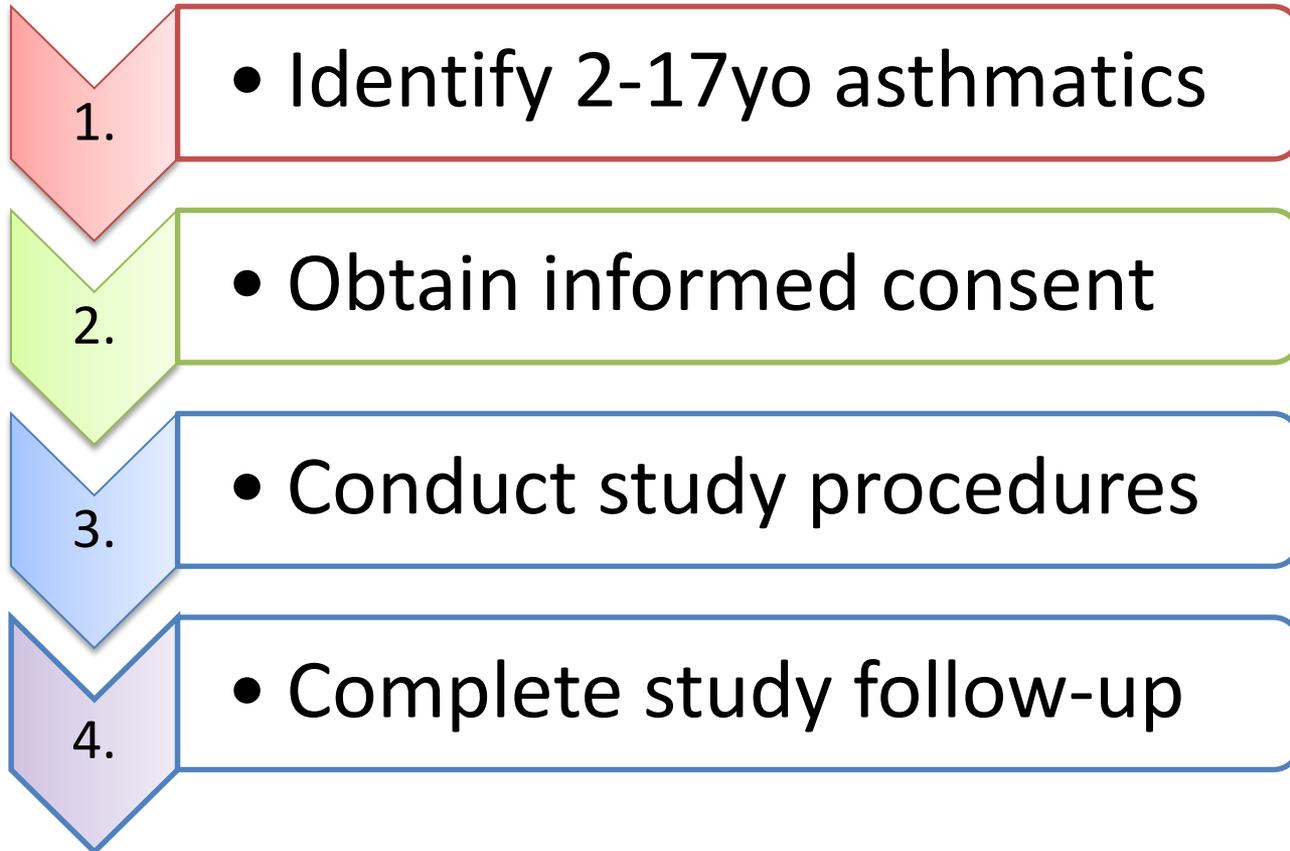
-Note: The child does not have to be seeking treatment for asthma to be eligible.

Exclusion

- NONE!

-Note: Children who are critically ill (e.g., undergoing trauma resuscitation) should not be approached.

Your Role



Your Role (continued)

Screening

- For everyone who comes through the ED ensure ≥ 2 and < 18 years
- Refer to their “Past Medical History” (PMH) section in the paper chart
- For all asthmatics using beclomethasone, please approach for consent

Your Role (continued)

PT NAME:		AGE:	SEX:	CHIEF COMPLT:	PCP:	
DATE:	INCIDENT TIME:	EMS CALL:	ETA:	ARRIVAL TIME:	TRIAGE TIME:	AGENCY/RESCUE:
ARRIVED BY: POV WC WALK CARRY AIR GROUND				ARRIVED FROM: HOME SCENE		ROOM #:
EMS/TRIAGE HPI:		RESP: WDL	SKIN: WDL	WEIGHT: KG		ACT EST SAID
		CV: WDL	MSKEL: WDL			
		NEURO: WDL	CRT: WDL			PAIN SCORE:
		TIME: T P R BP / O ₂ SAT				
		TIME: T P R BP / O ₂ SAT				
PTA MEDS:		GCS: E V M TTL		PTA FLUIDS		
MOI: ABUSE ASSAULT BITE BIKE BURN FALL GSW MCC MVC PEDEST SPORTS STAB		PTA TX: NEB O ₂ CPR IV ICE SPLINT C-COL SPINAL DRESSING		ACUTE CHRONIC		
TYPE: BLUNT CRUSH DROWN INGEST FB		RESTRAINT: BELT CAR-SEAT AIRBAG HELMET				
PMH: Asthma				IMMUNIZATIONS:		CURRENT NO UKN
ALLERGIES:				DATE:		
CURRENT MEDICATIONS: <input type="checkbox"/> MED REC FORM				TETANUS		CURRENT NO UKN
				DATE:		
TRIAGE ACUITY: RESUSCITATION EMERGENT URGENT SEMI-URGENT NON-URGENT				STATUS: F/U FAST-T		
EXPOSURES: NONE CHEMICAL CHICKEN POX MEASLES PERTUSSIS TB						
MEETS SHOCK CRITERIA YES NO		ED MD:		RN SIG:		
PRIMARY ASSESSMENT		TIME:		ASSESSMENT BY:		
SYSTEM	WDL	ABNORMALS (CIRCLE)				
AIRWY/BREATH		COUGH	CRACKLES	DYSPNEA	FLARING	IRREG
CARDIOVASC		EDEMA		MURMUR	RHYTHM	PULSE QUALITY
NEURO		SLURRED	A V P U	SENSATION	MOTOR	STRENGTH
ENT		CONGEST	PAIN	RED	FB	SWELLING
EYE		SWELLING	PAIN	RED	FB	SIZE
GI		DISTEND	RIGID	TENDER	GUARD	SOUNDS:
GU		DYSURIA	HEME	URGENCY	FREQ	FLANK PAIN
GYN		BLEED	# PADS	PREG?	YES NO	WEEKS
MUSC/SKEL		DEFORM	NUMB	PALLOR	↓ ROM	TINGLING
PAIN		SCORE:		SCALE:	0-10	FACES FLACC
PSYCH		AGITATED	ANXIOUS	COMBAT	FLAT	HALLUCINATE
SKIN		HARM:	SELF	OTHERS	SUB ABUSE	YES NO
TEACH/LEARN		BARRIERS:	HEARING	LANGUAGE	MED-CONDITION	VISION
RISK		FALL:	YES NO	SUICIDE:	YES NO	
NOTES:						Time Interventions

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Your Role (continued)

Consent

- Politely inquire with nurse / resident about approaching the family for consent
- Present study information and obtain signed consent documents
- Provide a signed copy to the family

Your Role (continued)

Study

Procedures

- Please utilize the **green** asthma folders
- Complete survey questions regarding severity of asthma symptoms
- Collect saliva sample
- Thank family for participation!

Your Role (continued)

- Completion**
- Using a Sharpie, label the saliva container with the patient's study ID, date and time of specimen collection
 - Store saliva sample in the refrigerator located in the Academic Associate office
 - Log the patient in Asthma Tracking Log
 - Drop the completed **green** folder in the lock box above the fridge

The Asthma Study

- Questions?
- Comments?
- Suggestions?



Asthma Checklist

- Screen **everyone** who comes through the ED that is ≥ 2 and < 18 years of age
- Check the “Past Medical History” (PMH) in the paper chart for a diagnosis of asthma
- Politely inquire with nurse / resident about approaching the family for consent
- Obtain a green asthma folder, and approach for consent
- Present study information and obtain signed consent documents
- Collect saliva sample
- Complete survey questions regarding severity of asthma symptoms
- Provide a signed copy to the family and thank family for participation!
- Using a Sharpie, label the saliva container with the patient’s study ID, date and time of specimen collection
- Store saliva sample in the refrigerator located in the Academic Associate office
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Asthma Severity Recruitment Script

Hello, my name is _____ and I am an Academic Associate here at Primary Children's. The reason why I have dropped by to talk with you today is because the doctors here at the hospital are running a study to look at asthma in kids, so that we can provide better treatment of asthma in the future. The medications which your child takes are broken apart in the lungs to provide some relief of symptoms. There are proteins within the lungs and airways that are called enzymes that are responsible for breaking down the medication. The amount of enzymes and the specific types which are present are different from kid to kid, and this may have an impact on which medication will work best for each child. In this study we would like to see how much of these enzymes are present in your child's saliva. The information that we get from this will help us to understand which medications will work best at controlling his/her asthma symptoms. The thought is that down the line, with the information we get from this study we could hopefully be able to find out which enzymes someone has and then give them the medication which will work best for controlling their asthma. Ultimately, it is our hope that we can provide better treatment of asthma with this information.

As I said before, we will be looking at the enzymes in your child's saliva. To accomplish this, I have a tube in which we will have your child spit. [*Or, alternatively:* To accomplish this, I have some swabs with small, soft sponges on the ends that you or I can gently place in your child's mouth.) At the same time, we will ask you about 5-7 minutes worth of questions about your child's asthma to see how well the medications that s/he takes work.

Of course, as with any research, your participation is totally voluntary.

What questions do you have?

Would you like to participate in the study?

Children's Development after Trauma (CDAT)- Multiple Choice Questions

1. As the study progresses the age categories for the TBI injuries will slowly fill up. What is the best source to find out if an age category is still open to enrollment or if enrollment has been completed?
 - a. Canvas
 - b. [Log Book in the AcA office \(updated weekly\)](#)
 - c. Wall calendar in AcA office

2. A mother comes to the ED with her 3 year old son because he bumped his head on a dresser at home. His GCS is 15 and beside a lump on his forehead he doesn't have any symptoms. Can he be enrolled in the study?
 - a) Yes
 - b) [No](#)

3. An 8 year old girl was diagnosed with a concussion 2 weeks ago. She was evaluated at the ED and discharged the same day. Today she comes in after falling off her bike and hitting her head on the curb. Shortly after the accident she complaint about a headache and vomited 3 times. Does she meet all eligibility criteria for the CDAT study?
 - a) Yes
 - b) [No](#)

4. What are all the possible methods how participants can complete study interviews/ questionnaires?
 - a. [Phone and /or web based interviews](#)
 - b. Phone interviews only

5. After obtaining consent you received the Intake Form back from the parent. Upon review you notice that the patient is going to the Alpine School District. What additional document should be completed and signed by the parent?
 - a. Permission Form for study staff to visit the school
 - b. [Consent to release educational records of student](#)
 - c. Both forms

6. For this study we will collect:
 - a. School records only
 - b. Blood
 - c. [Questionnaire and interview based data. School records 1 year prior and 3 years after the injury will be reviewed.](#)

7. There will be a total of 6 interviews to follow the development of the child. When will the last study interview take place?
 - a. 1 year after the injury
 - b. [3 years after the injury](#)
 - c. 5 years after the study

8. The main purpose of the study is:
 - a. [To understand how children develop after a traumatic injury such as a bone fracture or a brain injury](#)
 - b. To compare traumatic brain injury and orthopedic injury rates between the University of Utah and the University of Texas
 - c. To only follow traumatic brain injury children over time and evaluate their functional outcomes