The Autoimmunity Screening for Kids (ASK) Study

EPIC CUSTOMIZATION

AMBER CORR, MA
Objectives

1. E-consent, lab orders, and result sharing at Children’s Hospital Colorado (CHCO)

2. Confirmation & interpretation of results via EHR communication

3. ICD.10 codes and Best Practice Advisories
ASK eConsent

Electronic data capture system (EDC) RedCap.

- Automated alert to research coordinator for EPIC lab order
- eConsent can be sent via an EPIC smartphrase to participants using MyChart
Placing Lab Orders

- ASK **research coordinator** requests a lab order in EPIC
- ASK **PI** signs the labs & releases it to ‘held’ in chart

Depending on participant preference the order may be:

1. released to active so participant may go to any of the CHCO’s **outpatient labs** for their blood draw. **(most common workflow)**
2. left as a held lab for blood draw **at CHCO hospital:** ambulatory, in-patient, OR, or ED
ASK Family Communications

Family Notification upon Completion of ASK eConsent

Thank you for completing a screening form and consent for your child(ren) to be screened through the Autoimmunity Screening for Kids or ASK program. We screen for autoantibodies associated with the risk of developing Type 1 Diabetes and Celiac disease. A lab order will be requested so that your child(ren) can be screened at any of the Children’s Hospital Colorado outpatient labs.

It may take 5 – 7 business days for the lab order to be set. When the lab order is ready, you will receive a confirmation email from ASK with your copy of the lab requisition form. We ask that you please do not arrive at the outpatient lab before you receive this confirmation email from ASK as this is a Colorado University research study protocol and there will be no one onsite at Children’s Hospital that will be able to place the research lab orders for you.

*If you use Epic MyChart and prefer all future ASK study communications come through your patient portal, please make that request by replying to this email with the phrase, MYCHART.

Family Order Notification

The Children’s Hospital outpatient lab order is ready; your child(ren) may now be screened by ASK to test for the autoantibodies associated with the risk of developing Type 1 Diabetes and Celiac Disease.

Attached is your copy of the Research Lab Requisition Order. The outpatient lab staff will locate the ASK lab orders in the Children’s Hospital database by searching for your child(ren)’s medical registration number or MRN.

No appointment is required. Before arriving at your preferred Children’s Hospital outpatient lab location, please review their hours of operation, which can be found at our website ASKhealth.org.

Families can receive these ASK notifications via email or MyChart*

ASK Result Letter

Dear Parents,

Thank you for taking the time to speak with us about the autoantibody test results for [insert test results]. As we discussed on the phone, your child’s confirmed test results for diabetes and celiac screening are:

Type 1 Diabetes:
- Your child is positive or above normal for more than one diabetes-predicting autoantibody. We believe your child’s risk for type 1 diabetes is significantly increased. Close monitoring for diabetes by ASK is strongly recommended with visits to the Barbara Davis Center.

Celiac Disease:
- Your child’s celiac disease screening results were negative.

We use two laboratory methods to test for antibodies. Your child’s final screening results are listed below.

<table>
<thead>
<tr>
<th>Autoantibody</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>IAA - Positive</td>
<td></td>
</tr>
<tr>
<td>IA-2 - Positive</td>
<td></td>
</tr>
<tr>
<td>GAD - Negative</td>
<td></td>
</tr>
<tr>
<td>ZnT8 - Positive</td>
<td></td>
</tr>
<tr>
<td>Celiac autoantibody:</td>
<td>TG - Negative</td>
</tr>
</tbody>
</table>

Autoantibodies may develop at any time throughout childhood. Negative results do not mean that your child will never develop autoantibodies, diabetes, or celiac disease.

If you have any questions or concerns please contact the ASK team at 303-724-1275. Thank you again for your participation in the ASK Program.
Entering Results

- All ASK participant results are entered into a clinical EPIC workflow
- Results are placed in the ‘Enter/Edit’ tab of the chart
Interpretating Results

• An automated alert is sent to all providers in the ‘care team’ and to the family through MyChart

• Positive ASK results are flagged as ‘abnormal’

• Result narratives explain the participant’s risk status & recommended monitoring/care instructions
Positive islet autoantibodies may indicate an increased risk for developing symptomatic type 1 diabetes. These results need to be confirmed in order to estimate risk. Please contact the Autoimmunity Screening for Kids (ASK) study with questions.

Positive islet autoantibodies indicate that risk for developing symptomatic type 1 diabetes is significantly increased. This confirmed result indicates a 50% chance of symptomless diabetes in 5 years and a 70% chance in the next 10 years, with a lifetime risk approaching 100%.

Please contact the Autoimmunity Screening for Kids (ASK) study with questions.
Challenges in Staging & Monitoring Early-T1D in EHR

**Problem**- research communications such as memos, notes, & FYIs can become buried and ineffective in EHR

**Solution**- Using effective clinical communication tools:

- **Problem list entries** (mapped to ICD.10 codes) can indicate stage of early T1D
- ‘Best practice advisories’ (BPA) activated by problem list entry can alert HCPs:
  - Risk of progression to T1D
  - Signs and symptoms
  - Optional labs for evaluation

*When these two clinical mechanism are paired, it opens a pathway to effective communication and robust monitoring between clinical research teams and health care providers*
ASK Study EPIC Problem List Entries

**ASK Stage 1**

Presymptomatic normoglycemic type 1 prediabetes

ICD.10 Code: R73.03

EPIC Mapping Code: 1676361

EpicSmartPhrase: ASKSTG1

@FNAME@ tested confirmed **POSITIVE** for multiple islet autoantibodies. This means that the **risk for developing symptomatic T1D is significantly increased**. Youth with two or more positive islet autoantibodies have a 50% chance of developing symptomatic T1D in 5 years and a 70% chance in the next 10 years, with a lifetime risk approaching 100%.

@FNAME@ and family have been taught to monitor at home by checking finger stick blood glucose after meals a few times per month and to increase to daily checks during illness or with onset of symptoms (including polyuria, polydipsia, nausea, fatigue and weight loss). @FNAME@’s family has been instructed to contact Autoimmunity Screening for Kids (ASK) study staff and @HIS@ health care provider if they note any confirmed finger stick blood glucose >200 mg/dL or any of the above T1D symptoms. Recommended further evaluation may include HbA1c, blood glucose and blood or urine ketone measurement. Early recognition of T1D can prevent potentially life-threatening complications such as diabetic ketoacidosis (DKA). For **clinical consultation call the Pediatric Diabetes (Barbara Davis Center)** at One Call (720-777-3999) with questions or if labs show ketosis, HbA1c ≥ 6.5, or glucose >200 mg/dL.

**ASK Stage 2**

Presymptomatic dysglycemic type 1 prediabetes

ICD.10 Code: R73.03

EPIC Mapping Code: 1676362

EpicSmartPhrase: .ASKSTG2

@FNAME@ tested confirmed **POSITIVE** for one or more of the four islet autoantibodies tested. Additionally, @FNAME@ has shown **dysglycemia consistent with prediabetes on one or more measures**. This means that the **risk for developing symptomatic T1D is significantly increased**.

@FNAME@ and family have been taught to monitor at home by checking finger stick blood glucose after meals a few times per month and to increase to daily checks during illness or with onset of symptoms (including polyuria, polydipsia, nausea, fatigue and weight loss). @FNAME@’s family has been instructed to contact Autoimmunity Screening for Kids (ASK) study staff and @HIS@ health care provider if they note any confirmed finger stick blood glucose >200 mg/dL or any of the above T1D symptoms. Recommended further evaluation may include HbA1c, blood glucose and blood or urine ketone measurement. Early recognition of T1D can prevent potentially life-threatening complications such as diabetic ketoacidosis (DKA). For **clinical consultation call the Pediatric Diabetes (Barbara Davis Center)** at One Call (720-777-3999) with questions or if labs show ketosis, HbA1c ≥ 6.5, or glucose >200 mg/dL.
*Glucose measurements; results are entered before Stage 2 Problem List code

**ASK Study EPIC (BPA) Monitoring Early T1D**

**Statement of risk**

**Suggested order set options**

---

**Medium Priority - Clinical Care (1)**

1. Place orders to decrease risk of missing diagnosis

   Two has pre-symptomatic type 1 diabetes mellitus with dysglycemia (not yet requiring insulin) and is at risk for developing symptomatic (insulin-requiring) type 1 diabetes mellitus and diabetic ketoacidosis.

   Consider further evaluation, if clinically indicated.

   Contact Pediatric Diabetes (Barbara David Center) consult if labs show ketosis, HbA1c greater than 6.4, glucose greater than 200 mg/dL, or if questions.

<table>
<thead>
<tr>
<th>Order</th>
<th>Do Not Order</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin A1C</td>
<td></td>
</tr>
<tr>
<td>Glucose, Blood</td>
<td></td>
</tr>
<tr>
<td>Urine Dipstick</td>
<td></td>
</tr>
<tr>
<td>POCT Glucose</td>
<td></td>
</tr>
<tr>
<td>POCT Glucometer</td>
<td></td>
</tr>
<tr>
<td>Renal Function Panel</td>
<td></td>
</tr>
</tbody>
</table>

**Acknowledge Reason**

- Not indicated
- Reviewing chart
- Patient in code/trauma event
Case Example

• 4.5 yo female screened 2 antibodies positive in ASK
• Parents refused confirmation or monitoring but agreed to notation in EMR (Problem list entry)
• At 9y 10m, BPA launched during PCP visit, no symptoms noted
• HbA1c 6.9% resulted later that day
• PCP called family and on-call BDC physician
• Family presented to BDC next AM for insulin start and teaching
Future Goals

- Continue work with EPIC functionalities using BPA to target screening:
  - Well child visits (recommended ages)
  - Those with personal or family history of autoimmune disease
- Partner with additional children’s hospitals & HCP networks to support local EMR/EPIC outpatient lab screening protocols
- Implement a Laboratory Information System (LIS) for BDC labs to further expand access to our gold-standard assay for autoantibodies
Acknowledgements

Marian Rewers, P.I.
Cristy Geno Rasmussen
Kim Bautista
Judy Baxter
Amber Corr
Fran Dong
Daniel Felipe-Morales
Isabel Flores Garcia
Brigitte Frohnert
Tricia Gesualdo
Michelle Hoffman
Xiaofan Jia
Rachel Karban
Maricela Munoz
Holly O'Donnell
Meghan Pauley
Flor Sepulveda
Crystal Silva
Kimber Simmons
Andrea Steck
Iman Taki
Kathy Waugh
Joey Wong
Liping Yu
Brett McQueen
Rick Bacher
David Roth
Laura Pyle
Jill Norris

Sponsors

Patten-Davis Foundation

Partners

Edwin Liu, Marisa Stahl
Michelle Corrado, Mary Shull, Pooja Mehta,
Ed Hoffenberg, Monique Germone,
Sadie Nagle, Erin Sandene, Kevin Carney,
Amy Lewis, Chrisann Karr, Sondra Valdez,
Chris Martin, Alison Brent

Dan Feiten
Tracy Brekken

Martha Middlemist
Rebekah Phillips

Holly Frost
Sonja O’Leary
Kathy Love-Osborne

Our ASK participants, their families, and ASK provider partners!