The Autoimmunity Screening for Kids (ASK) Study

EPIC CUSTOMIZATION

AMBER CORR, MA



Barbara Davis Center for Diabetes

Autoimmunity Screening for Kids

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

Nic Mail	Patient Message
February 2023	Cody Zztest Jose Luis Guerrero Baez 🗸 Apple Zztest "Honeycrisp"
	To: 🔲 Jacob Earl Ezzell 🔄 Jonathan Zztest 🔄 Apple Zztest
	Regarding: Apple Zztest "Honeycrisp"
j In	ASK Screening
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.smartphrase	.askscre
	Name Description

Electronic data capture system (EDC) **RedCap**.

User ID Password

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

ASK	K Screening
☆	B 🗩 🍄 ち 🞣 🕂 Insert SmartText 🖷 🗢 🔿 🖶 📿
risk	toimmunity Screening for Kids program or- ASK screens for autoantibodies associated with the for developing type 1 diabetes and celiac disease. The screening consists of a simple blood dra I-2ml. All screening is free of cost and can be combined with a blood draw for other purposes.

Autoimmunity Screening for Kids

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:

- 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

	R	Date	Description			Status
Today						
PN .	æ	Today	ASK - tTG IgA Antibody	v		Held
	60	Today	ASK - Diabetes Autoan	tibodies		Held
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			Research G≣Patient in Research		Yes	20
			Protocol Name		14-0553	~ 🗆
			Principal Investigator		Rewers	
			Research Specimen(s) to be C	(1) SST or Red To		
			Research Procedure(s) to be	S	creening	



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 a drawn on 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.

Diabetes autoantibody:					
AA – Positive	A-2 - Positive				
GAD - Negative	ZnT8 - Positive				

Celiac autoantibody: TG – Negative

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.

Autoimmunity Screening for Kids

Entering Results

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

($ \rightarrow $	SnapShot	Research Studies	Chart Review	Enter/Edit Re 🔻	Results Review
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		09/05/2023 4	4:10 PM ASK -	Diabetes Autoa	ntibodies	

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🖋 🕐 🐼 🗛 Time Mar <u>k</u>	6/13/23 00:00	2/2/23 00:00	7/27/21 00:00	5/30/17 00:00
CHEMISTRY, GENERAL 🖂 😞				
A1c Hemoglobin - BDC	5.5	5.0		
GLUCOSE TOLERANCE 🖂 😞		1		
Glucose, Fasting - BDC			88	
Glucose, Fasting, -10 Minute - BDC			87	
Glucose, 2 Hours Post Meal - BDC			118	
DIABETES AUTOIMM 🖂 😞				
Insulin Auto-Antibody (IAA) - BDC				Positive 🛕
GAD Antibody - BDC				Positive 🛕
Islet Antigen 2 Antibody (IA-2) - BDC				Negative
Zinc Transporter 8 Antibody (ZNT8				Negative
TTG AB 🛛 🖄 🔅		2		
tTG IgA - BDC				Negative
tTG IgA Value - BDC				-0.011
tTG IgA Confirmation - BDC				Negative
tTG IgA Confirmatory Value - BDC				-0.011

Autoimmunity Screening for Kids

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

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		Care Team Members	Specialty
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		R,	Endocrinology
	2 million and an and a start of the start of	•n	Cardiology
	And Annual Concession	M.D.	Palliative Care
	The second second	8.S.N.	Palliative Care
	Transplant Te	am	
		lant - 7/29/2011 (#1)	Relationship
		e C, CPNP-PC	Heart Coordinator
	Interesting to the second s	Barrister, M.D.	Surgeon
0 Result Notes		0	
Component	Ref Range & Units	6 yr ago	
Insulin Auto-Antibody (IAA) - BDC	Negative	Positive !	
GAD Antibody - BDC	Negative	Positive !	
Islet Antigen 2 Antibody (IA-2) - BDC	Negative	Negative	
Zinc Transporter 8 Antibody (ZNT8) - BDC	Negative	Negative	
Resulting Agency		CHCO Anschutz Lab	

Narrative RESULTS FROM TYPE 1 DIARFTES SCREENING

screening for type 1 diabetes (T1D) using islet autoantibody testing through the Autoimmunity Screening for Kids (ASK) study on 5/30/2017.

ested POSITIVE for multiple islet autoantibodies. This means that the risk for developing symptomatic TID is significantly increased. Youth with 2 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%.

has been invited to continue monitoring for development of TID as part of the ASK study at the Barbara Davis Center for Diabetes. This monitoring is free and participation is voluntary. At each ASK Follow-up visit we repeat autoantibody testing and follow blood glucose levels. We also recommend doing an oral glucose tolerance test and/or continuous glucose monitoring (CGM) every 3 to 6 months as part of ASK clinic visits. are instructed to check finger stick blood glucose after meals a few times per month.

has been instructed to contact study staff and her health care provider if they note any of the following T1D sympt



A SIMPLE TEST TO DETECT **Childhood Diabetes** + Celiac Disease

Performed by: CHCO Anschutz La

ASK - Diabetes Autoantibodies

Collection date:	10/31/2023					🗇 PI	oviders	1				Sen	d Results:	No Yes	Cc list only
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No collection	information available						Resulting:								
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C <u>o</u> mponents	S <u>e</u> nsitivities Narr	ati <u>v</u> e <u>I</u> mj	pression										sult		
Component		Value	Flags	Low	High	Ref Range	Units	Comment				Re	sult date:	0/31/2023	
INSULIN AUTO-	ANTIBODY - BDC	Positive	Abnormal			Negative						Re	sult time:		
GAD ANTIBODY	- BDC	Positive	Abnormal			Negative						A	bnormal:	bnormal	
ISLET ANTIGEN	2 ANTIBODY - BDC	Negative				Negative							Status:	n process	
ZINC TRANSPO	RTER 8 ANTIBODY	Negativ ,0				Negative									
Positive islet autoa follow-up for confin	ntibodies may indicate an i mation with the Autoimmun	ncreased risk fo ity Screening fo	or developing or Kids (ASK) :	symptoma study.	atic type 1 o	diabetes. The	ese results	need to be confirmed in a	order to estimate risk. @FN	IAME@ SI	martPhrase N	/lanager	- search	result for	"askres"
Please contact the	Autoimmunity Screening for	or Kids (ASK) st	udy with ques	tions.						L	Level: User	Profile	Departme	nt Location	Facility
www.askhealth.org 303-724-1275	L										➡ <u>N</u> ew User SmartP	hrase 💉 <u>E</u> d	t 🛃 SmartP	nrase <u>L</u> ookup	🗘 <u>S</u> hare With
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Multiple positive islet autoantibodies indicate that risk for developing symptomatic type 1 diabetes is significantly increased. This confirmed result indicates a 50% chance of c							nce of d	ASKRESSBB		SBI	3-Confirmed				
symptomatic 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.								ASKRESTGCONF		PO	SITIVE TG con	firmed			
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www.askhealth.org 303-724-1275											ASKRESTGPOS		PO	SITIVE TG Scr	eening



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

e Problem List ₹	1	roblem List				EC •	5 1
ENT Seasonal allergic rhinitis		♦ Care Coordinator Note Search for new problem			Stow	Past Problems	
Endocrine and Metabolic BMI (body mass index), pediatric, 95-99% for age		Endocrine and Metabolic	Share To Edit Overview	A Change Dr.	Resolved	-	
BMI (body mass index), pediatric, 85% to less than 95% for age Stage 1 presymptomatic normoglycemic type 1 prediabetes		Stage 2 presymptomatic dysplycemic type 1 prediabetes Converse Stage 1 presymptomatic normoglycemic type 1 prediabete	East Coverview		X Relave dysglycentia consel 12/14/2022		
Skin Atopic dermatitis		Cverview Sectod POSITIVE for multiple call autoantibodes. This means that the risk for Mark as Epidemet					9
ASK Stage 1 Presymptomatic normoglycemic type 1 prediabetes ICD.10 Code: R73.03 EPIC Mapping Code: 1676361 EnicSmartDhrace: ASKSTC1	Endocrine and Met Stage 2 presymptomat		<u>ASK Stage 2</u> Presymptomatic dysglycemic type 1 prediabetes ICD.10 Code: R73.03 EPIC Mapping Code: 1676362				
EpicSmartPhrase:.ASKSTG1			Epic SmartPhrase: .ASKSTG2				

@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%.

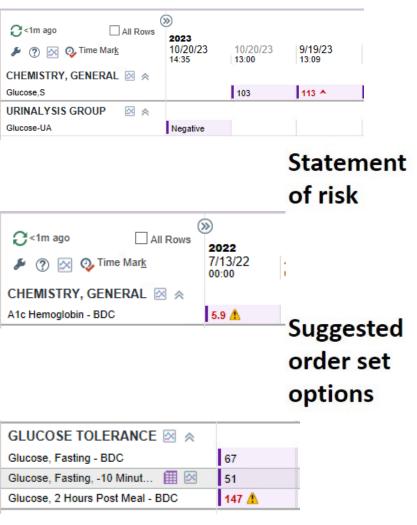
@FNAME@ and family have been taught to monitor at home by checking finger stick blood glucose after meals a few times per month and to increase to daily checks during illness or with onset of symptoms (including polyuria, polydipsia, nausea, fatigue and weight loss). @FNAME@'s family has been instructed 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 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 \geq 6.5, or glucose >200 mg/dL.

@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 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 \geq 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

dium Priority	- Clinical Care	e (1)		*			
Place orders to d	lecrease risk of mi	ssing diagn	nosis				
			llitus with dysglycemia (not yet requiring insulin) and is at risk for developing s mellitus and diabetic ketoacidosis.				
Consider further	evaluation, if clinic	ally indicat	ed.				
Contact Pediatric 200 mg/dL, or if c		a David Ce	enter) consult if labs show ketosis, HbA1c greater than 6.4, glucose greater than				
Order	Do No	ot Order	🔄 Hemoglobin A1C				
Order Do Not Order			🔄 🖓 Glucose, Blood				
Order	Do No	ot Order	🖙 Urine Dipstick				
Order	Do No	ot Order	POCT Glucose				
Order	Do No	ot Order	POCT Glucometer				
Order	Do No	ot Order	🔛 Renal Function Panel				
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

			Sponsors	Our	ASK
Kim BautistaJudy BaxterAmber CorrFran DongDaniel Felipe-MoralesIsabel Flores GarciaBrigitte FrohnertTricia Gesualdo	Maricela Munoz Holly O'Donnell Meghan Pauley Flor Sepulveda Crystal Silva Kimber Simmons Andrea Steck man Taki Kathy Waugh Joey Wong Liping Yu	Brett McQueen Rick Bacher David Roth Laura Pyle Jill Norris	THE LEONA M. AND HARRY B. HE LEONA M. AND HARRY B. HELEONA M. HELEONA M. HELEO	companies	ipants, amilies, ASK vider ners!
Children's Hospital Colorado	THEANTS ::	CHILDREN :: ADOLESCENTS	EDIATRICS 5280	DENVER HEALTH Level One Care For AL	
Edwin Liu, Marisa Stahl Michelle Corrado, Mary Shull, Pooja Ed Hoffenberg, Monique Germone, Sadie Nagle, Erin Sandene, Kevin C Amy Lewis, Chrisann Karr, Sondra Chris Martin, Alison Brent	, Carney,		Martha Middlemist Rebekah Phillips	Holly Frost Sonja O'Leary Kathy Love-Osbori	ne the early start study for pre-symptomatic TID



Autoimmunity Screening for Kids

Askthe Experts