



# *Strategies for a Pathway for Drugs and Devices for Pediatric Diabetes Care*

## *The Patient Perspective*

Kelly L. Close

Editor-in-Chief, diaTribe ([www.diaTribe.org](http://www.diaTribe.org)) &

Director, the diaTribe Foundation

President, Close Concerns

ADA 2014

June 14, 2014





# *Strategies for a Pathway for Drugs and Devices for Pediatric Diabetes Care*

## ~~*The Patient Perspective*~~

## ***Patients' Perspectives***

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# About Close Concerns and diaTribe



*“I founded Close Concerns to make everyone smarter about diabetes and obesity.”*

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## Three Key Questions...

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1. What is the hardest part about managing pediatric diabetes?
2. What is the biggest unmet need in pediatric diabetes?
3. What would be a complete home run for young patients with diabetes?

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## Three Key Questions...

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*are the hardest parts*

1. What ~~is the hardest part~~ about managing pediatric diabetes?
2. What is the biggest unmet need in pediatric diabetes?
3. What would be a complete home run for young patients with diabetes?

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# It's a Toxic Environment Out There

#ConferenceFoodFail



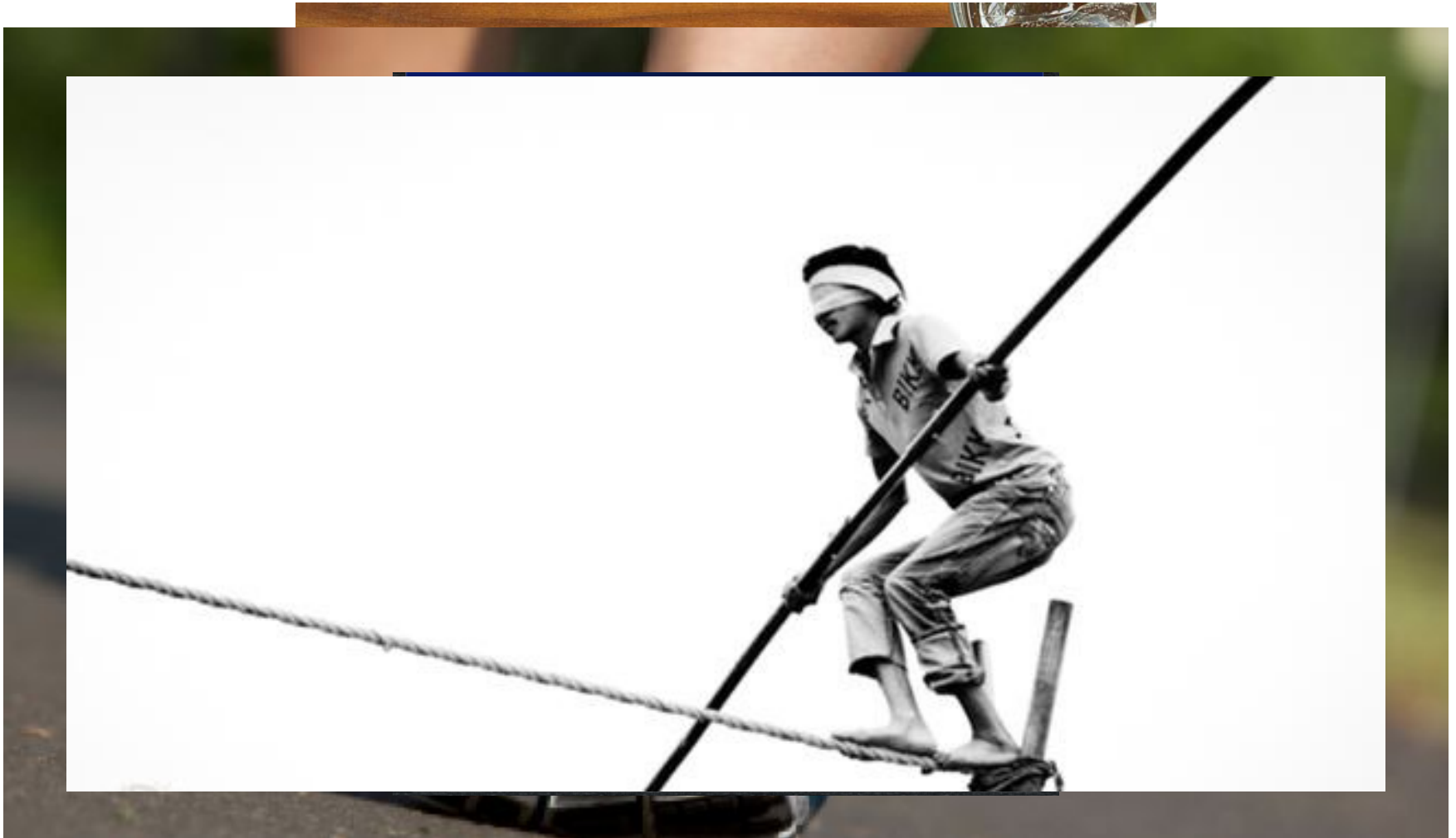


Every day is a new rollercoaster...



# Doing well requires A LOT of work and knowledge

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265 mg/dL

Wrong....

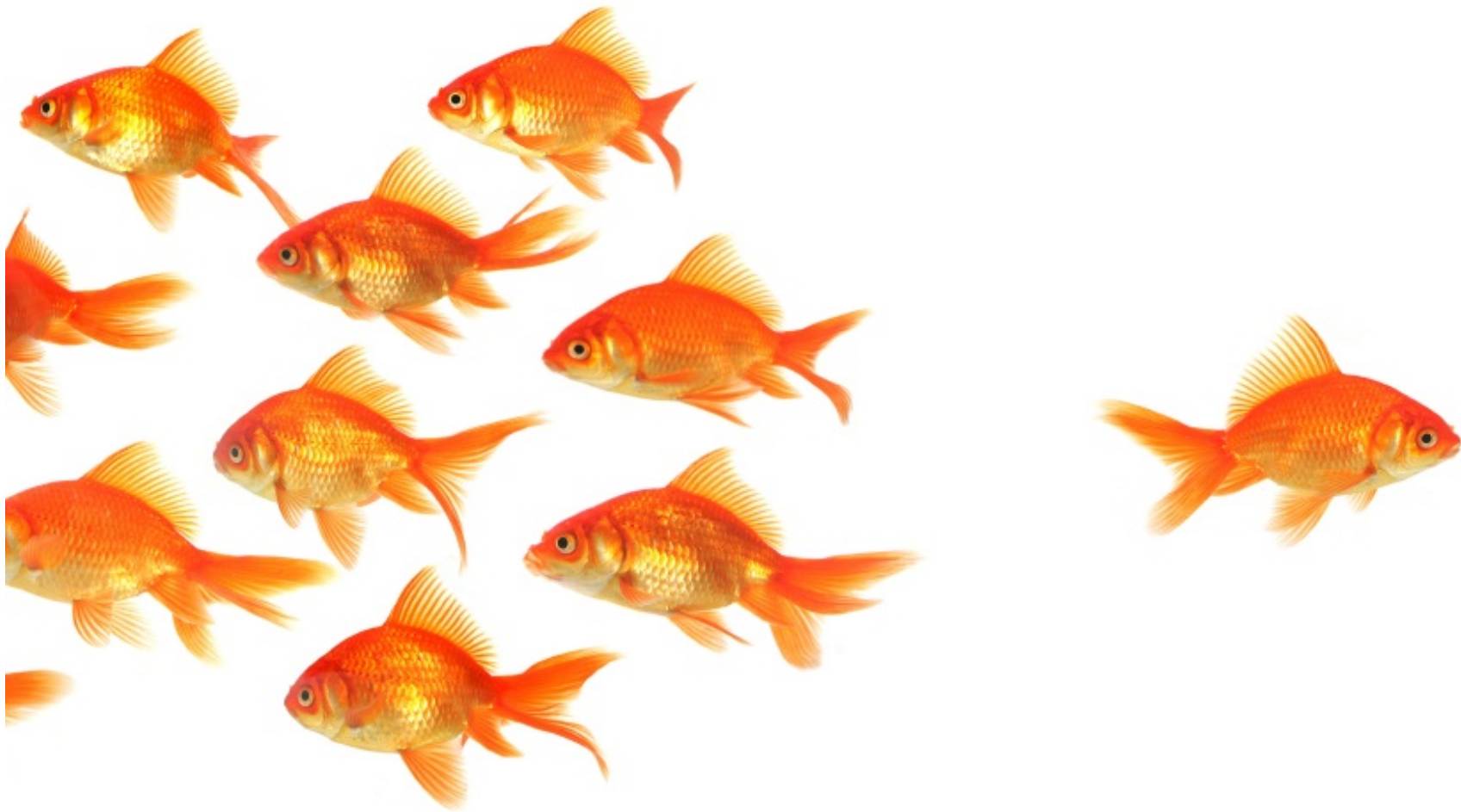




.... All the Time



# On Your Own





24/7, No Vacations





Invisible to Outsiders...



But Not to Insiders...



# Children (often) cannot care for themselves

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You must intentionally hurt your child.

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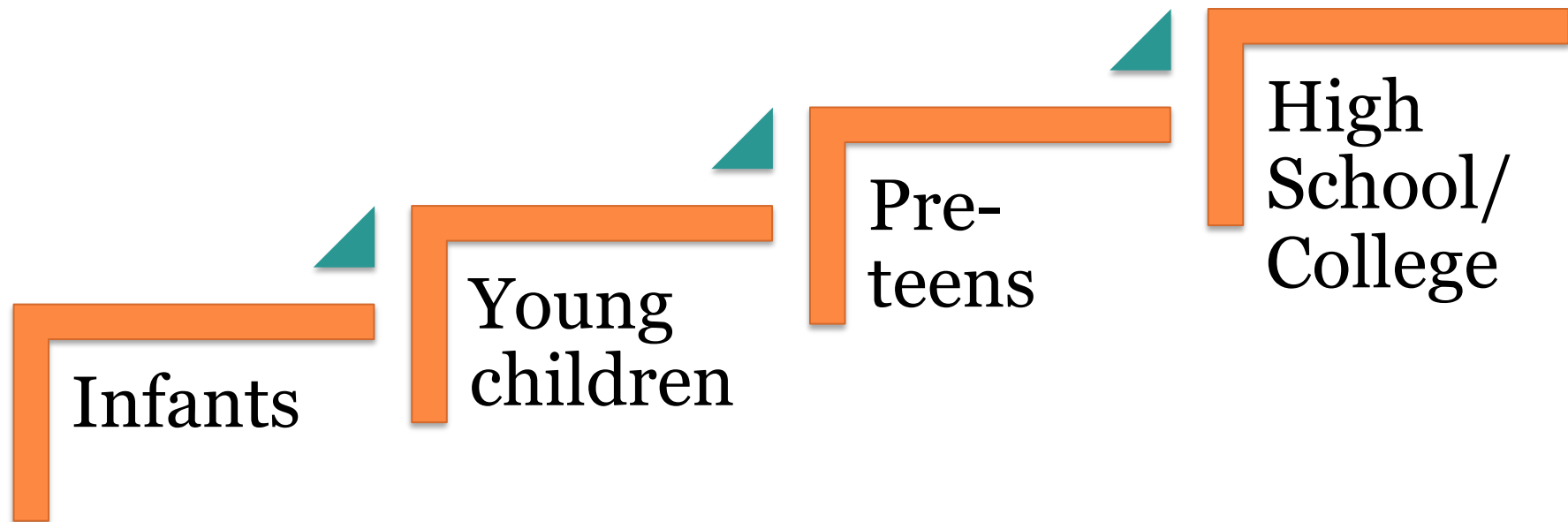


# Feeling normal even though you aren't normal



“Pediatrics” refers to MANY different patients

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# Social Stigma





## Three Key Questions...

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1. What is the hardest part about managing pediatric diabetes?
2. *are the biggest unmet needs*  
~~What is the biggest unmet need~~ in pediatric diabetes?
3. What would be a complete home run for young patients with diabetes?

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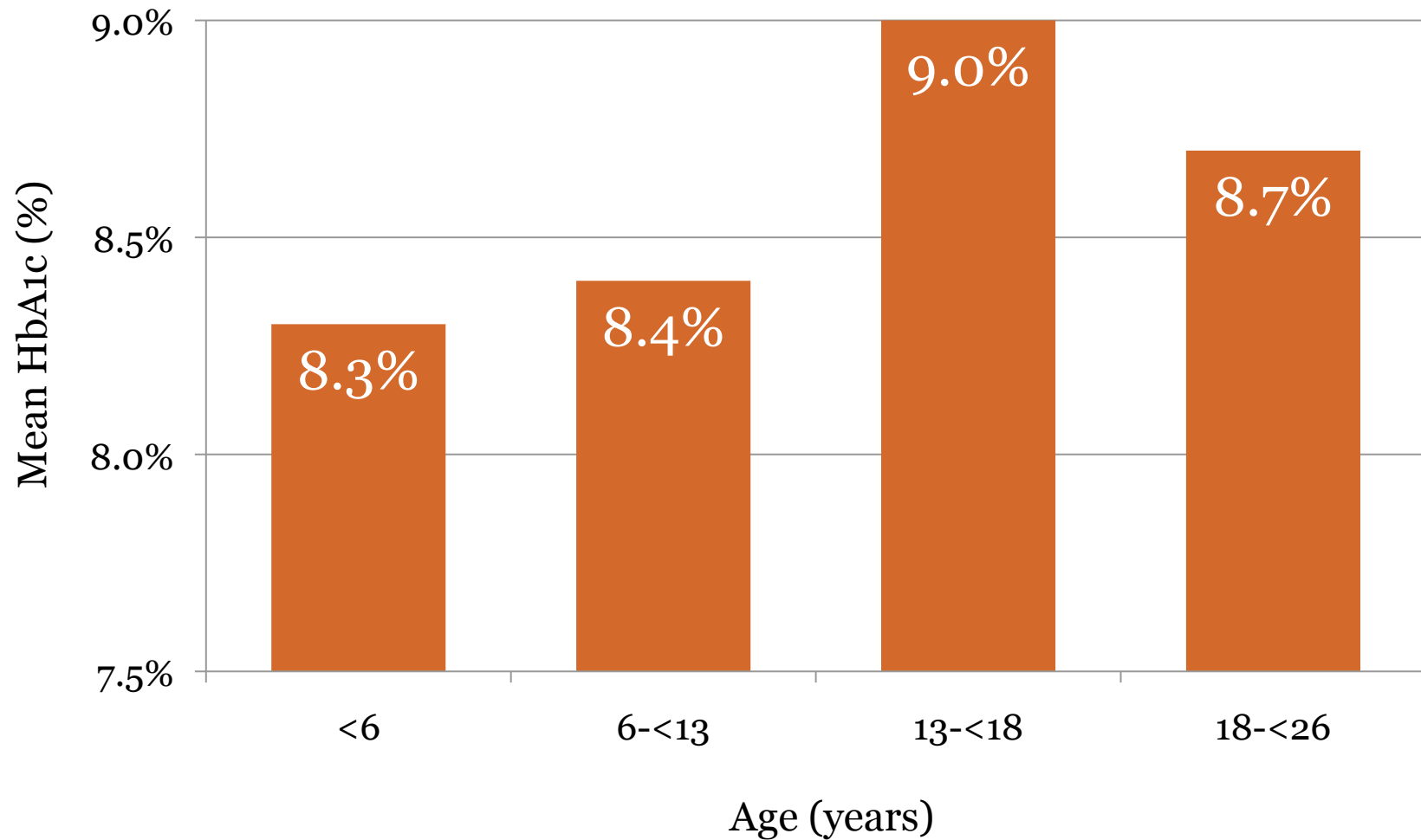




1. Despite better tools, patients  
are not reaching goal!

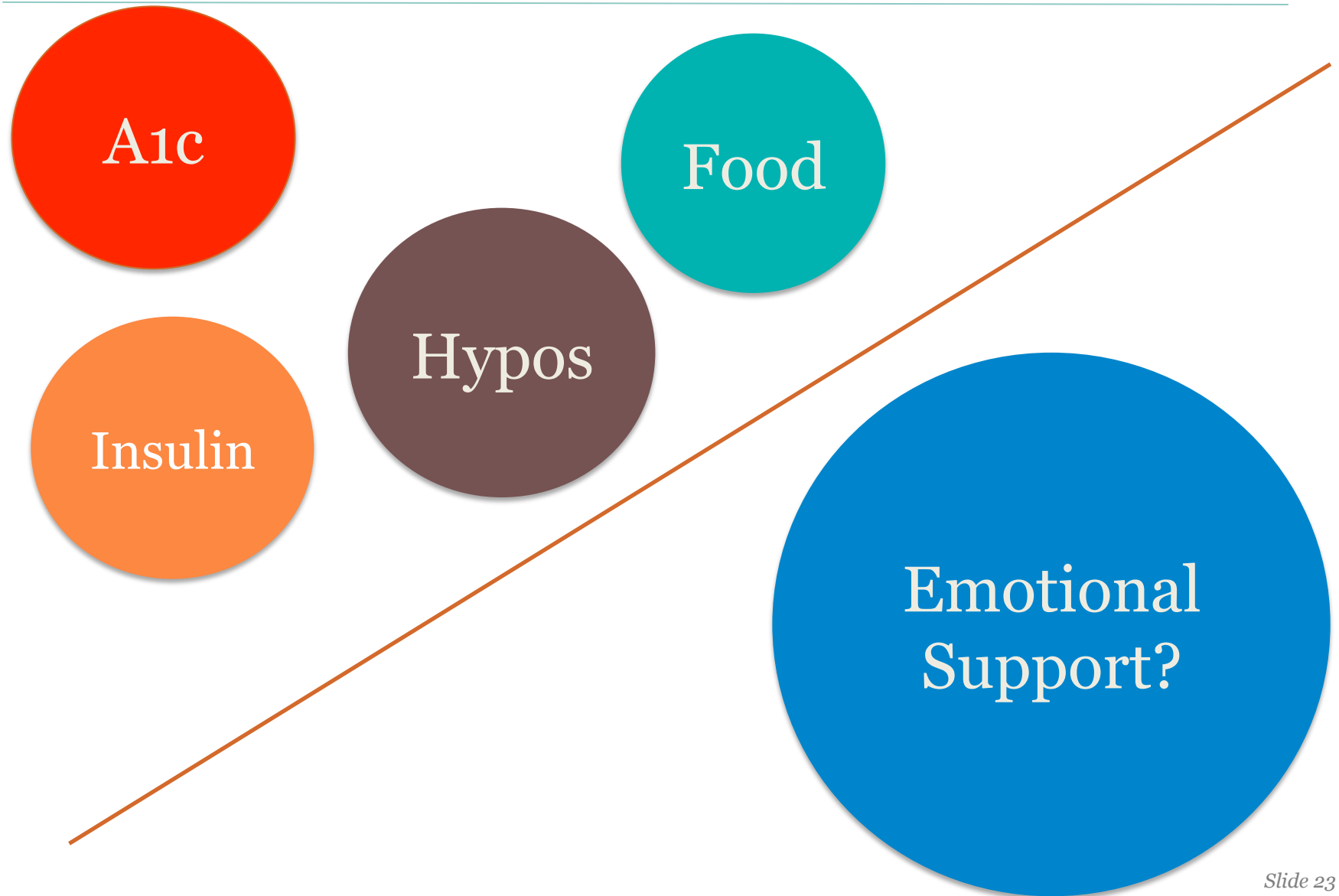
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## Mean A1c in T1D Exchange



## 2. Emotional/psychosocial support is often absent

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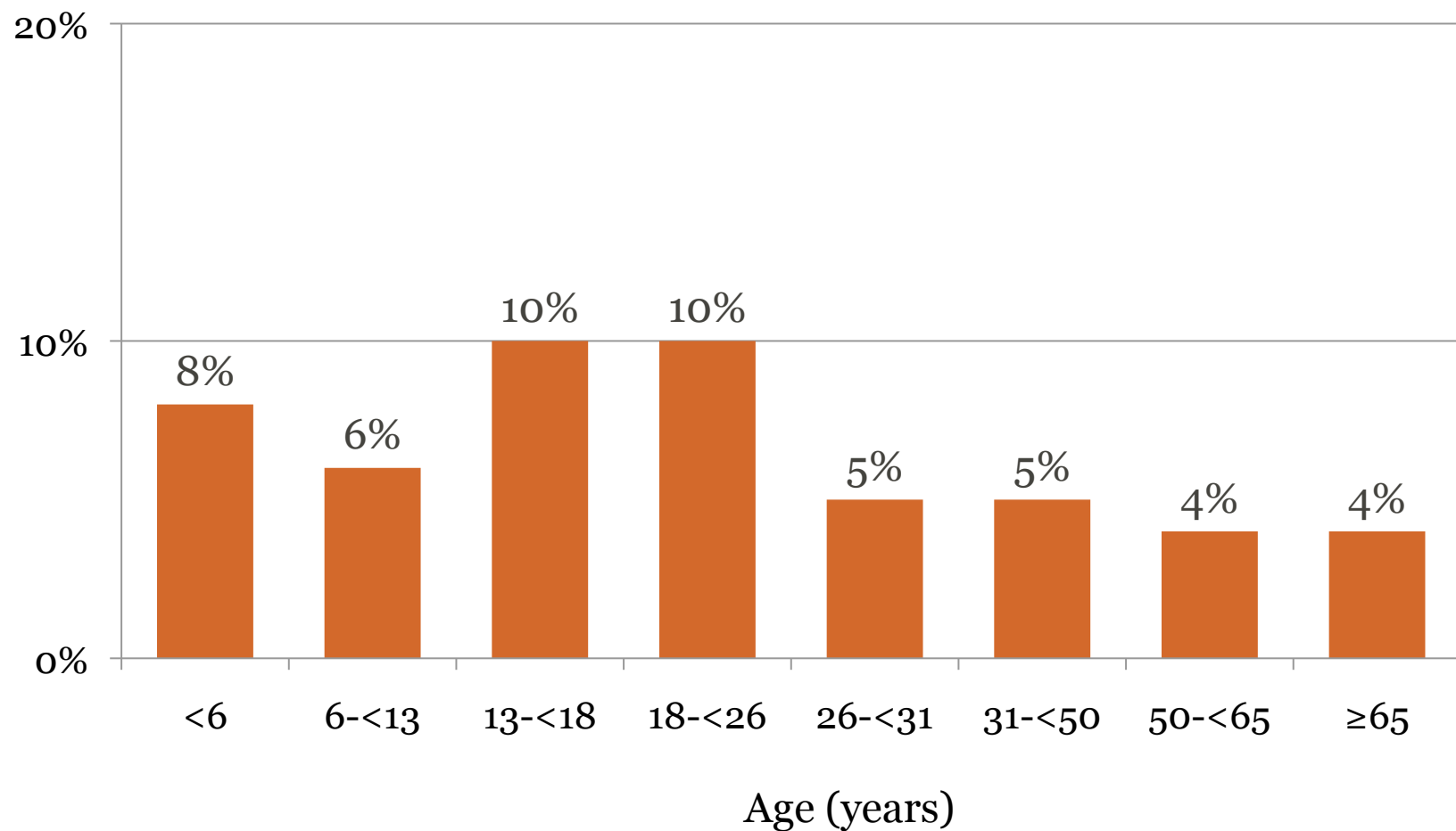


### 3. DKA is still widespread...

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# 12-month Frequency of Diabetic Ketoacidosis (DKA)\* in T1D Exchange

*\*One or more events in 12 months*



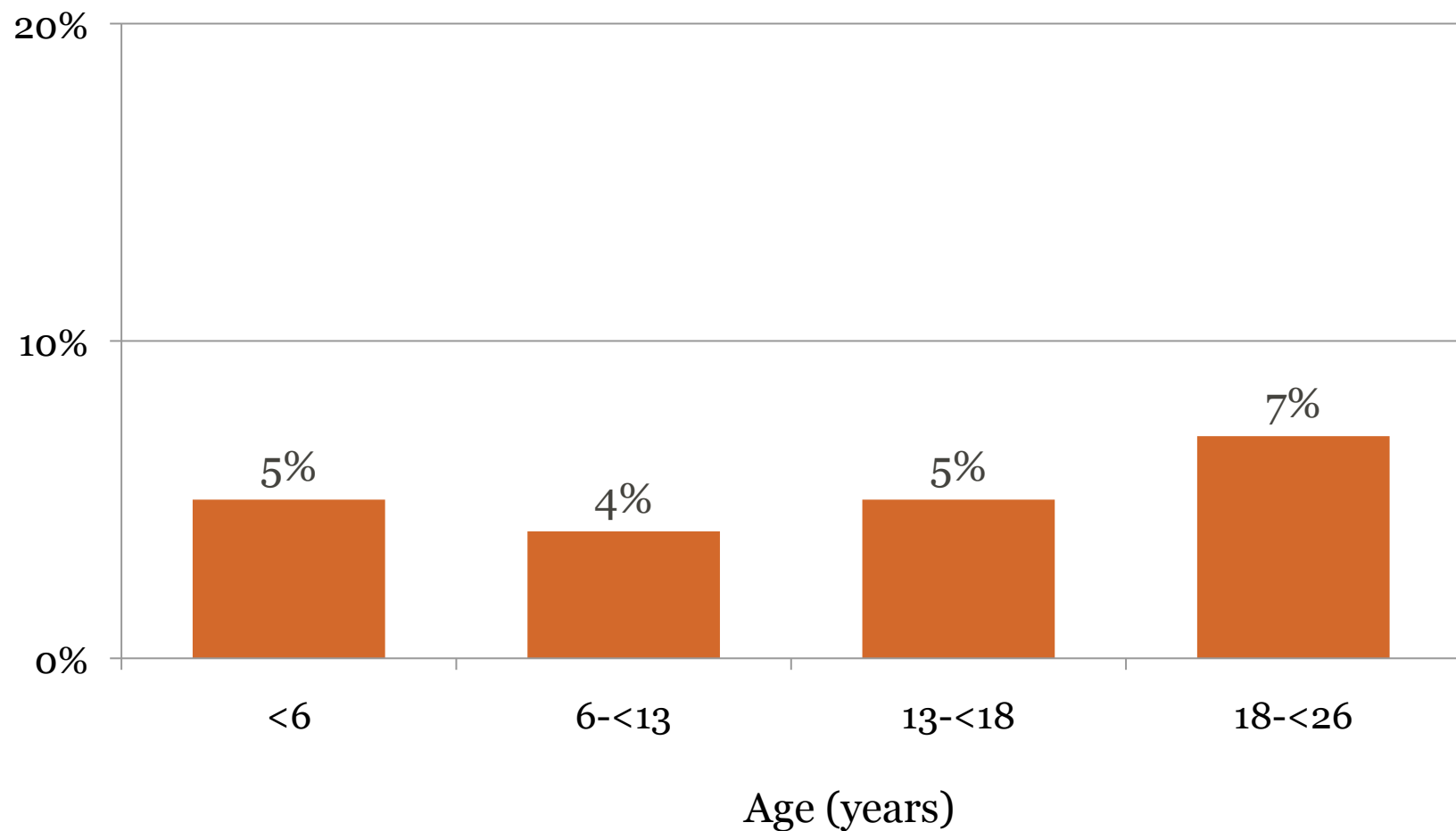


4. And so is severe hypoglycemia!

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# 12-month Frequency of Severe Hypoglycemia\* in T1D Exchange

*\* Seizure or LOC: One or more events in 12 months*



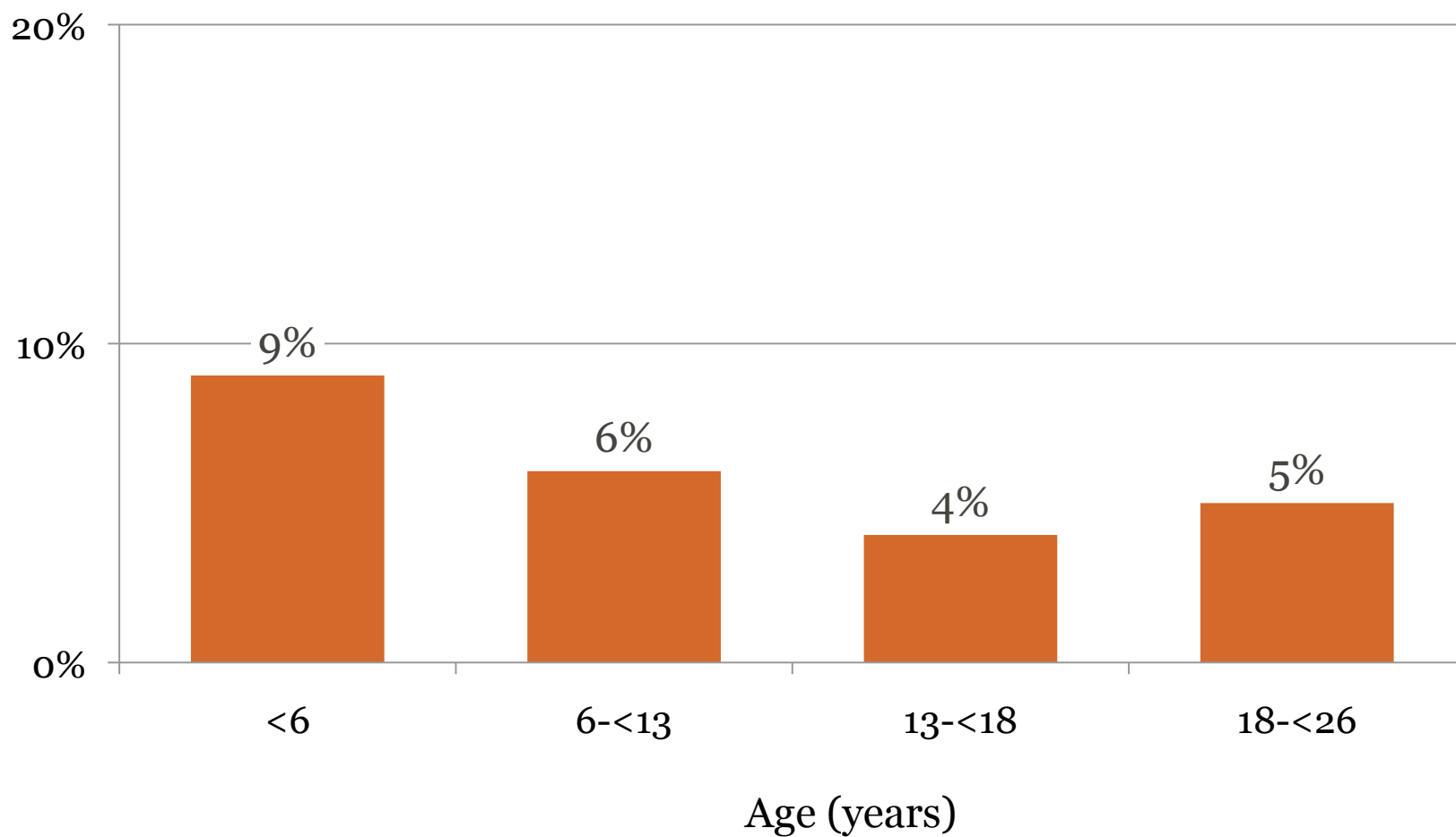


## 5. The best therapies are still underutilized

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## CGM Use in T1D Exchange



## 6. Studies cannot treat children like “miniature adults”

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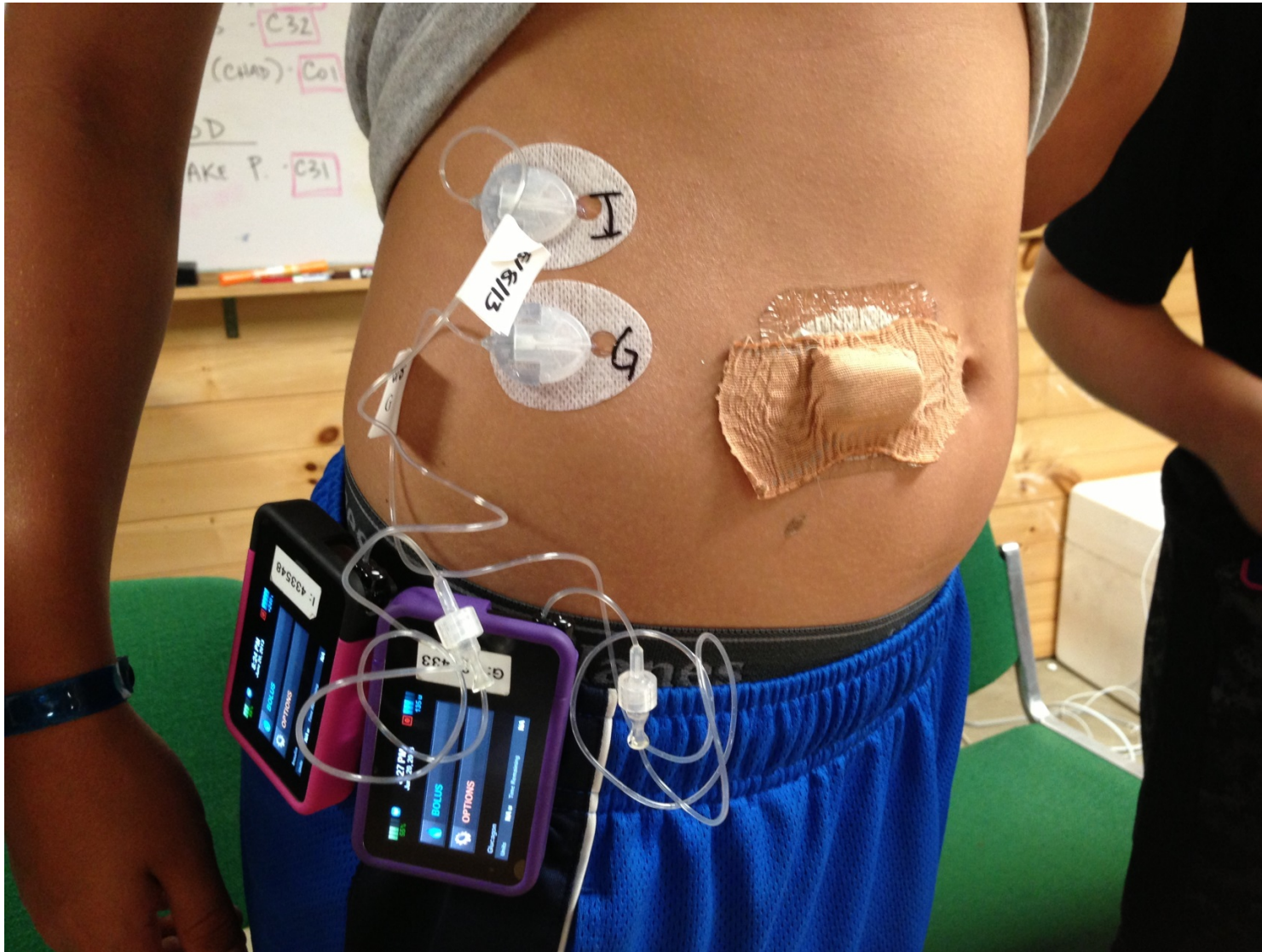


**You Must Be  
At Least This  
Tall to Use This  
Drug/Device**



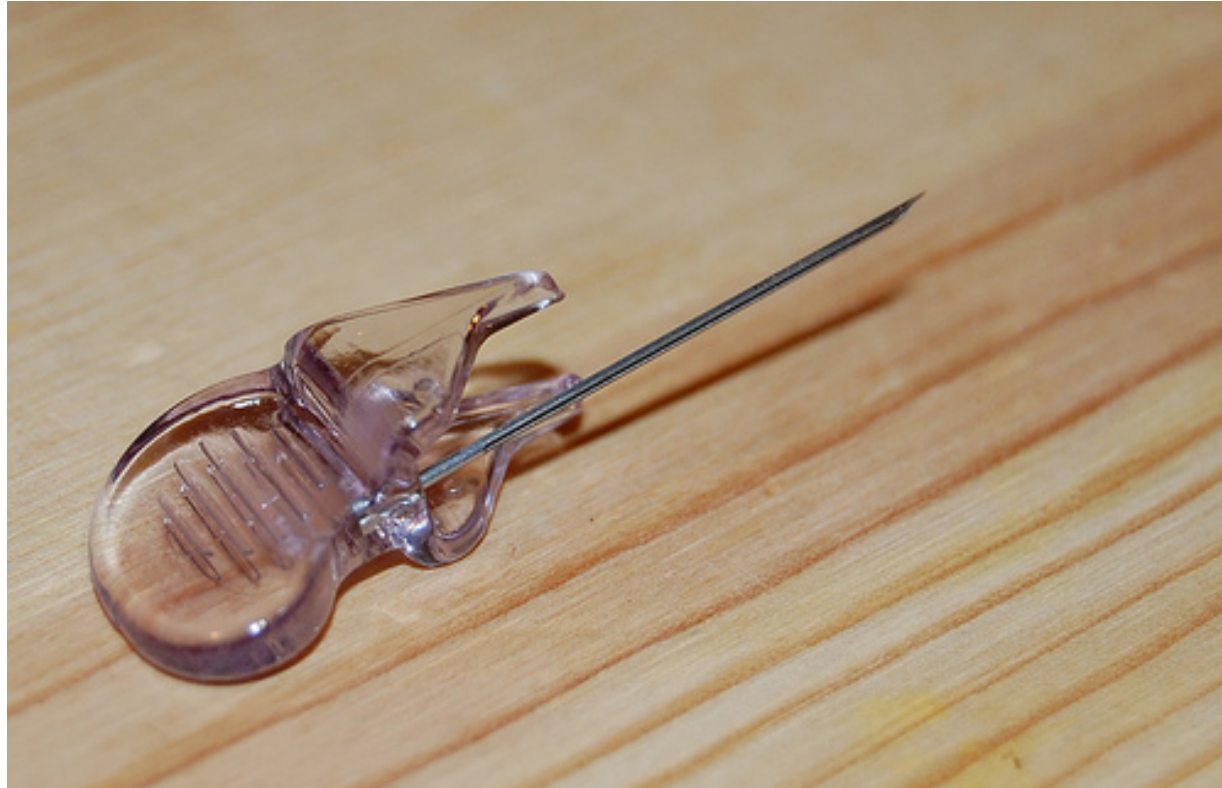
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## 7. On-body “real estate” is at a premium



## 8. Discomfort matters

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## Three Key Questions...

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1. What is the hardest part about managing pediatric diabetes?
2. What is the biggest unmet need in pediatric diabetes?
3. What would be a *complete home runs* ~~a complete home run~~ for young patients with diabetes?

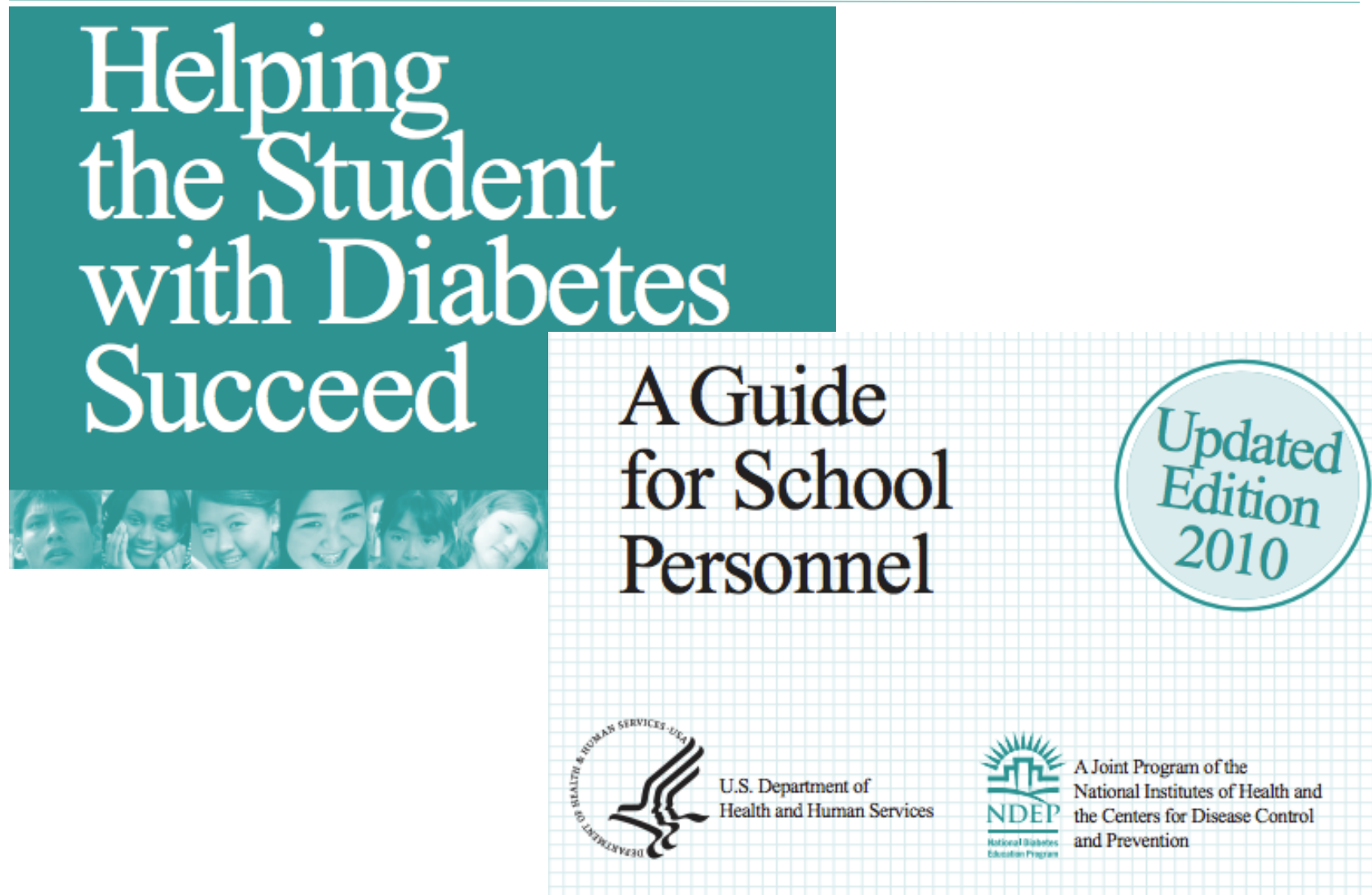
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# 1. Better access for all patients!

## Claims Past 12 Months

DATE	DESCRIPTION	TOTAL FEE
<b>05-16-12</b>	<b>Adam's prescription from Walgreens</b>	<b>\$434.97</b>
04-05-12	Adam's prescription from Walgreens	\$509.89
04-05-12	Adam's visit to Animas Diabetes Care, Llc	\$4,874.99
04-04-12	Adam's prescription from Walgreens	\$434.97
<b>03-13-12</b>	<b>Adam's visit to Minimed Distribution Corp.</b>	<b>\$325.96</b>
03-12-12	Adam's prescription from Walgreens	\$434.97
<b>02-15-12</b>	<b>Adam's prescription from Walgreens</b>	<b>\$434.97</b>
<b>01-31-12</b>	<b>Adam's prescription from Walgreens</b>	<b>\$427.99</b>
<b>01-26-12</b>	<b>Adam's prescription from Walgreens</b>	<b>\$289.99</b>
<b>01-20-12</b>	<b>Adam's prescription from Walgreens</b>	<b>\$509.89</b>
<b>01-01-12</b>	<b>Adam's prescription from Walgreens</b>	<b>\$389.97</b>
11-28-11	Adam's prescription from Walgreens	\$404.97
11-14-11	Adam's prescription from Walgreens	\$321.99
10-26-11	Adam's prescription from Walgreens	\$404.97

## 2. Improved care and support in schools



### 3. Making providers' lives much easier

**“11 out of eleven doctors recommend time travel”**

🍏 = Pre-meal/Préprandial      🍏 = Post-meal/Postprandial

Date	Breakfast/Déjeuner			Lunch/Dîner			Dinner/Souper			Other/Autre	Comments/Commentaires
	🍏	Medication/Insulin/Médicaments/insuline	🍏	🍏	Medication/Insulin/Médicaments/insuline	🍏	🍏	Medication/Insulin/Médicaments/insuline	🍏		
Apr 21	17.6	NPH NR	2.5 11	6.0 (10:00) 5.1 (12:15)				13.2 NR	5.0 4.5	8.4	11.6 (2pm) Belly lots of outdoor play
22	14.8	NPH NR	2.5 10	15.9 (9:35) 4.2 (10:40) 6.7 (11:10)			8.1 (11:10) 12.8 (1:40)	NPH NR	5.0 4.5	12.8	Arm
23	15.7	NPH NR	2.5 10	13.8 (9:40) 7.3 (11:40)			4.4 (10:30) 15.8 (2:10)	NPH NR	5.5 4.0	12.1	Vente
24	14.6	NPH NR	2.5 10	16.2 (9:30) 8.8 (11:10) 4.2 (12:15) → lunch juice 8.5 (12:40)			10.7 NR	NPH NR	5.5 4.0	13.8	Arm
25	12.4	NPH NR	2.5 8.5	12.3 (9:50) 9.3 (10:55) 4.2 (11:30) 6.2 (11:55)			7.8 NR	NPH NR	5.5 4.0	13.8	Didn't eat a.m. snack
26	6.4	NPH NR	2.5 8.5	5.4 (9:50) 2.8 (10:15) → juice 10.5 (10:55) 6.6 (11:35)			15.1 (1pm) 18.9	NPH NR	5.5 5.5	20.3	Low after recess
27	17.2	NPH NR	2.0 8.0	13.1 (10:52) 8.4 (12:00) 5.5 (12:20)			7.4 NR	NPH NR	5.5 4.0	5.7 (8:04 pm) 10.7 (1:12 pm)	Gymnastics Belly

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## 4. Patient-centered drug/device development

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### **Sanofi Appoints Dr. Anne C. Beal to the Newly Created Position of Chief Patient Officer**

***- Appointment is a First for a Top 10 Biopharmaceutical Company -***

**Paris, France - March 31 2014** - Sanofi (EURONEXT: SAN and NYSE: SNY) today announced the appointment of Anne C. Beal, M.D., MPH, to the newly created position of *Chief Patient Officer*.

*« The appointment of a Chief Patient Officer at Sanofi, the first for a top 10 biopharmaceutical company, shows our commitment to go further in meeting the needs of patients », said Pascale Witz, Executive Vice President, Global Divisions and Strategic Development at Sanofi. « Interactions with patients are a source of strength for the company and Dr. Beal's appointment will help ensure the patient perspective advances our approach to meeting the unmet needs of patients ».*

## 5. A patient-centered regulatory process

- **FDA Patient-Focused Drug Development: Disease Area Meetings Planned for Fiscal Years 2013-2015**

- 2013: Chronic Fatigue Syndrome, Lung cancer, HIV, Narcolepsy

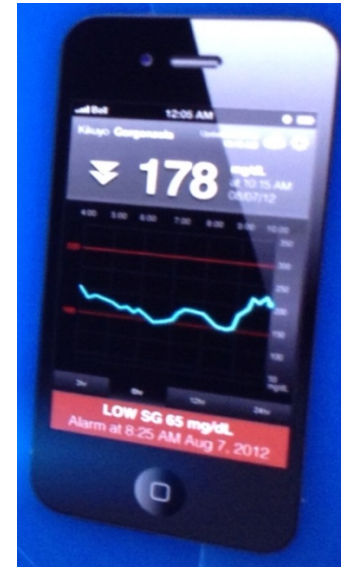
- 2014: Sickle cell disease, Fibrosis, Arterial Hypertension, Endocrinological and metabolism

- # WHERE IS

# WHERE IS DIABETES?!!

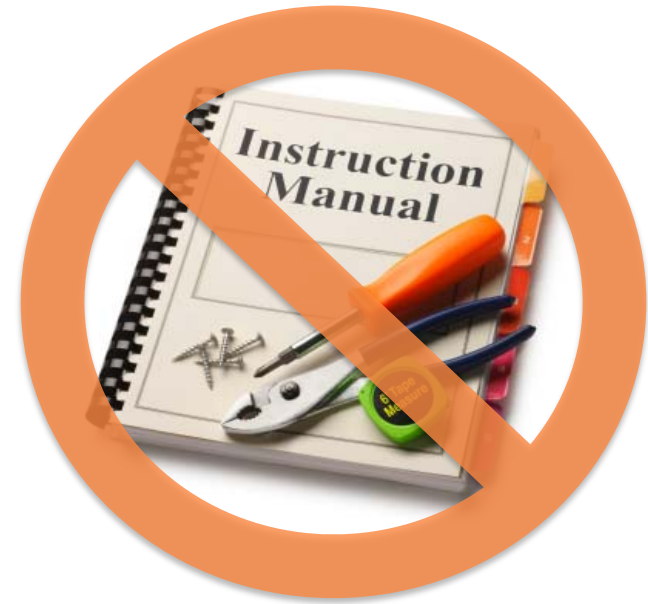
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## 6. Technology that gives peace of mind



## 7. Easy. Easy. Easy.

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**Take Once Daily  
Before Breakfast**

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## 8. Smaller, less painful, less noticeable devices

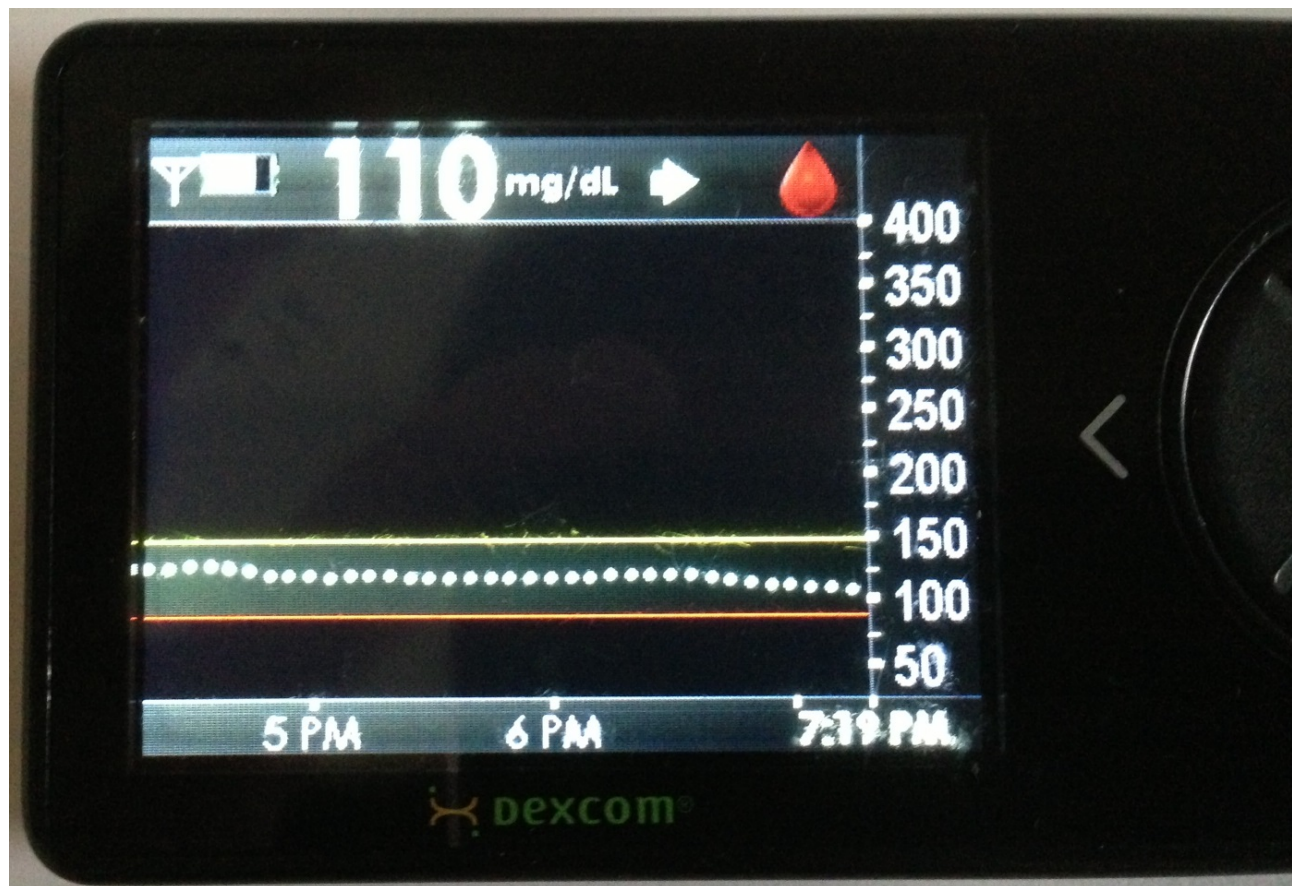
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## 9. Therapies That Increase Time in Zone



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## Three Key Questions...

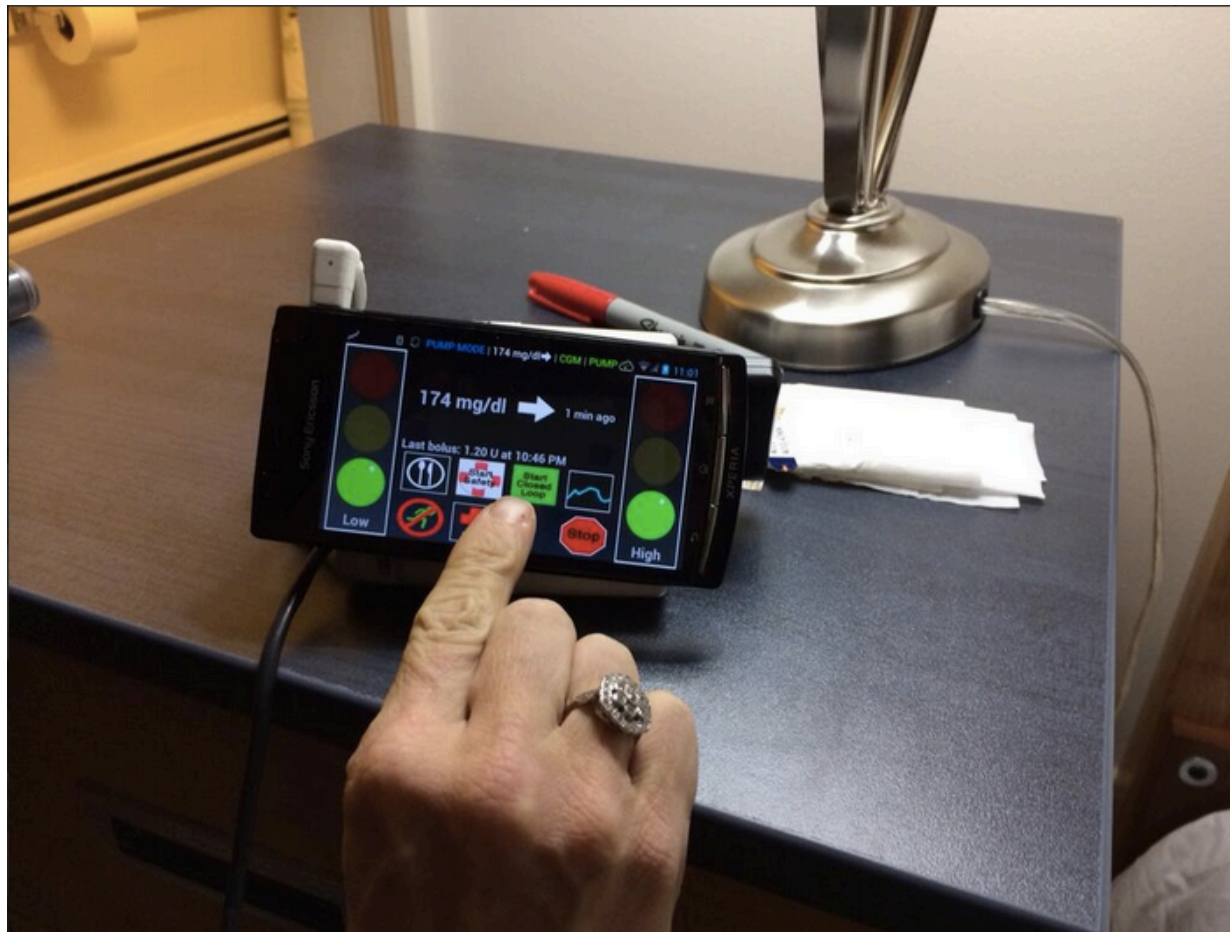
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1. What is the hardest part about managing pediatric diabetes?
2. What is the biggest unmet need in pediatric diabetes?
3. What would be a *grand slam* ~~a complete home run~~ for young patients with diabetes?

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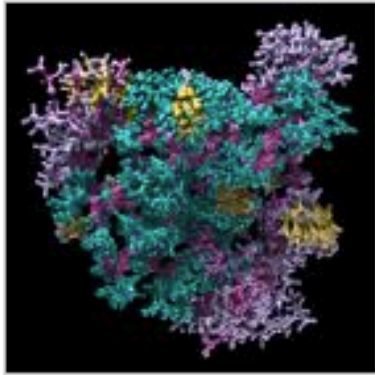
# 1. Automated Insulin Delivery

“CLOSED-LOOP ON”





## 2. Glycemic-dependent insulin



### A GRI (Glucose Responsive Insulin) for Better Treatment of Type 1 Diabetes

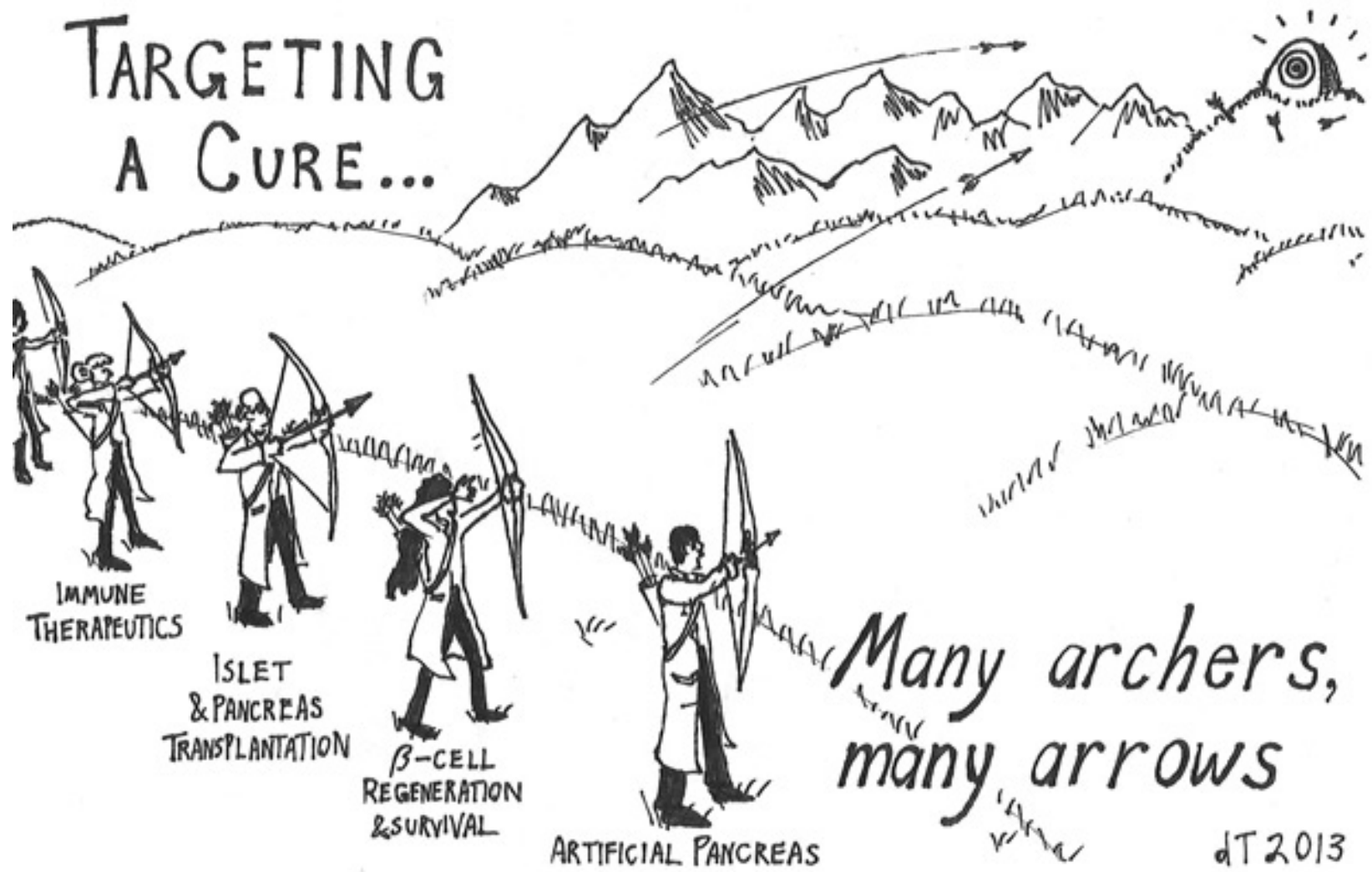
TAGS: Global Health, Life Sciences, Engineering/Design, Developing Countries, Nature, Food/Agriculture, Physical Sciences, The Economist, Chemistry, Theoretical-IP Transfer

STATUS: **Awarded** | ACTIVE SOLVERS: 382 | POSTED: 9/06/11

This Challenge, sponsored by the Juvenile Diabetes Research Foundation International (JDRF) (the Seeker), is looking for novel ideas for the development of "glucose-responsive insulin", an insulin that would work only when the body needs it, and deliver the precise amount of insulin activity in response to circulating glucose levels to control and maintain normal blood glucose levels throughout a daily routine with once-daily or less frequent dosing in people with insulin-dependent diabetes. JDRF envisions that the Winning Solution (or Solutions) from this Challenge will be further developed in a second phase that may involve the Winning Solvers and potentially partners from the commercial sector.

*This Challenge requires only a written proposal from the Applicant (Solver).*

### 3. And “real” cures



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# TARGETING A CURE *for* TYPE 1 DIABETES

## How Long Will We Have to Wait?

Lisa S. Rotenstein   Benjamin M. Kozak   Adam S. Brown  
Michael L. Dougan, MD, PhD   Hannah C. Deming   Kelly L. Close

*With a foreword by Robert Ratner, MD, and an introduction by Aaron J. Kowalski, PhD*





## Key Takeaways

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- Pediatric type 1 and type 2 diabetes are very challenging, complicated, and frustrating for patients, families, and providers
- There is lots of work to do to improve the current state-of-the-art in clinical care and emotional support
- The field is moving ahead on many fronts, and we must ALWAYS keep patients' and HCPs' experiences at the heart of new drug and device development – in industry, at FDA, and with payers

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## Key Questions

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- How do we address the underserved emotional side of managing pediatric diabetes?
- Should peds studies ALWAYS come after adult studies?
- Pediatric type 2 diabetes? Who will bring PT2 into fold?
- What about GLP-1s and SGLT-2s for pediatric type 1s and type 2s – what is the path to approval?
- What about access in general? The data shown is from patients who, in general, have higher income and more committed families.
- Who will help parents? How can we show commitment?
- How can pediatricians be helped?

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THANK YOU!

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