

Transition to Clinical Care

Challenges of Monitoring Children with Stage 1 or Stage 2 T1D

7th Symposium on Screening for T1D
November 15, 2024

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Disclosures

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- Advisory Board/Consultant – Sanofi, Shoreline Biosciences



Goals of Monitoring

Clinical Research

- To generate scientific knowledge about type 1 diabetes, including its natural history, risk factors, and the effectiveness of potential interventions or treatments.

Clinical Care

- To monitor and manage the individual's condition proactively to have shared decision making around treatment options and to optimize health outcomes.



Our Clinical Insights



Early T1D Clinic





Primary Care/GP

Progression to specialist
diabetes care

Pediatric or
adult endocrinologist



Initial Screening

Single IAb+

**Multiple IAb+
(Stage 1 T1D)**

Stage 2 T1D

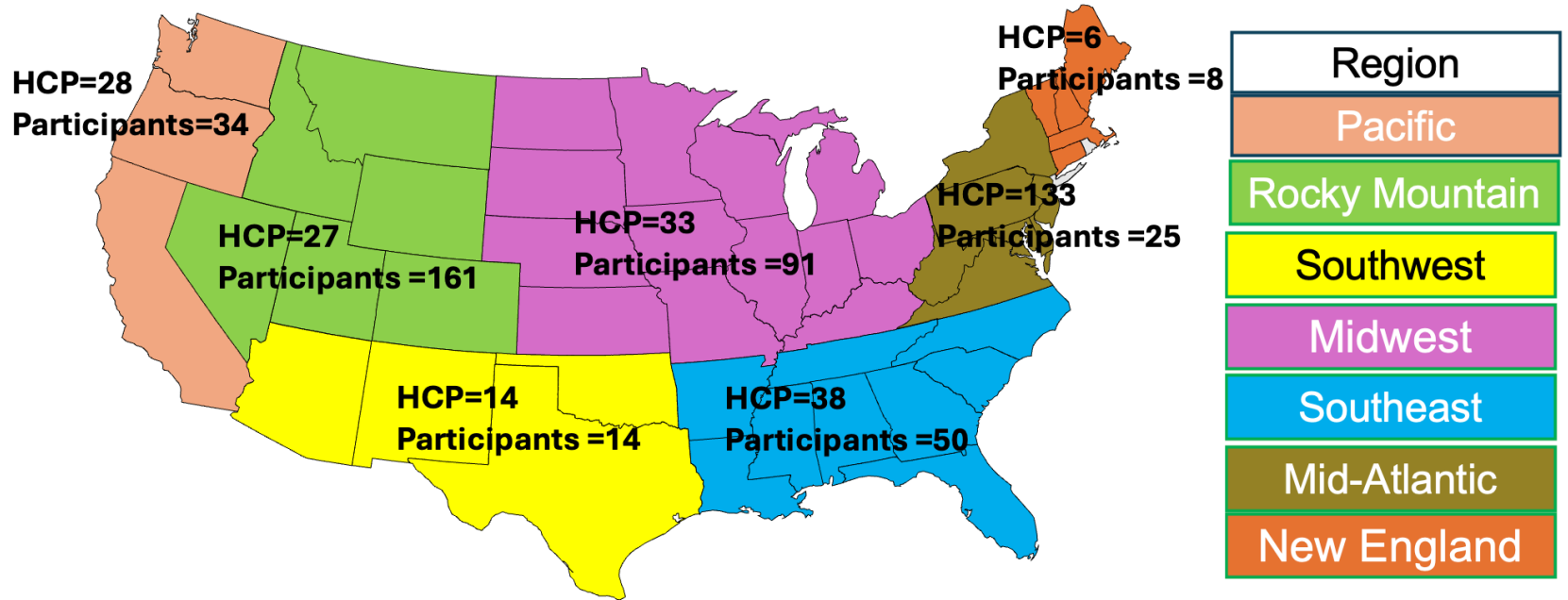
Stage 3 T1D





Ask the Experts

FOR EARLY T1D ANSWERS AND GUIDANCE





Monitoring Plan	% (n=91)
Enrolled in ASK follow-up (located in CO)	42.9% (n=39)
Local Expert HCP	25.3% (n=23)
Local Expert HCP in partnership with EXPERTS	18.7% (n=17)
EXPERTS with home glucose testing and CGMs	9.9% (n=9)
TrialNet	2.2% (n=2)
Enrolled in other screening/monitoring program	1.1% (n=1)

n=20, monitoring plan TBD



Early T1D Clinic at Barbara Davis Center

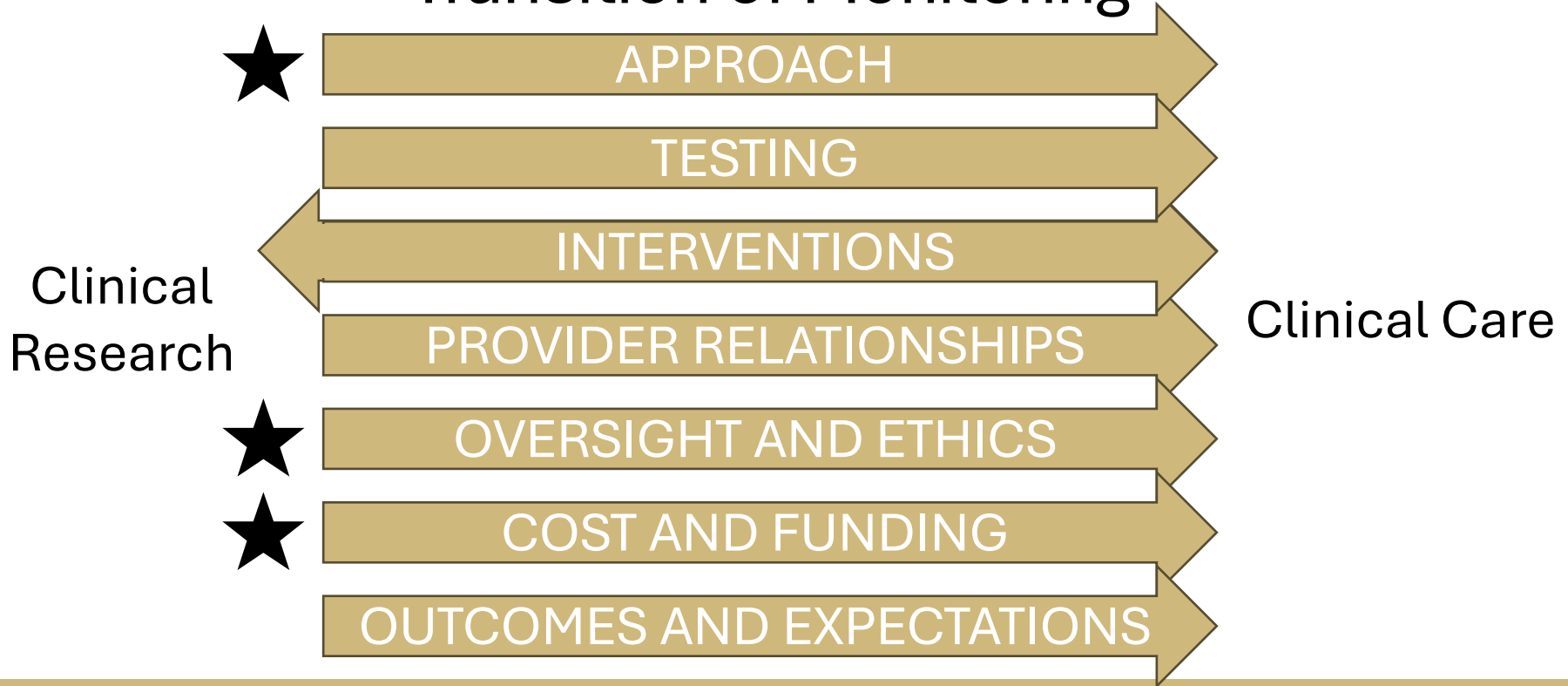
- Early T1D Clinic opened 12/9/2022
- 109 referrals, 103 new patient clinical visits
- 71 patients completed full metabolic staging
 - 42 youth
 - 29 adults



data current as on 11/9/2024



Transition of Monitoring



Clinical
Research



Clinical Care

GOAL: TO PREVENT AND CURE T1D



61%

of patients not invited
to participate

A BMC Health Service survey showed that the main barrier to taking part in trials appeared to be a lack of awareness, with most patients (61%) not being invited to take part by their physicians.¹



80%

of clinical trials fail to
meet enrollment timelines

Roughly 80% of clinical trials fail to meet enrollment timelines according to a study by the Center for Information and Study on Clinical Research Participation.²



20-25%

of clinical studies fail to
meet enrollment targets

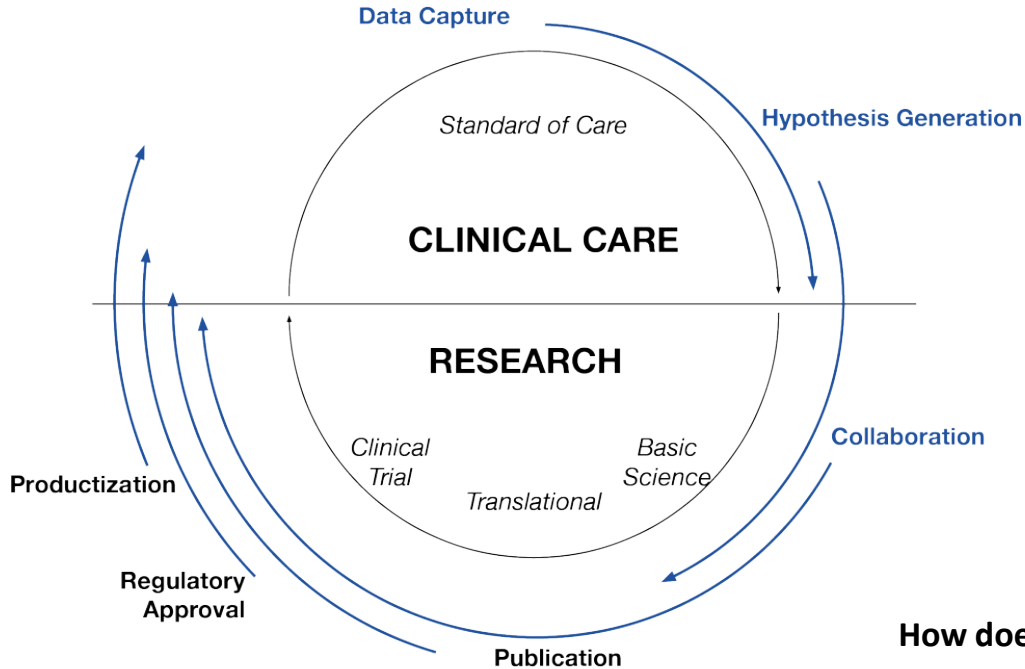
Approximately 20-25% of all clinical studies close because they fail to meet enrollment targets.³

DashMahapatra P, et al., BMC Health Serv Res, 2017; Brøgger-Mikkelsen M et al., J Med Internet Res, 2020; Summer M, WCG Insights, 2019



Barbara Davis Center for Diabetes
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

Transition is Cyclical



Consensus Guidance for Monitoring Individuals With Islet Autoantibody-Positive Pre-Stage 3 Type 1 Diabetes

Moshe Phillip, Peter Achenbach, Ananta Addala, Anastasia Albanese-O'Neill, Tadej Battelino, Kirstine J. Bell, Rachel E.J. Besser, Ezio Bonifacio, Helen M. Colhoun, Jennifer J. Couper, Maria E. Craig, Thomas Danne, Carine de Beaufort, Klemen Dovc, Kimberly A. Driscoll, Sanjoy Dutta, Osagie Ebekozi, Helena Elding Larsson, Daniel J. Feiten, Brigitte I. Frohner, Robert A. Gabbay, Mary P. Gallagher, Carla J. Greenbaum, Kurt J. Griffin, William Hagopian, Michael J. Haller, Christel Hendrieckx, Emile Hendriks, Richard I.G. Holt, Lucille Hughes, Heba M. Ismail, Laura M. Jacobsen, Suzanne B. Johnson, Leslie E. Kolb, Olga Kordonouri, Karin Lange, Robert W. Lash, Åke Lemmark, Ingrid Libman, Markus Lundgren, David M. Maahs, M. Loredana Marcovecchio, Chantal Mathieu, Kellee M. Miller, Holly K. O'Donnell, Tal Oron, Shivajirao P. Patil, Rodica Pop-Busui, Marian J. Rewers, Stephen S. Rich, Desmond A. Schatz, Rifka Schulman-Rosenbaum, Kimber M. Simmons, Emily K. Sims, Jay S. Skyler, Laura B. Smith, Cate Speake, Andrea K. Steck, Nicholas P.B. Thomas, Ksenia N. Tonyushkina, Riitta Veijola, John M. Wentworth, Diane K. Wherrett, Jamie R. Wood, Anette-Gabriele Ziegler, and Linda A. DiMeglio

Diabetes Care 2024;47(8):1276–1298 | <https://doi.org/10.2337/dci24-0042>

Goal: Strengthen “E” level of evidence

How does metabolic monitoring in early stage 2 T1D affect risk for disordered eating?



Approach to Monitoring

Clinical Research

- Care follows a strict research protocol designed to minimize variability and collect reliable data.
- Interventions may include experimental treatments or placebo to assess efficacy and safety.
- Limited flexibility; patient needs must align with the study's predefined procedures.

Clinical Care

- Care is patient-centered, focusing on the individual's specific health needs and preferences.
- Uses proven and evidence-based strategies for monitoring and risk reduction.
- Flexible and adaptive to changing clinical circumstances.



In Clinical Care, We Have to Adapt.

Misdiagnosed Adults



Early T1D: 32% of early T1D IAb+ adults had previously or were currently taking metformin, empagliflozin or semaglutide

Individuals Unlikely to Comply with Protocol



Early T1D: parent(s) not home during day, denial around diagnosis, family with many medical issues (lack of time)



Oversight and Ethics of Monitoring

Clinical Research

- Governed by strict ethical guidelines, including informed consent, IRB oversight, and data protection.
- Patients must meet strict inclusion/exclusion criteria to participate.

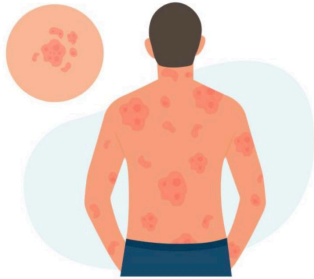
Clinical Care

- Governed by clinical practice guidelines, medical ethics, and patient consent.
- Care is provided to all individuals regardless of specific eligibility criteria.



In Clinical Care, We Monitor Everyone.

Individuals with Other
Autoimmune Conditions



Early T1D: 26yo with psoriatic arthritis
and psoriasis on ustemkinumab

EXPERTS: 13yo with dermatomyositis
and lymphocytic colitis on MMF

Individuals Diagnosed by
ADA Criteria Early



Early T1D and EXPERTS: patients with
2-hour OGTT glucose >200 mg/dl x 2 but
no symptoms, normal HbA1c, and
normal fasting glucose.



Cost and Funding of Monitoring

Clinical Research

- Costs are typically covered by research grants or sponsors.
- Participants are not charged for study-related procedures or medications.

Clinical Care

- Costs are borne by patients and their insurance plans.
- Coverage depends on the insurance policy and the clinical necessity of tests or interventions.



Costs During Monitoring in Routine Clinical Care

HbA1c
BG



OGTT



HCP E/M



CDCES
education



- Coverage of laboratory diagnostic testing, procedures, diabetes education, HCP E/M per insurance plan benefits



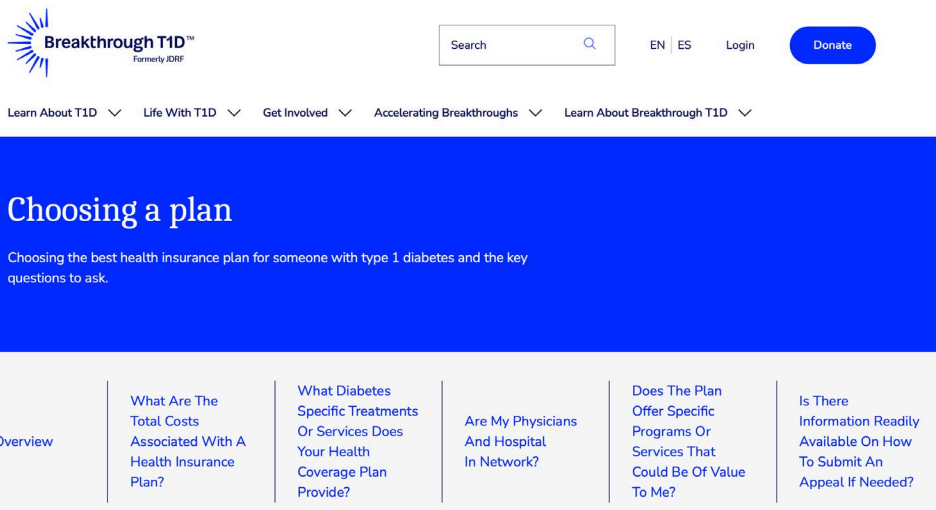
- Prescription coverage
 - Glucometer (100%)
 - Continuous glucose monitor (tracking coverage)
 - Teplizumab (BDC clinic 96%)



Practical Tips for Patient Transition to Clinical Care

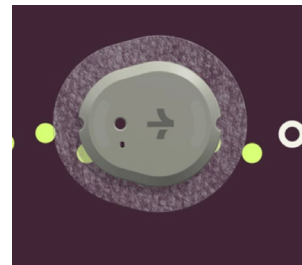
Pay attention to open enrollment.
Low deductible plans are best with T1D.

Access to unblinded CGMs is more clinically practical.



The screenshot shows the Breakthrough T1D website. At the top left is the logo with the text 'Breakthrough T1D™ Formerly ZDF'. To the right is a search bar, language options 'EN | ES', a 'Login' link, and a blue 'Donate' button. Below the navigation bar are several menu items: 'Learn About T1D', 'Life With T1D', 'Get Involved', 'Accelerating Breakthroughs', and 'Learn About Breakthrough T1D'. The main content area has a blue header with the title 'Choosing a plan' and a sub-header 'Choosing the best health insurance plan for someone with type 1 diabetes and the key questions to ask.' Below this is a grid of six article links: 'Overview', 'What Are The Total Costs Associated With A Health Insurance Plan?', 'What Diabetes Specific Treatments Or Services Does Your Health Coverage Plan Provide?', 'Are My Physicians And Hospital In Network?', 'Does The Plan Offer Specific Programs Or Services That Could Be Of Value To Me?', and 'Is There Information Readily Available On How To Submit An Appeal If Needed?'.

CGMs are available without a RX.



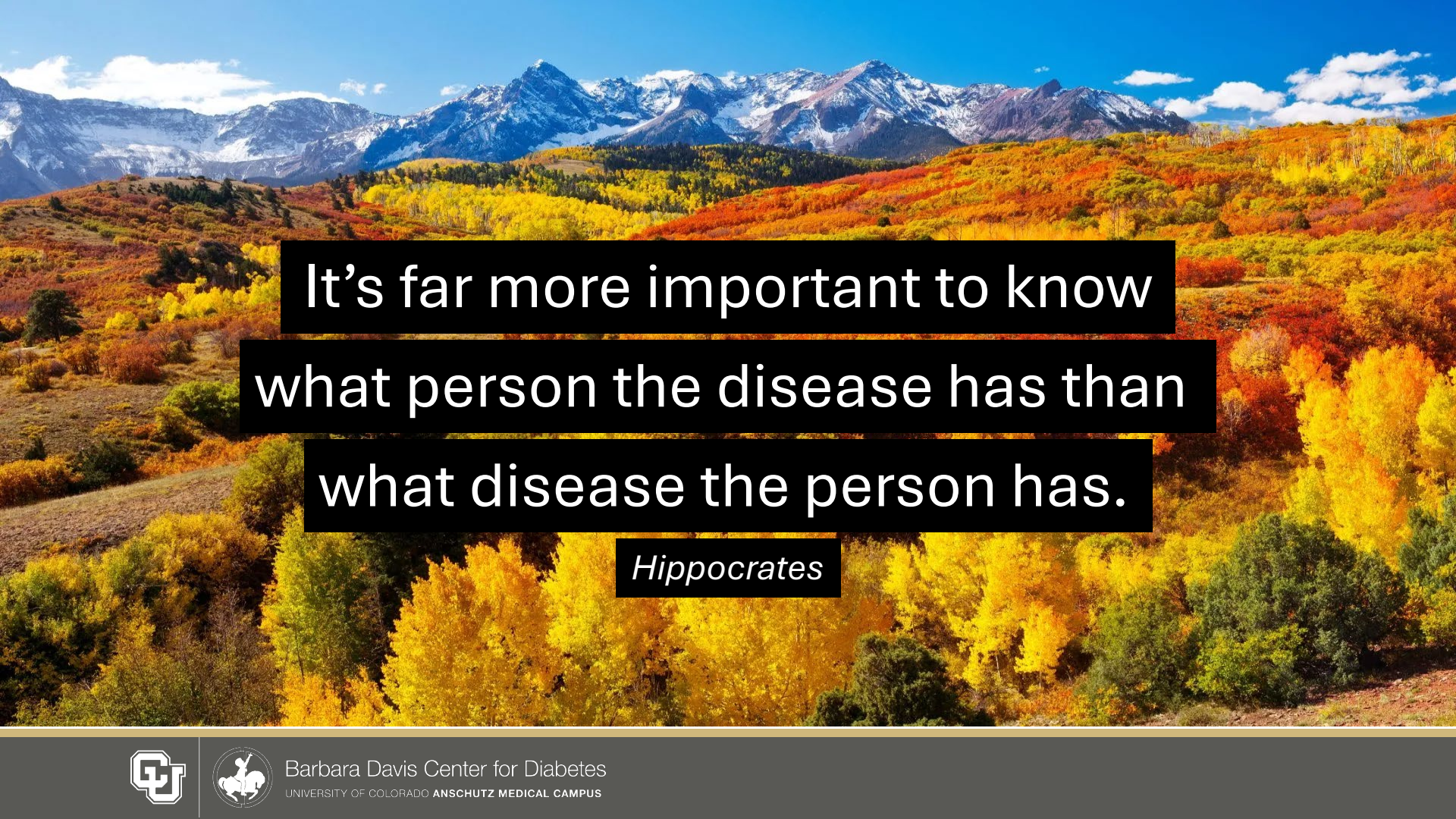
\$89/month



Conclusions

- The transition from research to clinical care is a cyclical and bidirectional process.
- Guidelines for monitoring may need to be adjusted for individuals in a real-world setting.
- Insurance policies dictate coverage; therefore, guidance on choosing a plan is important.





It's far more important to know
what person the disease has than
what disease the person has.

Hippocrates



Acknowledgements

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Sonya Walker

**Our study
participants,
patients, and
their families!**

Sponsors:

