



Beta Cell Preservation Working Group

Meeting Minutes
November 21, 2025

Participants:

Lauren Culbreth (TCH); Laura Jacobsen (UFL); Shideh Majidi (Children's National); Naomi Fogel (Lurie Children's); Laura Levin (Lurie Children's); Carla Demeterco-Berggren (Rady); Dan DeSalvo (TCH); Vana Raman (Utah); David Broome (U Michigan); Mary Pat Gallagher (Hassenfeld); Todd Alonso (BDC); Abha Choudhary (UT Southwestern); Mary McCauley (Lurie Children's);

T1D Exchange: David Walton, Nicole Riales, Trevon Wright, Emma Ospelt

Agenda

- **Welcome, introductions**
- **Commentary**
- **Roles and tasks for white paper**
- **Perspective**
- **Next Steps**
- **Questions**

Commentary Update

- Laura wrote the commentary last weekend. Carla reviewed and shared feedback. Final draft is being circulated to this group before it is submitted for publication.
- The commentary addresses the need for consistent, protocolized ways to preserve beta cell therapy and screen/preserve beta cell function in a clinical setting.
- The commentary emphasizes the need for safety, trained personnel, and reimbursement for departments involved.
- Carla will write a paragraph summarizing the commentary for submission to Diabetes Technology and Therapeutics.
- Todd forwarded the commentary title to Greg Forlenza, associate editor, as a pitch to accept the manuscript proposal.

White Paper and Change Package

- The white paper (Dec 2025) and change package (Oct 2026) should be considered separate pieces with different timelines and content.
- The white paper will compile current knowledge, while the change package will be more comprehensive, informed by ongoing work and understanding.
- The white paper will address immediate needs, while the change package will be developed further out.
- The white paper could include a case study on operations, using Texas Children's workflow as an example.
- The white paper will consist of sections, including:
 - Operational case study workflows and pathways
 - Financial case study
 - Education and equity materials for staff
 - Education and equity materials for patients
 - Measures
- Carla will compile the sections and write an executive summary.
- The goal is to have a first draft of each section by December 9th.
- Each section is estimated to be around three pages long.

Section Leads and Contributors

- Lauren Culbreth from Texas Children's will lead the operational case study section.
- Drs. Levin, Tuttle, and DeSalvo are proposed as contributors.
- Dr. Raman from Utah will lead the financial case study section.
- Dr. Gallagher will work on education and equity materials for staff. (Laura will send Mary Pat what she has for staff materials.)
- Dr. Jacobsen is assigned to education and equity for patients.
- Send Kimber an invite/request, CC Nicole.
- Dr. Choudhary wants to contribute to the education and equity materials for patients.

Measures

- Dr. Lonier and Broome added to Measures.
- The Lurie team has stepped up to work together for Measures representation.

Financial Points

- Question about centers that already have conversations with their administration regarding financial points.
- Dr. Choudhary: There is a significant amount of revenue the hospital is generating, but it is not coming to the division.
- Division chief wants to wait till stage three approval comes along.

- They do the buy and build, so there is a huge margin there.
- Sanofi may be willing to give help in terms of what that data might look like in terms of a business plan.
- After requesting information post-meeting, they were thanked for the inquiry and told someone would get back to them regarding what could be shared.
- BDC is the only practice getting billing to their clinic because they do the infusions there.
- Reimbursement happens based on the 340B plan, typically connected to a hospital.

Cost of Medication

- The cost of the medication is \$140,000, with the second one 30% cheaper.
- The Children's Hospital (UTSW) has been billing \$800,000 profit from the infusions.
- Someone mentioned that they were told it was 100k per patient, including Medicaid.
- Preliminary math showed that without the 340B, the cost of the drug is close to \$195-200,000.
- With 340B, there is a 30-50% discount, decreasing it to about \$100,000.
- One person feels like the prices are marked up, considering vascular access, nursing staff, and labs are involved.
- Most people don't only take 14 days due to monitoring parameters, often going into 17-21 days to complete the full protocol.
- There is upstream and downstream revenue that flows into the hospital.
- Last year, there was an attempt to get an infusion covered for a patient, but Sanofi's \$5,000 cap for the 14-day infusion was financially insufficient.

Data Collection

- Listing as many locations for data as possible is important because people may get it from different sources.
- Initial lab values like pH or bicarb are important, noting that the definition for DKA has changed from less than 15 to less than 18, so categorizing DKA depends on the year.
- Having actual pH and bicarb values allows for tiering people by DKA severity.
- Some centers collect bicarb pH with a flow sheet at diagnosis and ensure the data flows into their new onset node.

Family History

- Questioning the focus on first-degree relatives (FDR) in family history data collection.
- Many kids have grandparents who thought they had type two but may have had type one.

- The smart form has been updated to include "reason for screening" (autoimmunity, abnormal A1C) and a detailed list of family members (sibling, parent, cousin, grandparent).

Change Package and Publications

- A change package is planned for Q3 2026, informed by the content produced for the white paper.
- Planning for a Perspective publication, potentially submitted before the end of Q1 2026.
- Tentatively planning to submit the Perspective to JCEM.

Next Steps and Meeting Cadence

- Monthly meetings are considered reasonable, with ad hoc meetings for subgroups.
- A meeting poll will be sent out to find a suitable time for the larger group to meet.
- They are hoping to book most of these ad hoc meetings in the first week in December.
- Carla will draft a letter and send it to Laura for review and submission.
- The commentary will be circulated with the minutes of the call for everyone to read.

White Paper Details

- White papers are generally under 20 pages, with each section being around three pages long.
- Materials for patients, families, and clinical people will be included as references or in an appendix.
- The executive summary will be less than a page, and the introduction about half a page.
- The white paper should present an issue and propose a solution.
- The importance of the Collaborative developing a national registry should be highlighted.

Recording:

https://us02web.zoom.us/rec/share/-nLh3CQEkqh0sSdulWS5L3zLE8kQ-wfxC9aT3ugn2huirZV_9TJuM7X3_irkI2dR.19mDCJlOjmTX0rEH

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