Opportunities and Priorities for the Office of New Drugs: Optimizing Outcomes

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OND, FDA – November 7th, 2019
Thank you immeasurably!
Diabetes Management = Self-Management

People with diabetes spend **24,000 - 110,000 minutes** a year making decisions about their diabetes.

People with diabetes spend **15-120 minutes** a year with health care professionals.

Expand primary and secondary endpoints that affect patient outcomes

Self-management support

Improved medical and psychosocial outcomes

Lower costs to the entire healthcare system
THE MANY FACES OF A 7% A1C
(and an average blood glucose of 154 mg/dl)
"A Big Impact" On Daily Life, Rank Order: Many Differences, but Time in Range is #1 For All

Type 1 (n=1,016)
- Time in Range
- Unexpected BG Numbers
- Dosing Insulin
- Hypoglycemia
- A1c

Type 2 on insulin (n=1,141)
- Time In Range
- A1c
- Non-Diabetes Health Issues
- Dosing Insulin
- Unexpected BG Numbers

Type 2 no insulin (n=1,266)
- Time In Range
- A1c
- Non-Diabetes Health Issues
- Unexpected BG Numbers
- Symptoms of Complications

Patients are far from feeling “very successful” (n=3,455)

<table>
<thead>
<tr>
<th>Category</th>
<th>Type 1</th>
<th>Type 2 insulin</th>
<th>Type 2 non-insulin</th>
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<tbody>
<tr>
<td>Blood glucose goals/excursions</td>
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<td>Complications</td>
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<td>Emotional well-being</td>
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<tr>
<td>Burden of diabetes care</td>
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<td>&lt;33% feel ‘very successful’</td>
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<tr>
<td>Family/relationships</td>
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<tr>
<td>Social/stigma</td>
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<td>&gt;66% feel ‘very successful’</td>
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A cultural shift – seeing time in range, AGP, improving from any base

7 days Oct 23, 2019 - Oct 29, 2019

Time in Range
- 29% High
- 65% In Range
- 4% Low
- 2% Urgent Low

Glucose Management Indicator (GMI)
- Not enough data available

Average Glucose (CGM)
- 148 mg/dL

Patterns
- Nighttime Highs

Best Day
- Sunday, October 27

7 days Oct 5, 2019 - Oct 11, 2019

Time in Range
- 6% High
- 86% In Range
- 6% Low
- 2% Urgent Low

Glucose Management Indicator (GMI)
- Not enough data available

Average Glucose (CGM)
- 117 mg/dL

Patterns
- No patterns detected

Best Day
- Wednesday, October 9

7 Days
You reached your Goal: Time in Range 6 out of 7 days.

Edit Goal

Oct 6, 2019 - Oct 12, 2019

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<tr>
<th>Day</th>
<th>Time in Range</th>
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<tr>
<td>Su</td>
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<tr>
<td>Mo</td>
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Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials

Roy W. Beck,¹ Richard M. Bergenstal,² Tonya D. Riddlesworth,¹ Craig Kollman,¹ Zhaomian Li,¹ Adam S. Brown,³ and Kelly L. Close⁴

Diabetes Care 2019;42:400–405 | https://doi.org/10.2337/dc18-1444
Every 10% increase in TIR = ~0.5-0.8% A1C reduction

Each incremental 5% increase in TIR is associated with clinically significant benefits for type 1 and type 2 diabetes.

Policy Recommendations for FDA Office of New Drugs

Expand primary and secondary endpoints that affect patient outcomes

1. Establish hypoglycemia as a clinically meaningful endpoint and incorporate hypoglycemia into the label for therapeutic differentiation purposes
2. Acknowledge and establish time-in-range as an important complement to A1C
3. Investigate other endpoints that are meaningful to patients (e.g., weight loss, diabetes distress, fear of hypo)
Policy Recommendations for FDA Office of New Drugs

- Expand harmonization across FDA divisions, particularly related to glucose measurement
  - Assess CGM data and metrics in clinical trials for diabetes therapies

- Encourage greater harmonization among clinical, professional, patient, and regulatory adoption of advanced treatments to improve care and patient outcomes
Policy Recommendations for FDA Office of New Drugs

- Improve speed and transparency of guidance creation and dissemination process
- Create therapeutic labels that are even more clinically-relevant and patient-friendly
- Further consider greater focus on prevention; specifically, establishing a prediabetes pathway
At diaTribe, we are committed to improving the lives of people with diabetes and amplifying patient voices.
diaTribe.org/Join

200,000 subscribers
2.3M visitors annually