Transforming Diabetes Care

Barriers to Mealtime Insulin Dosing

Mark Peyrot, PhD
Loyola University Maryland, Baltimore, MD
Faculty Background

Principle Investigator
- DAWN and DAWN2 studies (Novo Nordisk)
- GAPP and GAPP2 studies (Novo Nordisk)
- Diabetes self-management education access (AADE)
- Clinical/user trials for medications, insulin pumps and pens, CGM

Developer of guidelines
- Psychosocial diabetes care
- Diabetes self-management education (DSME)
- DSME evaluation

Questionnaire design

Statistical modeling
“Drugs don’t work in people who don’t take them.”
- C. Everett Koop, M.D.¹

“Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments.”
- Dr R. Haynes²

“Adherence to long-term therapy for chronic illnesses in developed countries averages 50%. In developing countries, the rates are even lower.”
- World Health Organization³

Polling Question
Which of the following is the least well researched and understood aspect of insulin therapy implementation?

A) Initiation
B) Persistence
C) Adherence
D) Intensification
Medication Therapy Implementation

Adherence often used as an umbrella term, but important to distinguish several elements of treatment implementation

- Initiation – does PWD start taking medication
- Adherence – does PWD take all doses, as prescribed
- Persistence – does PWD continue taking medication
  - If PWD terminates, does s/he resume
- Intensification – does PWD take more medication (dose amount, # of doses) when needed

Initiation and persistence are the major elements, but adherence is the most often studied (degree of medication taking adherence, not absence of medication taking)

Initiation and intensification based on PWD expectations (physician has most influence); adherence and persistence based on PWD experience

PWD = People/person with diabetes
The Current Reality of the Diabetes Healthcare Gap in the U.S.

- Fewer than half of US adults with type 2 diabetes reach an HbA1c level of less than 7% despite the availability of multiple effective therapies and evidence-based guidelines\(^1\)

- Lack of adherence to guidelines and ineffective utilization of existing pharmacotherapies contribute to suboptimal care and an increased risk of morbidity and mortality\(^2\)

67% of Patients on Mealtime Insulin Therapy Are Not at Goal

2.5 million Type 1 and Type 2 patients are on mealtime insulin in the U.S.

1.7 million are not at A1C goal (measured by A1C>7)\(^1\)

Nonadherence is Prevalent

<table>
<thead>
<tr>
<th>Disease Condition</th>
<th>No. of Studies</th>
<th>Mean Adherence (percent)*</th>
<th>Random Effects 95% Confidence Interval for Mean Adherence (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV disease</td>
<td>8</td>
<td>88.3</td>
<td>(78.9, 95.2)</td>
</tr>
<tr>
<td>Arthritis</td>
<td>22</td>
<td>81.2</td>
<td>(71.9, 89.0)</td>
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<tr>
<td>Gastrointestinal disorders</td>
<td>42</td>
<td>80.4</td>
<td>(73.9, 86.2)</td>
</tr>
<tr>
<td>Cancer</td>
<td>65</td>
<td>79.1</td>
<td>(75.9, 84.2)</td>
</tr>
<tr>
<td>Seizures/brain disorders</td>
<td>9</td>
<td>78.4</td>
<td>(52.4, 95.7)</td>
</tr>
<tr>
<td>Genitourinary and STDs</td>
<td>17</td>
<td>77.0</td>
<td>(65.4, 86.9)</td>
</tr>
<tr>
<td>Skin disorders</td>
<td>11</td>
<td>76.9</td>
<td>(66.5, 85.9)</td>
</tr>
<tr>
<td>Cardio vascular diseases†</td>
<td>129</td>
<td>76.6</td>
<td>(73.4, 79.8)</td>
</tr>
<tr>
<td>ENT and mouth disorders</td>
<td>30</td>
<td>76.1</td>
<td>(68.6, 82.8)</td>
</tr>
<tr>
<td>Blood disorders (not leukemia)</td>
<td>7</td>
<td>75.6</td>
<td>(45.9, 95.7)</td>
</tr>
<tr>
<td>OB-GYN</td>
<td>19</td>
<td>74.8</td>
<td>(64.2, 84.2)</td>
</tr>
<tr>
<td>Infectious disease</td>
<td>34</td>
<td>74.0</td>
<td>(67.5, 80.0)</td>
</tr>
<tr>
<td>Eye disorders</td>
<td>15</td>
<td>72.6</td>
<td>(61.8, 82.3)</td>
</tr>
<tr>
<td>End-stage renal disease</td>
<td>20</td>
<td>70.0</td>
<td>(56.8, 81.6)</td>
</tr>
<tr>
<td>Pulmonary diseases</td>
<td>41</td>
<td>68.8</td>
<td>(61.1, 76.2)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>23</td>
<td>67.5</td>
<td>(58.5, 75.8)</td>
</tr>
<tr>
<td>Sleep disorders</td>
<td>16</td>
<td>65.5</td>
<td>(54.3, 75.8)</td>
</tr>
</tbody>
</table>

DiMatteo, 2004 Medical Care
Missed Mealtime Doses May Translate to Poor Glycemic Control

We spend 12 hours of every day in a postprandial state\(^1\)

A study found that for every 4 mealtime doses that are missed, there is a nearly 1% increase in A1C per week\(^2\)

Based on a 2006 survey of type 1 youth using CSII with suboptimal A1C levels \(\geq 8\) (n=48) in the U.S. Linear regression showed that at 3 months, there was a 0.92% increase in A1C for every four meal boluses missed.

Barriers and Challenges to Insulin Use
• Physicians are the major drivers of PWD therapy choices

• Physician reluctance to prescribe is major factor in delay of insulin initiation, low uptake of insulin pens and inhaled insulin, overuse of basal insulin

• Physician reluctance to prescribe is a function of treatment philosophy and amount of effort required rather than perceived efficacy
Main Physician Barriers to Insulin Intensification

Doctors are **lacking experience** with the available insulins

Doctors feel that **educating patients** about insulin intensification will **take too much time**

Doctors **do not believe** that patients will be able to cope with intensified insulin therapy

There is a **lack of guidance** about insulin intensification

There is a **lack of patient monitoring** to show when type 2 patients require intensified therapy

Doctors **lack belief** that **insulin intensification is necessary**

[US, ES, JP only n=300]: The **reimbursement** situation for insulin

**Other**

There are **no barriers** to insulin intensification in my country

**Question:** Which of the following, if any, do you think are the main barriers to insulin intensification for type 2 diabetes in your country?

Cuddihy et al. Diabetes Educ 2011;37:111-23
Polling Question

How common do physicians think patient difficulties with insulin therapy are?

A) Much more common than patients report
B) A little more common than patients report
C) A little less common than patients report
D) Much less common than patients report
The Patient Difficulty Most Often Reported by Physicians Was the Typical Patient Finds it Difficult to Take Insulin Frequently

- Taking insulin frequently: 58.5%
- Changing timing of insulin to meet daily needs: 57.7%
- Taking insulin at the prescribed time or with meals everyday: 54.5%
- Following HCP instructions: 45.4%
- Preparing injections: 35.0%

n=1,250 primary care physicians and specialists in China, France, Japan, Germany, Spain, Turkey, the UK and the USA
The Difficulty Most Often Reported by Insulin Treated Patients Was Taking Insulin at Prescribed Time or with Meals

- Taking insulin at prescribed time or with meals every day: 27.6%
- Number of daily injections: 23.1%
- Following healthcare professional instructions: 16.9%
- Adjusting insulin doses: 16.8%
- Preparing injections: 10.3%

n=1,530 patients with diabetes (type 2: 88.2%, in China, France, Japan, Germany, Spain, Turkey, the UK and the USA) Peyrot et al. Diabetic Medicine 2012;29:682–9

Reported Reasons for Insulin Omission/Nonadherence

- Too busy
- Travelling
- Skipped a meal
- Stress or emotional problems
- Injection embarrassment
- Challenging to take at the same time every day
- Forgot
- Too many injections
- Avoid weight gain
- Regimen is too complicated
- Injections are too painful

Patients (%)
Burden of Multiple Injections
Patient Burden Associated with Multiple Injections

Insulin experienced patients’ ratings of treatment burden*1

Burden of Multiple Injections May Explain Patients Skipping Insulin Doses

57% of insulin patients reported intentional insulin omission
   - 20% reported skipping injections “sometimes” or “often”

Patients who took more injections were significantly more likely to skip injections

Insulin omission is affected by the perceived burden of insulin therapy

<table>
<thead>
<tr>
<th>Reason</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily injection frequency</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Plan daily activities around insulin injections</td>
<td>0.002</td>
</tr>
<tr>
<td>Interference with activity of daily living</td>
<td>0.001</td>
</tr>
<tr>
<td>Dissatisfaction with injection pain</td>
<td>0.002</td>
</tr>
<tr>
<td>Dissatisfaction with injection embarrassment</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*Regression analysis conducted on standardised patient survey results to assess independent relationships with frequency of skipping insulin dose. Survey study of 502 self-reported insulin using diabetic patients using a standardised and controlled survey tool Adapted from Peyrot et al. Diabetes Care 2010:33;240-5
Currently Insulin Delivery Options Do Not Address Barriers to Mealtime Dosing

Lifestyle restrictions, injection challenges, and the fear of social stigma are all realities of current insulin delivery options.

How to Help Patients Take Better Care of Themselves
Polling Question
Which of the following statements is true?

A) Trying to help patients figure out how to take their medications as prescribed is a waste of time

B) Patients can figure out how to take their medications as prescribed without assistance

C) There are effective strategies for helping patients figure out how to take their medications as prescribed

D) Good patients always take their medication as prescribed
What’s the Problem?

Initiate Persist Adhere
What’s the Solution?
HCPs need to provide ongoing support to patients

HCP, healthcare professional
Self-Management Support

• It is not enough to get patients to understand what they need to do

• Many patients are not effective problem solvers if left to their own means

• Providers should help patients formulate plans for dealing with their problems

• Providers can support patients by a few simple steps
Behavior Change Counseling

1. Involve the patient
2. Specify the problem
3. Identify successes and failures
4. Negotiate a SMART goal
5. Identify barriers to goal attainment
6. Formulate strategies to achieve the goal
7. Contract for change
8. Track outcomes

Key Characteristics of Support

- **Empathize**
  - Respect and empathy

- **Communicate**
  - Speak the patient’s language

- **Holistic approach**
  - Deal with emotional and practical (not just technical) issues

- **Timing**
  - Support targeted to **critical junctures**
What are the Critical Junctures?

- **Initiation visit**
- **Initial prescription fill**
  - Within a few days after initiation
  - Especially if patient was not using at previous contact
- **First week of use**
  - Monitor adherence
  - Emergent problems
- **First month of use**
  - Major time of therapy termination
- **First prescription refill**
- **Every office visit**
  - Most important patient-reported information
Initiation Visit
Visit Objectives

**Traditional focus**
- Make/explain recommendation
- Get patient to agree

**Patient-centered focus**
- Ensure patient understands need for change in therapy
- Identify potential barriers to therapy implementation
- Identify potential solutions to barriers
- Establish ongoing support agreement

**PROBLEM**

Patient may:
- “Agree” with no intention of implementation
- Have difficulty in implementation
### Strategies for Assessing Barriers

| Ask about patient adherence to current regimen | • Lack of adherence may be reason for lack of efficacy  
| | • Easier to assess existing barriers/motivations than project new ones  
| | • Identify gaps between expectations and reality |

| Ask about patient perceptions of proposed regimen | • Identify patient information/misinformation  
| | • These must be dealt with |

| Do not dismiss misinformation — explore its foundations | • Beliefs are grounded in real experience  
| | • Failure to address foundations undermines provider credibility |
Addressing Barriers

1. **Expressed barriers**
   - Save unexpressed barriers for later

2. **Personalize relevance**
   - “Why do you believe that would happen to you?”

3. **Planning**
   - How would the patient deal with the barrier if it occurred?
     - Rationale?
     - What strategies may be useful?
     - Explore alternatives

4. **Assess past strategies**
   - Past success or failure can aid management of new regimen
Implementing the Decision

**Plan for follow-up**

- Let patient know you (or your delegate) will follow up with them
- Give a schedule and strategy for follow-up (ideally you will initiate contact at some particular day and time)

**Inform about problems**

- Let patient know what kinds of things to watch for/tell you about
- Don’t list every possible problem
- List the important ones that the patient should look for/contact you about
- If there are potential non-serious problems (which might be scary), let the patient know (e.g., GI problems)

GI, gastrointestinal
Follow-up Strategies

What NOT to do

- Ask leading questions
- Ask whether patient is following the regimen (they may not want to admit they’re not)
- Ask vague questions

What you CAN do

- Ask what is most difficult about taking medication
  - Easier for patients to provide information without having to admit non-adherence
- Ask whether the patient is having any difficulty getting the prescription filled
- Ask when they last got their prescription filled (addresses both persistence and adherence/consumption)
Conclusions

• Therapy implementation (initiation, persistence, adherence, intensification) is the key to successful treatment outcomes

• Therapy implementation works only if patients are motivated, based on the benefits they think they will achieve relative to the disadvantages

• Therapy regimens should be designed to reduce barriers to implementation
Conclusions

• Self-care is the most important part of diabetes care

• Patients make decisions about what they are willing to do in caring for their diabetes

• Patients may not be able to follow through on their self-care intentions without assistance and support

• HCP can support patient intentions to take better care of themselves and achieve better clinical outcomes

• Ongoing self-care support is one of the most efficient and effective interventions that HCPs can perform
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