Developing a medication decision aid for patients with type 2 diabetes

Giving Voice

Center for Innovation
Research
Current State
Decision Making Model

1. Patient and clinician begin consultation.
2. Patient and clinician discuss medications.
3. Patient leaves with a prescription.
4. Patient makes decision about medication.
Decision Making Model

- Patient and clinician begin consultation
- Patient and clinician discuss medications.
- Patient leaves with a prescription.
- Patient makes decision about medication.
Anatomy of a Decision/MD

- Medical Knowledge
- Practice Experience
- Clinician Preferences
Anatomy of a Decision/PT

- Personal Health View
- Lifestyle Preferences
- Own/Other experiences
Anatomy of a Decision/Environment

- History
- Ritual
- Tools
Decision Aid Criteria

Research Evidence

Decision Aid

Patient Values and Preferences

Within an exam room
Development & Prototypes
Prototyping Resources

Research Evidence & Practice Review

Decision Aid

Diabetes Advisory Group & Clinical Setting
Prototype 1

Baseball Cards
### Metformin
- **Form**: Pill
- **Used With**: Alone or with Sullfonylureas
- **Effectiveness**: Able to lower A1c by 1–2%
- **When Taken**: (once (1) daily)

#### Weight Side Effects
- Minimal to no weight gain
- **Other Side Effects**: Some nausea, diarrhea, and glucose possible in the first 2 to 6 weeks. Then most people can get used to it.

#### Severe Hypoglycemia
- 0 in 100 (within year of use)

#### Monitoring Needs
- None when used alone
- Occasional 2–5 times/week initially

### Exenatide
- **Form**: Injectable medication
- **Used With**: Metformin or Sullfonylureas
- **Effectiveness**: Able to lower A1c by 0.5–1%
- **When Taken**: (once (1) daily, in the 1 hour before breakfast and dinner)

#### Weight Side Effects
- Loss of 1.5–3kg (3–6 lbs) after 6–7 months
- **Other Side Effects**: Vomiting nausea, about 15 in 100 severe nausea 3 in 100 diarrhea 13–16 in 100

#### Severe Hypoglycemia
- None

#### Monitoring Needs
- Initial 2–5 times/week, less frequent after stabilization

### Glitazones
- **Form**: Pill (This can be split or arer for half doses)
- **Used With**: Alone or with Metformin and/or Sulfonylureas
- **Effectiveness**: Able to lower A1c by 1–2%
- **When Taken**: (once (1) daily)

#### Weight Side Effects
- Gain of 1–3kg (2–6 lbs) after 6–7 months

#### Severe Hypoglycemia
- 0 in 100 (within year of use)

#### Monitoring Needs
- Occasional 3–5 times/week or less

### Sullfonylureas
- **Form**: Pill
- **Used With**: Alone or with Metformin
- **Effectiveness**: Able to lower A1c by 1–2%
- **When Taken**: (once (1) daily)

#### Weight Side Effects
- Gain of 2–3kg (4–6 lbs)

#### Severe Hypoglycemia
- 0 in 100 (within year of use)

#### Monitoring Needs
- Daily, once (1) or twice (2) daily

### Insulin
- **Form**: Injectable medication
- **Used With**: Alone or with Metformin and/or Sulfonylureas
- **Effectiveness**: No limit to A1c reduction
- **When Taken**: (once (1) or twice (2) daily)

#### Weight Side Effects
- Gain of about 4kg (8–8.8 lbs)

#### Severe Hypoglycemia
- 1–3 in 100 (within year of use)

#### Monitoring Needs
- Daily, once (1) or twice (2) daily
### Metformin

**FORM**
- Pill

**USED WITH**
- Alone or with Sulfonylureas

**EFFECTIVENESS**
- able to lower A1c by 1–2%

**WHEN TAKEN**
- twice (2) daily
- with meals ideally but not absolutely necessary

**WEIGHT SIDE EFFECTS**
- minimal to no weight gain

**OTHER SIDE EFFECTS**
- some nausea, dyspepsia and diarrhea possible in the first two (2) weeks. Then most people can get used to it.

**SEVERE HYPOGLYCEMIA**
- 0 in 100 (within year of use)

**MINOR HYPOGLYCEMIA**
- 1-2 in 100 (within year of use)

**MONITORING NEEDS**
- none when used alone
- + Sulfonylureas: 2–5 times/week initially
- + insulin: daily

### Sulfonylureas

*glimepiride or Amaryl; glipizide or Glucotrol*

**FORM**
- Pill

**USED WITH**
- Alone or with Metformin

**EFFECTIVENESS**
- able to lower A1c by 1–2%

**WHEN TAKEN**
- once (1) daily
- could be used twice a day
- take 30 minutes before breakfast (meal)

**WEIGHT SIDE EFFECTS**
- gain of 2–3kg (4–6lbs)

**OTHER SIDE EFFECTS**
- nausea: about 1–2 in 100
- diarrhea: about 1–2 in 100
- rash: about 1–2 in 100

**SEVERE HYPOGLYCEMIA**
- 6 in 1000 (within year of use)

**MINOR HYPOGLYCEMIA**
- 21 in 100 (within year of use)

**MONITORING NEEDS**
- initially 2–5 times/week, less when stable
Findings

• Information was interesting and new but not necessarily helpful

• Strong desire to make comparisons between medications

• Unsuccessful in generating conversations
Prototype 2

Narrative Cards
### Exenatide

**FORM**
Injectable medication

**TYPICALLY USED WITH**
Metformin or Sulfonylureas

**WHEN TAKEN**
Twice (2) daily; in the morning and evening before eating

**MONITORING**
If taking Sulfonylureas, monitor daily after meals.

**EFFECTIVENESS**
Exenatide typically lowers A1c by 0.5–1.5%

**WEIGHT EFFECTS**
Exenatide has been shown to promote weight loss, an area of concern among many people with diabetes. If you are currently taking Metformin, you may lose 3 to 6 pounds after 6-12 months of taking Exenatide. If you are taking Metformin and Sulfonylureas, the weight loss will be less because Sulfonylureas have the side effect of weight gain. Still, you may experience a loss of about 3 pounds on Exenatide.

**HYPOLYCEMIA**
When used with Metformin, there is no risk of severe hypoglycemia and the chance of minor hypoglycemia is about 5 in 100. When used with Metformin and Sulfonylureas, the risk of severe hypoglycemia is less than 1 in 100 and for minor hypoglycemia 30–300 (within 30 weeks).

**OTHER SIDE EFFECTS**
Other side effects of Exenatide may include nausea and diarrhea. 100 people like you, 40 will experience initial nausea with 15 of those experiencing persistent nausea and 3 experiencing severe nausea. Between 12–16 of 100 people will have some form of diarrhea.

### Glitazones

**FORM**
Tablet

**TYPICALLY USED WITH**
Metformin and/or Sulfonylureas

**WHEN TAKEN**
Once (1) daily

**MONITORING**
Occasionally with Metformin; 3–5 times per week with Sulfonylureas. Once stable, you can monitor less often.

**EFFECTIVENESS**
With Metformin, Glitazones typically lower A1c by 1%. With Metformin and Sulfonylureas, Glitazones may be able to lower A1c by 1–2%.

**WEIGHT EFFECTS**
A common effect of Glitazones is weight gain. When paired with Metformin, which does not typically have a weight gain effect, the average weight gain is 2–5 pounds. When combined with Sulfonylureas, which do have a weight gain effect, the combined average weight gain can be between 2–13 pounds.

**HYPOLYCEMIA**
Glitazones cause no risk of severe hypoglycemia. The risk of minor hypoglycemia among 2 of 100 people like you may experience some symptoms within one year of use.

**OTHER SIDE EFFECTS**
The primary side effect of Glitazones is edema, fluid retention. Approximately 10 out of every 100 people like you may experience some swelling of the ankles, if you have heart failure, fluid retention may affect your breathing.

### Insulin

**FORM**
Injectable medication

**TYPICALLY USED WITH**
None of the above

**WHEN TAKEN**
Once (1) or twice (2) daily

**MONITORING**
Initially once (1) or twice (2) per day. Once stable, you can monitor less often.

**EFFECTIVENESS**
There is no limit to the amount of A1c reduction you can achieve with Insulin.

**WEIGHT EFFECTS**
Insulin is often associated with weight gain. On average, most people who use Insulin will see a weight gain of around 8–9 pounds.

**HYPOLYCEMIA**
Of 100 people like yourself who use Insulin, between 1 and 3 will experience severe hypoglycemia within a year of use. The risk of minor hypoglycemia is greater with between 30 and 40 people out of every 100 exhibiting some symptoms within a year of use.

**OTHER SIDE EFFECTS**
There are no other significant side effects associated with Insulin.

### Metformin (Glucophage)

**FORM**
Tablet

**TYPICALLY USED WITH**
None of the above

**WHEN TAKEN**
Twice (2) daily, with meals, ideally

**MONITORING**
Initially 3–5 times per week. Once stable, you can monitor less often.

**EFFECTIVENESS**
Metformin has shown an ability to lower your A1c by 1–2%.

**WEIGHT EFFECTS**
Metformin use has not been associated with significant changes in weight so you can expect minimal to no weight gain.

**HYPOLYCEMIA**
Metformin causes no risk of severe hypoglycemia. The risk of minor hypoglycemia among 1–2 people out of 100 like yourself experiencing some symptoms within one year of use.

**OTHER SIDE EFFECTS**
When you first begin taking Metformin, you may experience some nausea, dyspepsia or diarrhea in the first two (2) weeks. After that, most people become accustomed to the drug.

### Sulfonylureas

**FORM**
Tablet

**TYPICALLY USED WITH**
None of the above

**WHEN TAKEN**
Once (1) or twice (2) daily, 30 minutes before a meal

**MONITORING**
Initially 2–5 times per week. Once stable, you can monitor less often.

**EFFECTIVENESS**
Sulfonylureas typically lower A1c by 1–2%.

**WEIGHT EFFECTS**
A common effect of Sulfonylureas is weight gain. The average gain is between 4–6 pounds although it should be noted that some people don’t gain any weight at all and others may gain more than the average.

**HYPOLYCEMIA**
The risk of severe hypoglycemia with Sulfonylureas is less than 1 in 100 within a year of use. Within the same time frame (a year), the likelihood of experiencing minor hypoglycemia is 23% out of 100.

**OTHER SIDE EFFECTS**
Other side effects of Sulfonylureas include nausea, rash and diarrhea. In studies of people like you, the likelihood of experiencing nausea, rash or diarrhea is about 1–2 in 100.
**Metformin** *(Glucophage)*

<table>
<thead>
<tr>
<th><strong>FORM</strong></th>
<th><strong>WHEN TAKEN</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pill</td>
<td>Twice (2) daily; with meals ideally</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>TYPICALLY USED WITH</strong></th>
<th><strong>MONITORING</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Alone or with Sulfonylureas</td>
<td>Initially 2–5 times per week. Once stable, you can monitor less often.</td>
</tr>
</tbody>
</table>

**EFFECTIVENESS**
Metformin has shown an ability to lower your A1c by 1–2%.

**WEIGHT EFFECTS**
Metformin use has not been associated with significant changes in weight so you can expect minimal to no weight gain.

**HYPOGLYCEMIA**
Metformin causes no risk of severe hypoglycemia. The risk of minor hypoglycemia shows 1–2 people out of 100 like yourself experiencing some symptoms within one year of use.

**OTHER SIDE EFFECTS**
When you first begin taking Metformin, you may experience some nausea, dyspepsia or diarrhea in the first two (2) weeks. After that, most people become accustomed to the drug.
Findings

• Understanding of data was more nuanced
• Patients still struggled to act on information
• General sense of too much text
• Continued desire to make comparisons between medications
Prototype 3

Decision Board
Findings

• Prioritizing of issues allows patient an “in” they could relate to
• Saw an increase in questions being asked
• Still a lot of text to read in an encounter
• Form is cumbersome and difficult for physician to assemble dynamically during a conversation
Prototype 4

Issue Cards
**Weight Change**

- Metformin: None
- Insulin: 4 to 6 lb. gain
- Glitazones: More than 2 to 6 lb. gain
- Exenatide: 3 to 6 lb. loss
- Sulfonylureas: 2 to 3 lb. gain

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**Low Blood Sugar (Hypoglycemia)**

- Metformin
- Insulin: Undesire %
- Glitazones: 1%
- Exenatide: 1/2 to 1%
- Sulfonylureas: 1 to 2%

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**Blood Sugar (A1C Reduction)**

- Metformin: 1 - 2%
- Insulin: 5 - 8%
- Glitazones: 20 - 40%
- Exenatide: 1/2 - 1%
- Sulfonylureas: 1 - 2%

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**Daily Routine**

- Metformin
- Insulin
- Glitazones
- Exenatide: Take in the hour before meal.
- Sulfonylureas: Take 30 min. before meal.

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**Daily Sugar Testing (Monitoring)**

- Metformin: Monitor 1 - 2 times weekly, less often once state.
- Insulin: 5 - 8%
- Glitazones: 20 - 40%
- Exenatide: Monitor once or twice daily, less often once state.
- Sulfonylureas: Monitor once daily after meals when used with Sulfonylureas, as needed when used with Sulfonylureas.

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**Side Effects**

- Metformin: In the first few weeks after starting Metformin, patients may have some nausea, indigestion or diarrhea.
- Insulin: There are no other side effects associated with Insulin.
- Glitazones: Over time, 50 to 100 people may have fluid retention (swelling) while taking Glitazones. For some, fluid may build up in the lungs making it difficult to breathe. This may resolve after you stop taking the drug.
- Exenatide: After starting Exenatide, some patients may have nausea or diarrhea. In some cases, the nausea may be severe enough that a patient has to stop taking the drug.
- Sulfonylureas: Some patients get nausea, rash and other reactions when they first start taking Sulfonylureas. This type of reaction may force them to stop taking the drug.
### Weight Change

- **Metformin**
  - None

- **Insulin**
  - 4 to 6 lb. gain

- **Glitazones**
  - More than 2 to 6 lb. gain

- **Exenatide**
  - 3 to 6 lb. loss

- **Sulfonylureas**
  - 2 to 3 lb. gain

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### Daily Routine

- **Metformin**
  - AM

- **Insulin**
  - 24 OR AM PM

- **Glitazones**
  - 24

- **Exenatide (KEEP COLD)**
  - Take in the hour before meals.

- **Sulfonylureas**
  - Take 30 min. before meal.

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### Daily Sugar Testing (Monitoring)

- **Metformin**
  - Monitor 2 - 5 times weekly, less often once stable.

- **Insulin**
  - Monitor once or twice daily, less often once stable.

- **Glitazones**
  - Monitor 3 - 5 times weekly, less often once stable.

- **Exenatide**
  - Monitor twice daily after meals when used with Sulfonylureas, as needed when used with Metformin.

- **Sulfonylureas**
  - Monitor 2 - 5 times weekly, less often once stable.
Findings

• Patients gravitate towards weight change and daily routine cards (burden of care)

• Physical form encourages patients to own their decision

• Noticeable positive change in body language

• Card use prompts questions and encourages discussion but cards alone are not enough to give patients confidence
<table>
<thead>
<tr>
<th>Class</th>
<th>Notes</th>
<th>Cost per Day</th>
<th>Cost per 3 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Metformin</strong></td>
<td>(Generic available)</td>
<td>$0.10</td>
<td>$10 / 3 months</td>
</tr>
<tr>
<td><strong>Insulin</strong></td>
<td>(No generic available - price varies by dose)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lantus</td>
<td>Vial, per 100 units: $10</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pen, per 100 units: $43</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NPH</td>
<td>Vial, per 100 units: $6</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pen, per 100 units: $30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short acting analog insulin</td>
<td>Vial, per 100 units: $10</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pen, per 100 units: $43</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Glitazones</strong></td>
<td>(No generic available)</td>
<td>$7.20</td>
<td>$650 / 3 months</td>
</tr>
<tr>
<td><strong>Exenatide</strong></td>
<td>(No generic available)</td>
<td>$9.00</td>
<td>$800 / 3 months</td>
</tr>
<tr>
<td><strong>Sulfonylureas</strong></td>
<td>(Generic available)</td>
<td>$0.10</td>
<td>$10 / 3 months</td>
</tr>
<tr>
<td><strong>Gliptins</strong></td>
<td>(No generic available)</td>
<td>$6.20</td>
<td>$560 / 3 months</td>
</tr>
</tbody>
</table>

These figures are estimates and are for comparative reference only. Actual out-of-pocket costs vary over time, by pharmacy, insurance plan coverage, preparation and dosage. Under some plans name brands may be comparable in cost to generics.
Findings

• Gives permission to patients and clinicians to acknowledge cost as a factor in decision making

• Lack of ability to provide a specific answer isn’t viewed negatively
Conclusion
Findings

- Focusing on creating a conversation between patients and clinicians provides a way to deal with conflict which is an inevitable part of the healthcare delivery system.

- Tools structure the conversation and skill both the patient and the clinician.