Barriers to insulin initiation: The Translating Research Into Action for Diabetes (TRIAD) Insulin Starts Project

Andrew J. Karter PhD¹, Usha Subramanian MD, MS², Chandan Saha PhD³, Jesse C Crosson PhD⁴, Melissa M Parker MS¹, Bix E. Swain MS¹, Howard H. Moffet MPH¹, David G. Marrero PhD²

1. Kaiser Permanente - Division of Research, Oakland, CA 94612
2. National Institute for Fitness and Sport, Indiana University, Indianapolis 46202
3. Indiana University, Indianapolis, Indiana 46202
4. UMDNJ-Robert Wood Johnson Medical School - Department of Family Medicine, Somerset, New Jersey 08873

Running Title: Barriers to insulin initiation

Corresponding author:
Andrew J. Karter, Ph.D.,
Email: andy.j.karter@kp.org

Submitted 20 June 2009 and accepted 6 January 2009.

This is an uncopiedited electronic version of an article accepted for publication in Diabetes Care. The American Diabetes Association, publisher of Diabetes Care, is not responsible for any errors or omissions in this version of the manuscript or any version derived from it by third parties. The definitive publisher-authenticated version will be available in a future issue of Diabetes Care in print and online at http://care.diabetesjournals.org.
Objective- Reasons for failing to initiate prescribed insulin (primary non-adherence) are poorly understood. We investigated barriers to insulin initiation following a new prescription.

Research design and methods - We surveyed insulin-naïve patients with poorly controlled type 2 diabetes, already treated with ≥2 oral agents who were recently prescribed insulin. We compared responses for respondents prescribed, but never initiating, insulin (n=69) to those dispensed insulin (n=100).

Results - Subjects failing to initiate prescribed insulin commonly reported misconceptions regarding insulin risk (35% believed that insulin causes blindness, renal failure, amputations, heart attacks, strokes or early death); plans to instead work harder on behavioral goals; sense of personal failure; low self-efficacy, injection phobia; hypoglycemia concerns; negative impact on social life and job; inadequate health literacy; healthcare provider inadequately explaining risks/benefits; and limited insulin self-management training.

Conclusions - Primary adherence for insulin may be improved through better provider communication regarding risks, shared decision making, and insulin self-management training.
Insulin is typically recommended for patients with type 2 diabetes if they have failed to achieve adequate glycemic control despite treatment with multiple oral agents at maximal dose, especially when beta-cell function declines. Despite the known benefits of insulin, many patients fail to begin insulin treatment. In a previous study, we followed a cohort of patients with diabetes prescribed new glucose-lowering medications. We observed that 4.5% of insulin-naïve patients who were prescribed insulin never filled that prescription (were primary non-adherent) and an additional 25.5% had zero refills (early-stage non-persistence). Thus, one in three insulin-naïve patients who were prescribed insulin never became ongoing users.

A patient’s reluctance to initiate insulin has been dubbed “psychological insulin resistance” (PIR). Current understanding of PIR is based largely on surveys of insulin-naïve patients queried about their hypothetical willingness to initiate insulin. However, the reasons why patients fail to initiate therapy after actually agreeing to and receiving a first prescription for insulin have not been explored. In this study, we evaluate barriers and attitudes among insulin-naïve patients who had failed to initiate newly prescribed insulin therapy (i.e., primary non-adherent) versus those who did initiate insulin therapy (i.e., primary adherent).

**RESEARCH DESIGN AND METHODS**

Subjects for this study of insulin adherence came from Kaiser Permanente Northern California (Kaiser) and the University of Medicine and Dentistry of New Jersey (UMDNJ) and were participants in the Translating Research Into Action for Diabetes (TRIAD) Study, an ongoing study of quality of care and self-care for people with diabetes in managed care settings across the U.S.

We identified poorly-controlled, insulin-naïve and insulin-eligible type 2 diabetes patients receiving a new electronic prescription for insulin. Eligibility criteria included: i) newly prescribed insulin during 8/2007-2/2008; ii) ≥2 diagnoses for type 2 diabetes 18 months prior to the new insulin prescription; iii) no insulin use in prior 2 years; iv) already taking one oral agent at maximum and a second oral agent at maximal/sub-maximal dose; v) 2 consecutive A1c’s ≥8% 2.5-12 months apart or last A1c ≥ 9%; vi) ≥2 clinic visits in previous 12 months. Patients > 85 years, with limited English proficiency, life-limiting malignancy, hospice care enrollment, significant cognitive deficits, psychiatric illness (excluding major depression), or visual impairment limiting insulin self-administration were excluded.

We identified a random sample of eligible subjects who were primary adherent (at least one dispensing of insulin) and primary non-adherent (not dispensed the newly prescribed insulin within 60 days of the prescribing date) from pharmacy records. Computer-assisted telephone interviews and self-administered mailed surveys were used to collect insulin treatment, provider communication, self-management training, health literacy, depressive symptoms. We used standard Council of American Research Organization algorithms for calculating response rates. The human subjects review boards in the TRIAD translational research centers involved with this study (Kaiser Permanente, UMDNJ and Indiana University) approved this study.

**RESULTS**

We mailed an invitation letter to 195 and 186 primary non-adherent and adherent subjects, respectively, following approval of their providers. Responses included 69 non-adherent and 100 adherent patient responses to the survey and are the basis for this study. The CASRO response rate, which assumes
those whom could not be contacted or eligibility confirm had the same proportion of eligibility as those contacted, was 60% overall (50% in the non-adherent, 68% in adherent group). The cooperation rate (% survey completion among eligible subjects we were able to reach) was 98% (100% in the non-adherent, 92% in adherent group). None of the patient characteristics differed significantly between adherent and non-adherent subjects. Non-adherent subjects had a mean age of 61 and included 35% women, 49% minority ethnic heritage, 37% with income <$40,000, 33% with no college education and 48% were retired or unemployed. Adherent subjects had a mean age of 58 and included 47% women, 54% minority ethnic heritage, 22% with income <$40,000, 31% with no college education and 33% were retired or unemployed.

Among non-adherent patients, the most commonly cited reasons for failing to initiate insulin included: patient planned to change health behaviors instead of starting insulin (25%), injection phobia (13%), negative impact on work (9%), concerns about long-term medication use (9%), inconvenience (6%), and not believing insulin was needed (6%). Non-adherent patients believed that people who require insulin “have not taken care of themselves in the past” (47%), that “taking insulin can cause...” blindness (20%), renal failure (32%), amputations (15%), heart attacks or strokes (19%) and early death (19%). In all, 35% of the insulin non-adherent group reported that they believed insulin causes harm (at least one of the possible complications listed above). Compared to adherent patients, non-adherent patients expressed significantly more concern about their inability to adjust insulin dosage, impact on social life and work, injection pain, and side effects, particularly hypoglycemia (Table 1). Significantly more non-adherent patients reported problems learning about their medical condition because of difficulty understanding written information (inadequate health literacy) and claimed providers failed to adequately explain insulin’s risk and benefits. Substantially fewer non-adherent patients reported receiving insulin self-management training from their doctor, nurse, health educator or a class.

CONCLUSIONS
Among poorly controlled patients with type 2 diabetes newly prescribed insulin, the major predictors of insulin non-adherence included plans to improve health behaviors in lieu of starting insulin, negative impact on social and work life, injection phobia, concerns about side effects or hypoglycemia. Non-adherent patients often blamed themselves, believing prior poor self-management caused the current need for insulin, and erroneously conceptualized insulin as itself the cause of future complications. These patient-level findings are consistent with previous studies of attitudes about insulin.10,11 Not previously reported is our finding that non-adherent patients frequently felt their provider had not adequately explained risks and benefits of insulin. The importance of provider communication is underscored by the association between insulin initiation and health literacy.12 Primary non-adherence likely also reflects inadequate shared decision-making or lacking self-management training. Interventions for PIR need to address both provider and system level factors.13-15

ACKNOWLEDGEMENTS
This research was funded jointly through TRIAD (Program Announcement number 04005 from the Centers for Disease Control and Prevention (Division of Diabetes Translation) and the National Institutes of Health (National Institute of Diabetes and Digestive and Kidney Diseases (R01 DK065664 and R01DK080726, RC1 DK086178). It's contents are solely the
responsibility of the authors and do not necessarily represent the official views of The Centers for Disease Control and Prevention, the National Institute of Diabetes and Digestive and Kidney Diseases. The authors acknowledge the participation of the two health plan partners (Kaiser Permanente Northern California and Horizon Blue Cross Blue Shield of New Jersey), TRIAD staff and participants that made this study possible. The authors acknowledge the participation of our health plan partners.

**Disclosure:** Authors have no relevant conflict of interest to disclose.
REFERENCES


(15) Polonsky W. Psychological insulin resistance: the patient perspective. Diabetes Educ. 2007;33 Suppl 7:241S-244S.
Table 1. Comparisons of survey responses for primary non-adherent and adherent patients newly prescribed insulin*

<table>
<thead>
<tr>
<th>Stated moderate/extreme concerns (versus not at all or a little concerned) regarding:</th>
<th>Non-adherent (n/N)</th>
<th>Adherent (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The cost of insulin shots</td>
<td>12/51 24%</td>
<td>22/82 27%</td>
</tr>
<tr>
<td>How insulin shots might restrict your activities or “hold back” your lifestyle</td>
<td>20/54 37%</td>
<td>20/82 24%</td>
</tr>
<tr>
<td>The additional burden associated with home monitoring of blood sugar</td>
<td>15/59 25%</td>
<td>19/82 23%</td>
</tr>
<tr>
<td>Difficulty giving insulin due to things like poor eyesight, shakiness or arthritis</td>
<td>23/55 42%</td>
<td>24/81 30%</td>
</tr>
<tr>
<td>Your ability to make dose adjustments †</td>
<td>22/54 41%</td>
<td>10/82 12%</td>
</tr>
<tr>
<td>How insulin shots may negatively impact your social life †</td>
<td>21/56 38%</td>
<td>15/82 18%</td>
</tr>
<tr>
<td>A negative impact on your job (if you work outside the home) †</td>
<td>15/45 33%</td>
<td>6/72 8%</td>
</tr>
<tr>
<td>The insulin shots being painful †</td>
<td>17/56 30%</td>
<td>12/82 15%</td>
</tr>
<tr>
<td>Possible side effects of giving yourself shots †</td>
<td>24/55 44%</td>
<td>10/81 12%</td>
</tr>
<tr>
<td>Insulin shots causing you to have low blood sugar †</td>
<td>22/51 43%</td>
<td>13/81 16%</td>
</tr>
</tbody>
</table>

**Patient-provider interactions and communication**

| Never or only sometimes (versus usually or always) felt confidence or trust in personal physician that manages diabetes | 11/68 16% | 11/97 11% |
| Moderately or extremely difficult (versus not at all difficult or a little difficult) to talk with doctor about concerns about diabetes medication or insulin | 9/66 14% | 10/100 10% |
| Risks and benefits were not very well or not well at all (versus somewhat well or very well) explained † | 37/67 55% | 37/96 39% |
| Inadequate health literacy: Sometimes, often or always (versus never or rarely) have problems learning about medical condition because of difficulty understanding written information (not including problems due to poor vision) † | 35/69 51% | 30/99 30% |

**How was the insulin self-management training provided**

| Doctor trained † | 1/66 2% | 13/77 17% |
| Insulin self-management class † | 5/66 8% | 31/77 40% |
| Nurse trained † | 4/66 6% | 33/77 43% |

*N takes into account missing responses; †significant contrasts (p<0.05)