

## Assessment by Patients with Diabetes Mellitus of Two Insulin Pen Delivery Systems Versus a Vial and Syringe

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### ABSTRACT

Two multicenter surveys were conducted in a total of 1310 insulin users over a 3-week period. The first survey, in which 803 patients participated, assessed the effects of using the Novolin Prefilled insulin delivery system on lifestyle; compliance with insulin, diet, and exercise regimens; and feelings of well-being compared with the traditional insulin vial and syringe. The second survey, in which 507 patients participated, assessed attitudes and perceptions of the NovoPen 1.5 insulin delivery system compared with the traditional insulin vial and syringe. Both delivery systems are dial-a-dose insulin pens containing a single-use NovoFine 30 insulin needle and are designed to be portable and discreet. Patients using the Novolin Prefilled delivery system completed a three-part questionnaire (two parts at the initial survey visit and the third at the end of 3 weeks); those using the NovoPen 1.5 completed a questionnaire at the end of 3 weeks. Seven hundred twenty-nine (92%) of 793 patients in the Novolin Prefilled group and 482

(98%) of 492 patients in the NovoPen 1.5 group reported that it was easy to use these delivery systems; 672 (85%) of 791 patients reported that they missed no injections while using the Novolin Prefilled system, compared with 566 (72%) of 789 patients using the vial and syringe. With the NovoPen 1.5, 333 (73%) of 456 patients said that the dosing mechanism was more accurate, and 351 (77%) of 456 patients found it easier to comply with their insulin regimen. In both groups, patients reported a strong desire to continue using the insulin pens and a willingness to recommend their use to someone else. Because patients were more physically and psychologically comfortable injecting insulin with the Novolin Prefilled or NovoPen 1.5 system than with an insulin syringe, their overall attitude toward insulin therapy improved, as did their confidence about managing their disease. An improved attitude toward insulin therapy might be expected to lead to better acceptance of and compliance with an insulin regimen. **Key words:** diabetes, insulin, quality of life, compliance, insulin delivery systems, insulin pens.

## INTRODUCTION

Diabetes has an enormous impact on patients' lives, requiring regular glucose monitoring, modifications in diet and lifestyle, frequent visits to physicians and diabetes educators, daily administration of medication, and, for many, self-injecting with insulin. The health-care professional plays an important role in helping patients achieve the best quality of life possible, which means that professionals and patients both must do more than focus on stabilizing blood glucose levels. Equally important are education about diabetes and its treatment, active participation in instituting diet and lifestyle changes, and fostering a positive attitude about patients' ability to comply with medication regimens.<sup>1</sup>

A significant number of patients resist taking insulin because of its inconvenience or imagined pain, the stigma of using a vial and syringe, or fear of self-injection.<sup>1-3</sup> This may be especially true for patients with type 2 diabetes, many of whom had at one time been able to control their diabetes with diet and exercise, oral medication, or both. These patients may view the need for insulin as a sign that their disease is worsening or that they have failed to take care of themselves properly.<sup>2</sup> Health professionals should be aware of these feelings and be able to recommend appropriate self-care options for the patient's consideration.

The Novolin Prefilled<sup>®</sup> system (a disposable pen) and NovoPen<sup>®</sup> 1.5 (a durable pen with a replaceable cartridge)

are alternative insulin delivery systems that allow patients to take insulin without having to use a traditional insulin vial and syringe. Each pen uses the NovoFine<sup>®</sup> 30 insulin needle, which is disposed of after one injection. The NovoPen 1.5 uses Novolin PenFill<sup>®</sup>, a 1.5-mL cartridge (150 U) of human insulin (recombinant DNA origin) in an NPH, regular, or 70/30 formulation. By dialing a dose, patients can select delivery of up to 40 U per dose in 1-U increments. The Novolin Prefilled disposable insulin pen contains 150 U of human insulin and allows delivery of up to 58 U per dose in 2-U increments. A 4-week clinical study<sup>4</sup> with the Novolin Prefilled system showed significant patient acceptance among 64 insulin users, 98% of whom found the pen convenient and easy to use. The present study employed two large, multicenter surveys to assess users' acceptance of the Novolin Prefilled and NovoPen 1.5 insulin delivery systems.

## PATIENTS AND METHODS

### *Patients*

Centers for the two study surveys were selected on the basis of geographic considerations and willingness and ability to carry out the survey. The first survey, which included 803 insulin users in 24 centers across the United States, evaluated the Novolin Prefilled pen using the following variables: (1) patients' participation in normal daily activities and social activities compared with their participation while using a traditional vial and syringe; (2) patients' compliance with insulin, diet, and exercise regimens; and (3) patients' overall sense of well-being. The second survey, which included 507 insulin users in 64 centers, assessed the

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\*NovoPen<sup>®</sup>, Novolin R Prefilled<sup>™</sup>, Novolin N Prefilled<sup>™</sup>, Novolin 70/30 Prefilled<sup>™</sup>, NovoFine<sup>®</sup>, Novolin<sup>®</sup>, and PenFill<sup>®</sup> are trademarks of Novo Nordisk A/S, Copenhagen, Denmark.

## CLINICAL THERAPEUTICS\*

effect of the NovoPen 1.5 on patients' attitudes about taking insulin, improving compliance, and perceiving their comfort.

Patients were eligible to participate in either survey if they had type 1 or type 2 diabetes; could administer insulin, as assessed by a health-care professional; could read and understand English; and could follow printed instructions. On consideration by the relevant institutional review boards, it was determined that approval was not required because participation in these surveys involved no risk to the subjects. A health-care professional asked the patient if he or she wanted to participate, and the patient agreed or refused. Patients who chose to participate did not have to pay for the insulin delivery system.

Patients in both groups were given the insulin pen delivery system by a research coordinator (a physician, nurse, or other diabetes educator), who recorded the patient's name and assigned the patient an identification number. During the initial site visit, which was a routine medical visit at a physician's office, patients were instructed in the proper use of the insulin pen, according to the approved product labeling. Each patient was given sufficient supplies to last 3 weeks, and arrangements were made for their completion of the survey. All patients were informed that the surveys were supported by Novo Nordisk Pharmaceuticals Inc. (Princeton, New Jersey) and that the research sites would receive an honorarium for participating. Investigators received an honorarium but were not paid for enrolling patients or prescribing the delivery systems.

Patients in the first survey (Novolin Prefilled insulin pen vs traditional vial and syringe) completed the first two parts of a three-part questionnaire during the initial site visit. The first part contained 7 general questions about demographics and diabetes

history; the second part contained 18 questions about patients' current treatment regimen with insulin vial and syringe. The latter part included questions on the effects on patients' lifestyle of using the traditional vial and syringe and on their feelings about using this delivery system.

Patients completed the third part of the questionnaire at the physician's office after they had used the disposable insulin pen for 3 weeks. This contained 26 questions comparing compliance and control, effects on lifestyle, and opinions and perceptions while using the new delivery system with experiences while using the vial and syringe. Each question in the second part of the questionnaire was repeated in the third part to allow comparison of patients' experiences with the insulin vial and syringe and the Novolin Prefilled insulin pen.

Patients in the second survey (NovoPen 1.5 vs traditional vial and syringe) completed a questionnaire containing 25 questions about their history and experience with insulin and their attitudes and opinions about the NovoPen 1.5 compared with the vial and syringe after using the insulin pen for 3 weeks.

The two surveys contained questions that had been used in a previous study<sup>4</sup> as well as questions based on the input of diabetes professionals practicing in a variety of settings throughout the United States. The data were tabulated by Distinctive Marketing, Inc. (Montclair, New Jersey). No data were collected retrospectively. Not all patients answered all questions.

## RESULTS

### *Demographic Characteristics*

More extensive information was obtained on the group using the Novolin Pre-

filled delivery system (Table I) than on the group using the NovoPen 1.5 (Table II). Adverse event data were not collected.

A wide range of insulin-using patients participated in the Novolin Prefilled survey. Four hundred sixty-four (58%) of the

803 patients were 36 to 65 years of age, 190 (24%) were ≥66 years of age, and 149 (19%) were ≤35 years of age. Two hundred sixty (32%) of 801 participants had been taking insulin for 1 to 5 years; 355 (44%) of 801 had been taking insulin for >5 years.

Table I. Demographic characteristics of participants in the Novolin Prefilled<sup>®\*</sup> insulin delivery system survey (N = 803, but not all patients answered all questions).

| Variable                             | No. (%) of Patients |
|--------------------------------------|---------------------|
| Age (y)                              |                     |
| ≤35                                  | 149/803 (19)        |
| 36–55                                | 299/803 (37)        |
| 56–65                                | 165/803 (21)        |
| ≥66                                  | 190/803 (24)        |
| Type of diabetes                     |                     |
| Type 1                               | 252/786 (32)        |
| Type 2                               | 453/786 (58)        |
| Not certain                          | 81/786 (10)         |
| Length of time receiving insulin (y) |                     |
| <1                                   | 186/801 (23)        |
| 1–5                                  | 260/801 (32)        |
| >5                                   | 355/801 (44)        |
| Type of human insulin used           |                     |
| 70/30                                | 295/779 (38)        |
| NPH                                  | 141/779 (18)        |
| NPH + regular                        | 227/779 (29)        |
| NPH + regular + 70/30                | 26/779 (3)          |
| NPH + 70/30                          | 8/779 (1)           |
| Regular                              | 19/779 (2)          |
| Regular + 70/30                      | 12/779 (2)          |
| Other                                | 51/779 (7)          |
| Brand of insulin used                |                     |
| Humulin <sup>®†</sup>                | 413/763 (54)        |
| Novolin                              | 298/763 (39)        |
| Novolin + Humulin                    | 26/763 (3)          |
| Not certain                          | 26/763 (3)          |
| Current insulin regimen              |                     |
| QD                                   | 105/745 (14)        |
| BID                                  | 431/745 (58)        |
| ≥TID                                 | 209/745 (28)        |

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†Trademark of Eli Lilly and Company, Indianapolis, Indiana.

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Table II. Demographic characteristics of participants in the NovoPen® 1.5\* insulin delivery system survey (N = 507, but not all patients answered all questions).

| Variable                                          | No. (%) of Patients |
|---------------------------------------------------|---------------------|
| Length of time receiving insulin (y) <sup>†</sup> |                     |
| <1                                                | 96/507 (19)         |
| 1–3                                               | 86/507 (17)         |
| 4–9                                               | 106/507 (21)        |
| ≥10                                               | 219/507 (43)        |
| Type of human insulin used                        |                     |
| 70/30                                             | 46/507 (9)          |
| NPH                                               | 76/507 (15)         |
| NPH + regular                                     | 229/507 (45)        |
| Regular                                           | 30/507 (6)          |
| Regular + other                                   | 96/507 (19)         |
| Other                                             | 30/507 (6)          |
| Brand of insulin used                             |                     |
| Humulin®‡                                         | 304/507 (60)        |
| Novolin                                           | 143/507 (28)        |
| New to insulin                                    | 50/507 (9)          |
| Other                                             | 10/507 (2)          |
| Current insulin regimen                           |                     |
| QD                                                | 40/504 (8)          |
| BID                                               | 126/504 (25)        |
| TID                                               | 338/504 (67)        |

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<sup>†</sup>Mean = 8.51 y.

<sup>‡</sup>Trademark of Eli Lilly and Company, Indianapolis, Indiana.

Approximately one third of the patients had type 1 diabetes, and 72% (536/745 patients) took insulin injections once or twice daily.

Table II presents demographic data for the 507 patients who used the NovoPen 1.5. Age and sex data were not collected in this group. Almost two thirds (64%) of the patients had been taking insulin for ≥4 years, with 219 patients (43%) taking insulin for ≥10 years. Fifty (10%) of the 507 patients had never taken insulin before participating in this survey and thus were not asked to answer questions comparing the syringe and pen.

**Responses to the Novolin Prefilled Delivery System Survey**

When patients' attitudes and perceptions about taking insulin before and after using the Novolin Prefilled disposable insulin pen were compared, substantial changes in outlook were noted. Table III presents patients' responses to the Novolin Prefilled delivery system survey. The responses are grouped by category (medical, social/lifestyle, convenience, and overall evaluation) and include attitudes toward both the Novolin Prefilled delivery system and the insulin

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