

Risk of Needlestick Injuries Among Nurses Using NovoFine® Autocover® Safety Needles and Nurses' Satisfaction with the Needles: The NOVAC Study

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ABSTRACT

Background: Needlestick injuries among health care professionals are a costly problem, both economically and in terms of anxiety and stress. NovoFine® Autocover® (NFA) 30G safety needles (Novo Nordisk A/S, Bagsvaerd, Denmark) were designed to minimize the risk of such injuries when used with insulin pens, which are increasingly preferred over syringes for injecting insulin.

Objective: This prospective study compared the risk of needlestick injury with NFA needles and regular needles on insulin pens among nurses who administered insulin to patients.

Methods: Nurses with ≥ 3 months' experience in diabetes care were eligible for participation. Nurses were trained in the use of NFA needles and then instructed to use them in their daily practice for 4 weeks, recording details of the injections administered and any injuries that occurred in a logbook.

Results: A total of 143 nurses at 52 hospitals located throughout France received training. Demographic data were available for 139 nurses (mean age 38.4 years, 96.4% female, with a mean of 8 years' diabetes experience): 123 of the nurses used NFA needles (7854 injections administered), 122 of whom also used regular needles (4491 injections). No needlestick injuries occurred with NFA needles, whereas 1 needlestick injury occurred with a regular needle. Nurses were very satisfied with the NFA needles, giving them a score of 8.1 on a scale of 0 to 10, rating personal safety as a particularly important benefit (score 9.5). Nurses preferred NFA needles to both regular needles on insulin pens and needles on syringes, citing personal safety and the saving of time as the main reasons.

Conclusions: These results suggest that NFA needles could reduce the risk of needlestick injuries and that nurses would welcome their other advantages, such as ease of use and saving of time. (*Insulin*. 2008;3:232–237) © 2008 Excerpta Medica Inc.

Key words: needlestick injuries, safety needles, insulin, insulin pens.

INTRODUCTION

Needlestick injuries are an occupational hazard for health care professionals, particularly nurses. The Centers for Dis-

ease Control and Prevention has estimated that health care professionals suffer between 600,000 and 1 million injuries from conventional needles and sharps annually in the

United States, and that ≥ 1000 health care professionals contract serious infections annually from needlestick and sharps injuries.¹ The economic costs of follow-up for high-risk accidental exposures and the human costs in terms of anxiety and stress are considerable.

For injecting insulin, insulin pens offer advantages over syringes. In France, pens are used much more frequently than syringes, accounting for ~80% of the market for insulin-injecting devices, and in the United States, the use of pens is increasing. The pens may be used by patients or by nurses who need to administer subcutaneous insulin to diabetic patients in hospitals or outpatient clinics. However, needlestick injuries may occur with handling. A recent study in France found rates of 23.5 and 3.9 needlestick injuries per 100,000 injections given by health care workers for insulin pens and syringes, respectively.²

To reduce the risk of accidental needlestick injuries, Novo Nordisk A/S (Bagsvaerd, Denmark) developed the NovoFine® Autocover® (NFA) 30G safety needle. The NFA needle is designed to fit Novo Nordisk insulin pens and insulin pens with a type A interface (ISO11608-2). The NFA needle incorporates a plastic shield that covers the needle before injection, retracts during injection, and then slides back into place to cover the needle again, locking permanently in a shielding position after insulin delivery and thus preventing reuse of the needle (**Figure 1**). These single-use devices may be helpful to nurses who administer insulin to certain classes of patients (eg, pediatric patients and those with needle anxiety).

The primary objective of this study (the NOVofine AutoCover [NOVAC] study) was to compare the risk of

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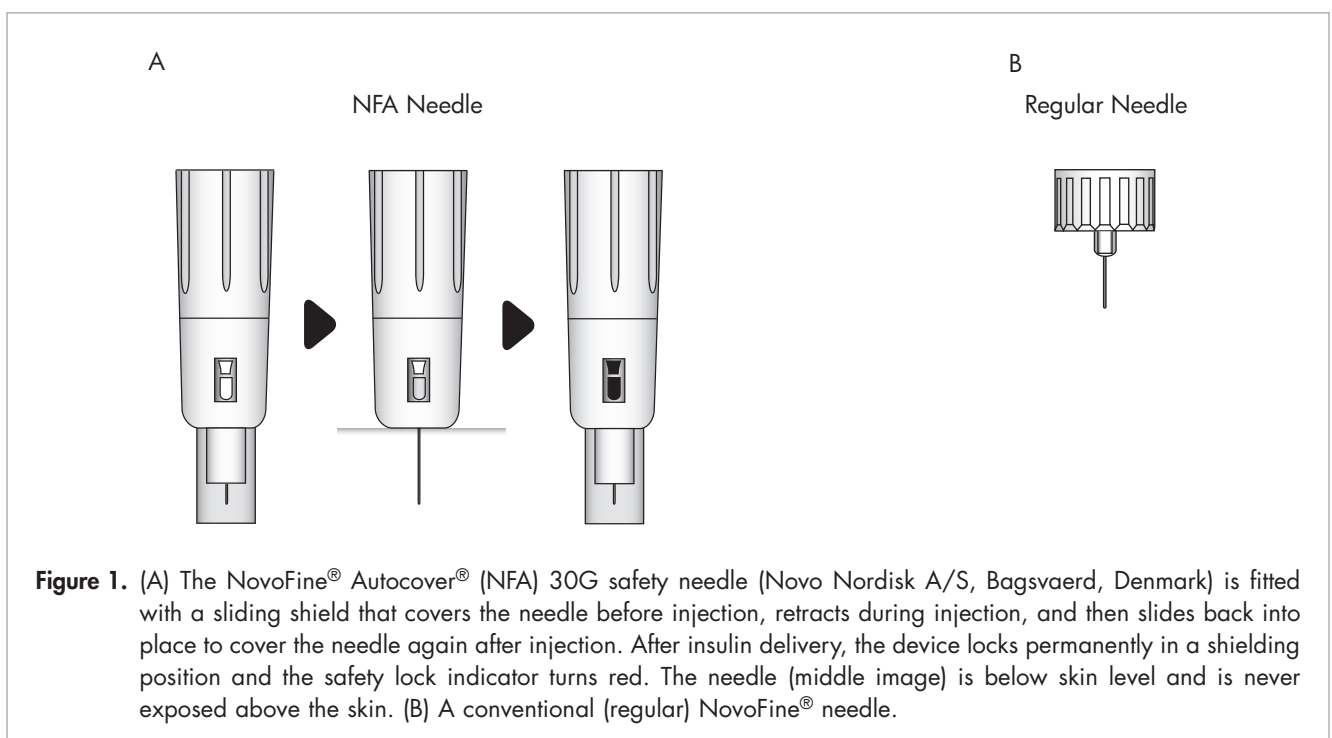
needlestick injury with NFA needles and regular needles on insulin pens among nurses in French diabetes departments who, after training in the use of NFA needles, used them in their daily practice over a 4-week period. Secondary objectives were to examine nurses' satisfaction with NFA needles and determine their preference for NFA needles versus regular needles on insulin pens or needles on syringes.

METHODS

Study Design and Population

This was a 4-week, prospective, multicenter, observational study conducted at 52 hospitals in France in accordance with Good Clinical Practice. Because no patient data were collected and no interventions that might alter the patient–nurse relationship were performed, patient consent and submission of the study to an ethics committee were not required. All participating nurses were required to sign consent forms.

The study population consisted of nurses working in diabetes departments at hospitals in France. The department heads approved the study, and each diabetes department had to use insulin-injecting pens during the study;



52 departments were recruited to provide good geographic coverage throughout the country.

Each department head nominated a physician or senior nurse to be in charge of the study; this person in turn nominated 3 nurses who were invited to participate. Nurses had to have been working in the hospital (any department) for ≥ 1 year, to have ≥ 3 months of experience in diabetes care, and to continue working in the same department throughout the study. Novo Nordisk specialist hospital representatives (SHRs) invited nominated nurses to participate until 160 nurses accepted. The SHRs also arranged for all the necessary study materials to be supplied to the hospital pharmacists.

Study Procedures

Nurses were trained in the use of NFA needles by an SHR. The theoretical training was followed by a practical training period, during which the nurses performed injections using NFA needles (target, 30 injections). Details of the number of injections administered and any needlestick injuries that occurred during the training period were to be recorded in a special logbook. These data were not included in the analysis of the study results, which covered only the 4-week study period. The logbook also included questions about the quality of the training.

Each nurse was given 100 NFA needles and instructed to use them with an insulin pen for consecutive injections over a 4-week period. During this time, nurses again recorded in a logbook the number of injections given and any needlestick injuries that occurred with either NFA needles or regular needles. In addition, all needlestick injuries were reported in accordance with the usual procedure of the hospital concerned, as well as on a form that was faxed to Novo Nordisk.

At the end of the 4-week study period, the nurses responded to questions in the logbooks, including the merits of various features of the NFA needles (eg, ease of use, personal and patient security). Responses were recorded on visual analogue scales of 0 to 10 (0 = dissatisfaction, or a low rating; 10 = satisfaction, or a high rating).

Statistical Analysis

The primary end point was the number of accidental needlestick injuries that occurred with NFA needles, expressed as a percentage of the injections given using these needles. For comparison, the percentage of accidental needlestick injuries that occurred with regular needles on insulin pens was also calculated.

Analysis of the posttraining results was performed on the posttraining population (ie, all nurses who returned their logbooks after training). Analysis of the results of the 4-week study period was performed on the end-of-study population (ie, all nurses who gave ≥ 20 injections using NFA needles during the entire study [training period plus 4-week study period] and who returned their logbooks after completion of the study).

Because data on the incidence of needlestick injuries using NFA needles in clinical practice were not available, a worst-

case scenario of injuries—50% of all injections—was assumed. To obtain a significant result with $\alpha = 5\%$, it was calculated that 15,000 injections should be administered. It was decided to recruit 160 nurses, based on 100 injections per nurse and a 5% to 10% nonreturn rate for logbooks.

Statistical analysis was performed using SAS 8.02 PC, Ad Clin 3.0 software (SAS Inc., Cary, North Carolina).

RESULTS

This study was conducted between January and March 2006. In all, 143 nurses from diabetes departments at 52 hospitals located throughout France were recruited and trained. The posttraining population consisted of 140 nurses (3 nurses were excluded because of lack of information in their logbooks); demographic data were available for 139 nurses (Table I). Completed logbooks were received from 138 nurses. However, 15 nurses were excluded from the end-of-study population because they did not administer ≥ 20 injections using NFA needles during the entire study (training period plus 4-week study period); none of the 15 nurses experienced any needlestick injuries. Thus, the end-of-study population consisted of 123 nurses who returned their logbooks and used NFA needles (total, 7854 injections), 122 of whom also used regular needles (total, 4491 injections).

Results From the Training Period

During the training period, no needlestick injuries occurred among nurses using NFA needles, whereas 1 needlestick injury occurred among nurses using regular

Table I. Characteristics of the nurses in the study (N = 139).

Sex, no. (%)	
Female	134 (96.4)
Male	5 (3.6)
Age, y	
Mean (SD)	38.4 (9.5)
Range	22–59
Length of service as a nurse, y*	
Mean (SD)	14.8 (9.8)
Range	1–35
Experience in diabetes care, y	
Mean (SD)	8.0 (6.8)
Range	1–33
Type of practice, no. (%)	
Hospital only	138 (99.3)
Hospital plus private practice	1 (0.7)
Employment in diabetes department, no. (%)	
Full time	120 (86.3)
Part time	19 (13.7)

*Demographic data were missing for 1 nurse (n = 138).

needles. However, as stated in the protocol, this injury was not included in the study results. At the end of the training period (on a scale of 0–10), nurses gave a mean satisfaction score of 8.7 for the training they received in the use of NFA needles.

Results From the 4-Week Study Period
Number of Needlestick Injuries

No needlestick injuries occurred among nurses using NFA needles, whereas 1 needlestick injury occurred among nurses using regular needles. Records for needlestick injuries were kept for all nurses, but details on the number of injections given per nurse were available for 117 nurses using NFA needles and 89 nurses using regular needles (Table II).

Nurses' Satisfaction with NFA Needles

At the end of the 4-week study period (on a scale of 0–10), nurses gave NFA needles a mean satisfaction score of 8.1. When asked to rate their satisfaction with the various features of the NFA needle, nurses responded with values of 7.7 or higher. Personal safety received the highest score (9.5).

Among the 121 nurses who responded to these questions, 98 nurses (81.0%) stated that NFA needles made their daily work easier. The reason cited most often was the increase in safety (44.5% of comments). Other greatly appreciated aspects of NFA needles were that they saved time (26.8% of comments) and they were easy to use (8.5%).

Nurses preferred NFA needles over both regular needles on insulin pens (80.0% vs 13.3%; $P < 0.0001$) and needles on syringes (Figure 2). The main reason for preferring NFA needles was personal safety (95.8% with NFA needles vs

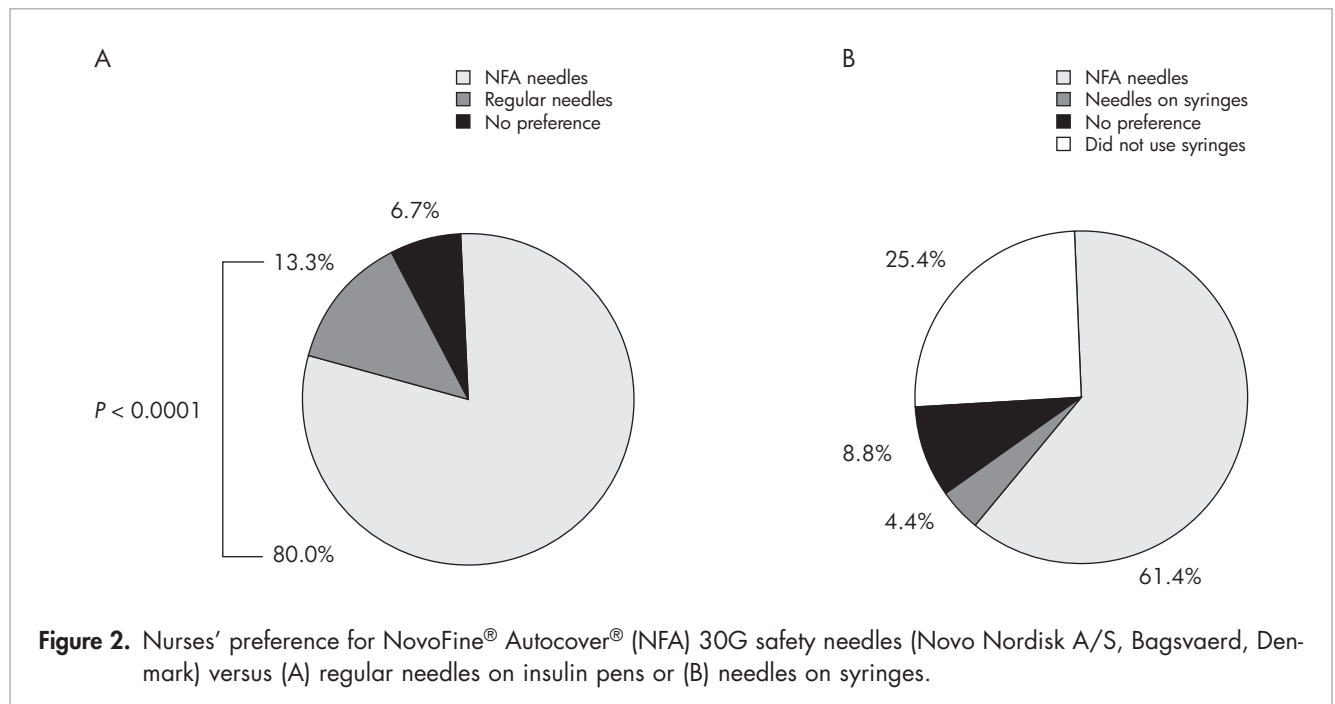
Among 121 nurses who responded to questions about the features of the NFA needle, 98 nurses (81.0%) stated that NFA needles made their daily work easier.

Table II. Numbers of injections given and needlestick injuries reported using NovoFine® Autocover® (NFA) 30G safety needles (Novo Nordisk A/S, Bagsvaerd, Denmark) or regular needles on insulin pens during the 4-week study period.

	NFA Needles	Regular Needles
No. of nurses	123	122
No. of injections administered		
Total	7854	4491
Mean (SD) per nurse*	67.1 (30.4)	50.5 (108.6)
Range per nurse*	12–100†	0–800
No. (%) of accidental needlestick injuries	0	1 (0.02%)

*Records of needlestick injuries were kept for all nurses, but details on the number of injections per nurse were available for 117 nurses using NFA needles and 89 nurses using regular needles.

†Some nurses gave <20 injections during the 4-week study period, but all nurses gave ≥20 injections in total (training period plus 4-week study period).



18.8% with regular needles, $P < 0.001$; for needles on syringes, the numbers were too low to analyze statistically).

Nurses were asked to rate the relative safety of different needles for health care professionals. Using a visual analogue scale where 10 represented NFA needles and 0 represented the alternative, nurses gave values of 8.9 to NFA needles versus regular needles on insulin pens and 9.1 to NFA needles versus needles on syringes.

Nurses were invited to write comments on their experience with NFA needles. The most frequently noted points were as follows: increased safety for the health care professional (20.2% of all comments), ease of use (7.2%), the importance of injecting insulin in a continuous movement to deliver the dose correctly (6.7%), and reduced pain for patients (5.8%). Some nurses (7.7% of comments) indicated that it is not possible to evaluate the insulin dose that was injected with NFA needles because the needle is covered by the plastic shield.

DISCUSSION

In this study, no needlestick injuries occurred among 123 nurses who administered 7854 insulin injections using NFA needles on insulin pens, and 1 needlestick injury occurred among 122 nurses who administered 4491 injections using regular needles on insulin pens. Nurses were very satisfied with the NFA needles, and most of the nurses preferred NFA needles over regular needles on insulin pens as well as needles on syringes. Personal safety was the key reason for their preference and the attribute of NFA needles that nurses rated most highly.

The NFA safety needles were specifically designed to reduce the risk of accidental needlestick injuries among health care professionals who administer subcutaneous insulin to patients. The development of these needles followed a recent study in France, which showed that insulin pens were associated with more needlestick injuries than were syringes.² Interestingly, the rate of 23.5 injuries per 100,000 injections (0.02%) with insulin pens reported in that study closely matches the observed rate of needlestick injuries with regular needles on insulin pens in our study (1 injury out of 4491 injections, or 0.02%).

NFA safety needles were specifically designed to reduce the risk of accidental needlestick injuries among health care professionals who administer subcutaneous insulin to patients.

Because insulin pens offer many advantages over syringes (eg, ease of use, accurate dosing), many health care professionals and patients prefer to use the pens.³ In some countries such as France, insulin pens account for a larger proportion of the insulin-injection device market; in other countries such

as the United States, use of the pens is increasing. The National Institute of Sanitary Prevention in France stated in a recent report that safety devices for insulin pens are essential and looked forward to their forthcoming availability.⁴

NFA needles are the only safety needles designed for use with insulin pens that are commercially available in France, and this article is the first published report on their use. The NFA needle was designed to fit Novo Nordisk insulin pens and insulin pens with a type A interface (ISO11608-2). Unfortunately, this means that NFA needles do not fit all insulin pens that are available in France.

This study is likely to be representative of real life because large numbers of patients were involved: >12,000 injections were administered, and the study was conducted at 52 hospitals located throughout France.

Needlestick injuries are an important concern among health care professionals. The National Institute of Public Health in France reported that in 1997 there were 13 cases of HIV infection due to needlestick injuries and a further 29 presumed infections.⁵ Nurses accounted for 12 of the 13 confirmed cases and 11 of the 29 presumed cases of HIV infection. At least 5 of the accidents occurred after injection (during recapping or disposal of needles). There were also 33 cases of infection with hepatitis C virus, 25 of which occurred in nurses, following accidents with needles. The number of needlestick injuries was reported as 0.07 per nurse per year in France in 2002.⁶ The Alerting, Investigation, and Surveillance Network for Nosocomial Infections in France reported a rate of accidental exposures to blood of 6.9 to 7.2 per 100 full-time nursing equivalents at participating institutions in 2005.⁴

A recent systematic synthesis of the English-language literature on needlestick/sharps injuries reported an annual incidence of 562 to 839 injuries per 1000 health care professionals in prospective studies.⁷ Furthermore, several surveys have shown that nurses are the category of health care professionals most affected by needlestick injuries.⁸ A study in the United States found that 28% of 400 nurses caring for patients with diabetes had experienced ≥ 1 needlestick injury in the preceding 12 months, and that 66% of these injuries were punctures that drew blood.⁸

Cost implications of using NFA needles were not explored in this study. It has been suggested that, in some cases, health care professionals do not have access to safety devices because the authorities consider them too costly.⁷ However, the economic costs of needlestick injuries are high.^{7,9} These include the costs of follow-up tests, postexposure prophylaxis, counseling, lost productivity, treatment of any resulting infections, and legal actions. The human costs in terms of anxiety and stress are also high, and ethical considerations suggest that health care professionals should be protected, as far as possible, against the possibility of accidental injury. When all of these factors are considered, the benefits of using safety needles become clear. In fact, according to a directive from the Ministry of Health in France, one of the recommendations for reducing accidental exposure to blood is the use of safety devices.¹⁰

The economic costs of needlestick injuries are high; these include the costs of follow-up tests, postexposure prophylaxis, counseling, lost productivity, treatment of any resulting infections, and legal actions.

The current study has some limitations. We cannot exclude the possibility that the nurses were particularly careful in administering injections because they knew that they were participating in a study. If so, it seems reasonable to assume that extra care would have been taken in using both NFA needles and regular needles. The nurses involved were experienced nurses working in diabetes departments and thus were the most likely segment of health care professionals to administer insulin to patients; when NFA needles are used by less experienced nurses, the reduction in risk relative to regular needles may be even greater. Another possible limitation is that nurses were asked about their preferences relative to needles on syringes, and no specific mention was made of safety-engineered needles that are available for syringes.

Some nurses were unsure whether insulin had been injected successfully with NFA needles because the needle is hidden behind the shield. Correct use of the NFA needle (after priming and selecting the appropriate dose) involves one fluid movement, in which the nurse pushes down gently on the patient's skin to insert the needle and, when the needle is fully inserted, presses on the pen's button to inject

the insulin. This ensures successful insulin injection, without the need for visual inspection.

In the US survey mentioned earlier,⁷ some injuries occurred because the safety feature of the needled device was not fully activated. This suggests that any safety feature should be an integral part of the device and be easy to use. The safety shield forms an integral part of NFA needles and cannot be dismantled; once the needle has been used, it is locked and cannot be reused. Furthermore, nurses were very satisfied with the ease of use of NFA needles.

CONCLUSIONS

In the NOVAC study, NFA needles were compared with regular needles on insulin pens in real-life conditions at multiple hospitals in France. No needlestick injuries occurred with NFA needles, whereas 1 needlestick injury occurred with a regular needle. Nurses were very satisfied with the NFA needles, citing increased safety, the saving of time, and ease of use as key features they appreciated. These results suggest that NFA needles could reduce the risk of needlestick injuries and that they would be welcomed by nurses who administer insulin to patients with diabetes.

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