

Usability, Participant Acceptance, and Safety of a Prefilled Insulin Injection Device in a 3-Month Observational Survey in Everyday Clinical Practice in Australia

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Abstract

Background:

SoloSTAR[®] (SOL; sanofi-aventis, Paris, France) is a prefilled insulin pen device for the injection of insulin glargine and insulin glulisine. This is the first Australian survey to determine its usability, participant acceptance, and safety in clinical practice.

Methods:

A 3-month, nonrandomized, noncomparative, observational survey in Australia was conducted in individuals with diabetes. Participants were given SOL pens containing glargine, the instruction leaflet, and a toll-free helpline number. Training was offered to all participants. Safety data, including product technical complaints (PTCs), were gathered from ongoing feedback given by the participant or health care professional (HCP) and by independent interviews conducted 6–10 weeks after study start.

Results:

Some 2674 people consented to take part across 93 sites (150 HCPs), and 2029 participated in interviews. Of these, 52.6% had type 1 diabetes, 16.3% had manual dexterity problems, and 15.5% had poor eyesight not corrected by glasses. At the time of interview, 96.8% of participants were still using SOL. None of the eight PTCs reported were due to technical defects; most were related to handling errors. Some 62 participants reported 77 adverse events; none were related to a PTC. The vast majority of participants (95.4%) were “very satisfied” or “satisfied” with using SOL, and 89.7% of the participants had no questions or concerns using SOL on a daily basis. Similar positive findings were reported by participants with manual or dexterity impairments.

Conclusions:

In this survey of everyday clinical practice, SOL had a good safety profile and was very well accepted by participants.

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Abbreviations: (AE) adverse event, (CI) confidence interval, (FP) FlexPen, (HCP) health care professional, (NGFP) Next Generation FlexPen, (PTC) product technical complaint, (SOL) SoloSTAR

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