



Worldwide Injection Technique Questionnaire Study: Population Parameters and Injection Practices

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Abstract

From February 1, 2014, through June 30, 2015, 13,289 insulin-injecting patients from 423 centers in 42 countries took part in one of the largest surveys ever performed in diabetes. The goal was to assess patient characteristics, as well as historical and practical aspects of their injection technique. Results show that 4- and 8-mm needle lengths are each used by nearly 30% of patients and 5- and 6-mm needles each by approximately 20%. Higher consumption of insulin (as measured by total daily dose) is associated with having lipohypertrophy (LH), injecting into LH, leakage from the injection site, and failing to reconstitute cloudy insulin. Glycated hemoglobin values are, on average, 0.5% higher in patients with LH and are significantly higher with incorrect rotation of sites and with needle reuse. Glycated hemoglobin values are lower in patients who distribute their injections over larger injection areas and whose sites are inspected routinely. The frequencies of unexpected hypoglycemia and glucose variability are significantly higher in those with LH, those injecting into LH, those who incorrectly rotate sites, and those who reuse needles. Needles associated with diabetes treatment are the most commonly used medical sharps in the world. However, correct disposal of sharps after use is critically suboptimal. Many used sharps end up in public trash and constitute a major accidental needlestick risk. Use of these data should stimulate renewed interest in and commitment to optimizing injection practices in patients with diabetes.

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In preparation for drafting the new insulin delivery recommendations (published in this issue),¹ a large international survey of current injection practices was undertaken. The rationale was to understand the nature of the problems before proposing the solutions. From February 1, 2014, through June 30, 2015, the insulin Injection Technique Questionnaire (ITQ) survey was conducted with 13,289 patients from 423 centers in 42 countries, making it one of the largest international surveys of its kind ever performed.

The objectives of the ITQ were to chart the epidemiologic profiles for the major insulin injection parameters; to determine the degree of variability in injection technique and its causes, interactions, and associations with glucose control and other outcomes; and to understand patients' perceptions of the injection process, including the psychological aspects.

Previous ITQs were performed in 1995,² 2000,³ and 2009,⁴ each surveying an increasing number of patients, centers, and countries. The similarity in wording and design of the questionnaires in the 4 surveys permits comparison of injection practice across time and geographic locations. The results of the current ITQ were presented at the Forum for Injection Technique and Therapy: Expert Recommendations (FITTER) workshop.⁵

Methods

The ITQ survey consists of an initial patient section (administered by an experienced diabetes nurse) followed by a section completed by the patient's nurse, physician, or diabetes educator after observation of injection technique and meticulous examination of all injection sites. Results are provided based on either the patient's or the health care provider's (or both) survey responses and are indicated as

such. The various language versions of the ITQ (patient and professional forms) are available via the Fitter4Diabetes website.⁶ Although 17 different languages were used, the content of each survey version was identical.

Besides participant demographic information, the key insulin injection parameters queried by the questionnaire were as follows: current practice (injection device and needle length, number of injections per day, choice of injection site, use and characteristics of lifted skinfolds [pinch-up], needle entry angle, size of the injecting zone, site rotation, disinfecting before injecting, dwell time of needle under the skin, site inspection by a health care professional, needle reuse, sharps disposal, and injection through clothing), observed anomalies at injection sites (insulin leakage, bleeding, bruising, lipoatrophy, lipohypertrophy [LH], inflammation, and pain), knowledge about injections (identity of trainer, themes covered in injection training, adequacy of the coverage of these themes, and desire for more knowledge), blood glucose anomalies (episodes of hypoglycemia and hyperglycemia, hospitalizations for hypoglycemia, history of ketoacidosis, glucose variability, and unexpected hypoglycemia), and safety (needlestick injuries [NSIs], risk factors for blood-borne infections, and disposal habits for used sharps).

Centers were selected to be, as much as possible, representative of diabetes care in the countries involved. Approximately a third were specialist diabetes clinics/hospitals, a third were community diabetes centers, and a third were general practice centers or private offices. All the selected centers participated willingly and without financial incentive.

Participating centers were required to understand and agree with the ITQ. Each was expected to recruit approximately 25 patients within the allotted time frame. Patients were not placed at any risk by the study, therapy decisions were not based on the study, and no financial compensation was offered for participation. Verbal informed consent was obtained from all the participants.

Patient identity was kept confidential at all times, and the study was conducted according to Good Clinical Practice and the Helsinki accords. The ITQ was organized in cooperation with BD (Becton, Dickinson & Co., Inc., Franklin Lakes, NJ). BD associates in each

country distributed questionnaires to centers and collected them once filled out. BD played no role in the discussions with patients or in the completion of forms. No participant identifying information was made available to BD. Ethics committee approval, although not required for such a survey, was nevertheless obtained whenever specifically requested by a center or by local regulators.

All the participants had insulin-treated diabetes and had been injecting with a pen, syringe, or both for at least 6 months before taking the survey. To eliminate selection bias, patients were recruited into the study on a sequential basis, ie, eligible and consenting participants were accessioned consecutively as they entered the clinic or health care setting. A total of 13,289 participants with diabetes who had both patient and nurse forms filled out were included in the database. Not every parameter will reflect this total number owing to the occasional skipping of an item in the survey. However, the large overall numbers help overcome any potential bias that missing data may introduce.

Patient demographic data included age, sex, type of diabetes, years with diabetes, years injecting, and devices used. We recognize the importance of economic standing of patients, availability of health care resources, and rural vs urban settings in influencing outcomes. However, it was decided not to pursue such detailed socioeconomic data in an already-lengthy survey with so much intercountry variability. Although we do not have precise data on place of residence, we do know that most centers that performed the survey were in urban areas, especially in countries such as India and China.

There were 3853 Chinese patients in the study, 29% of the total. Of these, 3354 were given a slightly shorter questionnaire (although with identical questions from the full study questionnaire) and 499 were given the complete questionnaire. Health care in China is often delivered in very rapid physician visits; it is not uncommon for a physician to see up to 100 outpatients in a day. In such a fast-moving system, it is difficult to complete a full ITQ survey. For this reason, the shorter questionnaire was used in most patients ($n=3354$), with the full questionnaire used in the remaining 499. To prevent undue weighting of the worldwide data by the Chinese

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