



New Insulin Delivery Recommendations

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Abstract

Many primary care professionals manage injection or infusion therapies in patients with diabetes. Few published guidelines have been available to help such professionals and their patients manage these therapies. Herein, we present new, practical, and comprehensive recommendations for diabetes injections and infusions. These recommendations were informed by a large international survey of current practice and were written and vetted by 183 diabetes experts from 54 countries at the Forum for Injection Technique and Therapy: Expert Recommendations (FITTER) workshop held in Rome, Italy, in 2015. Recommendations are organized around the themes of anatomy, physiology, pathology, psychology, and technology. Key among the recommendations are that the shortest needles (currently the 4-mm pen and 6-mm syringe needles) are safe, effective, and less painful and should be the first-line choice in all patient categories; intramuscular injections should be avoided, especially with long-acting insulins, because severe hypoglycemia may result; lipohypertrophy is a frequent complication of therapy that distorts insulin absorption, and, therefore, injections and infusions should not be given into these lesions and correct site rotation will help prevent them; effective long-term therapy with insulin is critically dependent on addressing psychological hurdles upstream, even before insulin has been started; inappropriate disposal of used sharps poses a risk of infection with blood-borne pathogens; and mitigation is possible with proper training, effective disposal strategies, and the use of safety devices. Adherence to these new recommendations should lead to more effective therapies, improved outcomes, and lower costs for patients with diabetes.

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Correct technique in insulin delivery is critical for optimal control of diabetes. This article reviews the most recent studies in the field and then offers new injection and infusion recommendations for insulin users. It is meant to complement and extend the injection recommendations published in 2010.¹ These latest recommendations were based on the results of the fourth Injection Technique Questionnaire (ITQ) survey (published elsewhere in this issue). From February 2014 through June 2015, 13,289 insulin-injecting patients with diabetes from 42 countries participated in the ITQ survey, one of the largest multinational studies of its kind. A smaller Infusion Technique Questionnaire survey was undertaken concurrently with the ITQ in 356 patients using continuous subcutaneous insulin infusion (CSII) in four countries and informed the drafting of the new infusion recommendations.

The ITQ survey results (for injection and infusion) and the initial draft of these recommendations were presented at the Forum for Injection Technique and Therapy: Expert Recommendations (FITTER) workshop held in Rome, Italy, on October 23 and 24, 2015, at which 183 physicians, nurses, educators, and allied health care professionals (HCPs) from 54 countries (see the list in [Supplemental Appendix 1](#), available online at <http://www.mayoclinicproceedings.org>)² met to debate, revise, and adapt these proposals. FITTER was the fourth in a series of expert workshops that have issued recommendations on insulin delivery.^{1,3-5}

MATERIALS AND METHODS

Publications were identified using Medline, EMBASE, PubMed, and Cochrane Controlled Trials. The search was focused on the period between January 2008 and December 2015,



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although we had at our disposal the medical literature going back to 1980. We used the terms *subcutaneous injections*, *insulin*, *injection technique*, *insulin infusion*, *CSII sets*, *infusion sets*, and *glucagon-like peptide-1 receptor agonists* (GLP-1). For those seeking other related terms, a glossary is also available as [Supplemental Appendix 2](#) (available online at <http://www.mayoclinicproceedings.org>).² Of 368 articles found, 254 met the criteria for inclusion as outlined in the Cochrane Handbook for Systematic Reviews of Interventions.⁶

One of us (K.W.S.) drafted the initial version of the recommendations. This draft was then extensively revised during 12 monthly web conferences with a group of international experts in injection and infusion techniques (see authors). This new draft was then extensively revised by the 183 expert invitees to the FITTER meeting in Rome. After FITTER, additional revisions were made by FITTER attendees. The current version reflects the collective input of these diabetes experts from around the world and bears little resemblance to the earlier drafts.

The panel used a previously established scale^{1,4,7} for the strength of each recommendation: A = strongly recommended, B = recommended, and C = unresolved issue. For grading the degree of scientific support for each recommendation, we used the following scale: 1 = at least 1 rigorously performed study that is peer reviewed and published (excludes observational studies); 2 = at least 1 observational, epidemiologic, or population-based published study; and 3 = expert consensus opinion informed by broad patient experience.

This simplified version of the grading scales commonly used⁷ was believed to be more appropriate for our field, where randomized, controlled outcome trials are rarely available but good-quality studies on the performance of devices do exist. Each recommendation is followed by a letter and number in bold (eg, **A2**). The letter indicates the importance that the recommendation should have in practice, and the number indicates its level of evidence in the medical literature. The most relevant publications bearing on a recommendation are also cited or summarized. Although these recommendations will be suitable for most patients, individual exceptions may occur for which the guidelines should be adapted.

ANATOMY

Skin Thickness

The skin is the first obstacle a needle must traverse when giving an injection or infusion. A variety of studies of adult skin at injection sites using various imaging techniques have all shown similar results: the skin varies in thickness from approximately 1.25 to 3.25 mm in 90% of individuals and averages approximately 2.0 to 2.5 mm. Studies have included both healthy volunteers and persons with diabetes, and their results are consistent across age groups, sexes, body mass indexes (BMIs), and geographic locations. Studies included four ethnic groups in the United States⁸; Italian⁹ and South African¹⁰ children and adolescents with type 1 diabetes; and groups of Chinese,¹¹ Indian,¹² Filipino,¹³ and Korean adults¹⁴ (most with type 2 diabetes). Details of these studies are summarized in [Supplemental Figure 1](#)⁸ and [Supplemental Tables 1-4](#) (available online at <http://www.mayoclinicproceedings.org>).⁹⁻¹⁵

The skin is slightly less thick in children, but by puberty it increases to adult levels. However, these differences are small and are irrelevant for insulin injections and infusions. In both children and adults, even the shortest needles (4 mm) reliably traverse the skin and enter the subcutaneous (SC) fat.

SC Thickness

The distance from the surface of the skin to the muscle fascia (ie, the sum of skin and SC thickness) determines the potential for intramuscular (IM) injection. Compared with skin thickness, which is relatively constant, SC tissue thickness varies widely. Ultrasound measurements of skin and SC thickness at insulin injection sites in adult patients with diabetes have recently been published.^{11,13} See [Supplemental Tables 1-4](#)⁹⁻¹⁵ for a summary of findings from the most important of these studies. Gibney et al⁸ and Hirsch et al¹⁵ (separate reports on the same study) measured SC fat depth at single locations in the thigh, arm, abdomen, and buttock. Studies by Ludescher et al¹⁶ and Sim et al¹⁴ (where 8-10 measurements were taken and averaged for each body site) largely confirmed the ultrasound study findings from a single site.

Several rules of thumb have emerged from these studies: SC fat thickness increases in

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