Forums for Injection Technique (FIT), India: The Indian Recommendations 2.0, for Best Practice in Insulin Injection Technique 2015
FIT India is constituted to provide evidence-based information on best practices on injection technique, to all those using injectable therapies for diabetes care, in order to achieve best possible health outcomes, ensuring that the right dose is delivered at the right injection site, using the right technique, each time.

Objectives

• Identify the injection technique currently being used in practice amongst Indian healthcare professionals (HCPs) and people living with diabetes.

• Raise awareness of the impact that existing and emerging research related to injection technique may have on health outcomes.

• Facilitate opportunities in which best injection practice can be discussed, developed, implemented and evaluated throughout India.

Foreword

Further to the formation of the International FIT recommendations, there was a strong need to arrive at recommendations that would best suit the local needs of developing nations such as India.

In view of the above, the FIT India document has been established to promote best practice in injection technique for all involved in diabetes care. This document, authored by an interdisciplinary team, is based on evidence as well as consensus, and has been thoroughly reviewed by 76 leading experts in India and 6 from neighbouring South Asian countries.

Implementation of these recommendations may have a direct impact on the health outcomes of individuals living with diabetes who require injection therapy. This document will be distributed to healthcare professionals involved in injectable therapy for diabetes in India.

Acknowledgement

The authors acknowledge the significant contribution made by members of the South Asian Referee Group and the Indian Review Panel.

An abridged version of the ‘FIT First Indian Insulin Injection Technique Recommendations’ was published in Indian Journal of Endocrinology & Metabolism, November 2012 issue. Addenda have also been published in November 2013 and November 2014 issues of the journal.
I congratulate Forum for Injection Technique (FIT), India for developing recommendations for the best Insulin Injection Technique. These recommendations are extremely important because insulin therapy is vital to people with diabetes. The recommendations cover many gaps in the knowledge of health-care workers regarding needle length, site rotation and safety issues. The Diabetes Educators, and in turn, people with diabetes are expected to benefit immensely from these recommendations.

Prof. (Dr.) Hemraj B. Chandalia
President, Association of Diabetes Educators

It is estimated that India will add 244 patients to the world diabetes population every hour for the next 20 years. For a country slated to be the world’s third largest economy by 2030, this is a serious concern. We, at Biocon, are on a mission to arrest the ticking of this clock through our philosophy of Winning with Diabetes. This philosophy is the driving force behind our endeavour of making innovative, yet affordable therapy accessible to people with diabetes and physicians across the globe. Our support to FIT India, in which we take much pride, stems from the common goal of extending proper care to people with diabetes. FIT India, through its evidence-based recommendations, goes a long way in helping Healthcare Professionals understand the importance of good injection technique and convey this to people with diabetes under their care. We believe that this will make a big difference.

Rakesh Bamzai
President- Marketing, Biocon Limited

Advances in the treatment of diabetes have led to an increase in the number of injectable therapies available. Correct technique is of paramount importance in order to ensure the benefits of injectable therapies such as insulin. The Forum for Injection Technique (FIT) provides comprehensive evidence-based guidelines to improve the process and education of self-injection technique for people with diabetes. As a company committed to improving the care of patients with diabetes, Lilly India welcomes the FIT initiative as an important step in supporting diabetes care in India.

Dr. Anurita Majumdar
Medical Director, Eli Lilly & Co. (India) Pvt. Ltd.

India is infamously called “The Diabetes Capital of the World” and it is our collective responsibility to work towards control of this menace. Emphasis on preventive approaches, effective management tools, and standardized care complimented with greater public awareness can have a far-reaching impact on the holistic efforts to deal with this. Lupin- an innovation led transnational pharmaceutical organization having global footprints has always been on the forefront to alleviate the suffering of patients, promoting health across the globe and especially in India. Insulin has revolutionized the way diabetes is treated and FIT- India has done a momentous contribution by developing the first ever evidence-based Indian recommendations for best practice in Insulin injection technique. In addition of making the best quality, affordable anti-diabetic drugs and Insulin, our support to FIT reflects our commitment to help our healthcare professionals in effectively controlling the menace of diabetes. We believe, by joining hands together and making collective efforts in the fight against diabetes we can reduce the sufferings and can make our country a “Global Leader” in true sense.

Dr. Alok Chaturvedi
Sr. GM-Medical Services, Lupin India
**Forum for Injection Technique (FIT), India:**
The Indian Recommendations 2.0, for Best Practice in Insulin Injection Technique 2015

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Insulin therapy is an essential part of diabetes management; all type 1 and most type 2 diabetes patients require insulin at some stage. As injectable therapies such as human insulin, insulin analogues and glucagon-like peptide-1 receptor agonists are used to manage diabetes, correct injection technique is vital for achievement of glycaemic control. Specific recommendations to collate and explain best practices in insulin injecting technique are needed for people with diabetes as well as HCPs. The Forum for Injection Technique (FIT) India acknowledged this need for the first time in India, and worked to develop evidence-based recommendations on insulin injection technique, to assist healthcare practitioners in their clinical practice. These recommendations are described in this communication.

Keywords
Adherence; aspart; degludec, detemir; diabetes; education; glargine, glucagon-like peptide 1 receptor agonists, glulisine; injections; injection sites; injection technique; insulin; insulin analogues; lipohypertrophy; lispro; needle length; skin-fold; storage.
An alarmingly rising prevalence of diabetes has been reported in recent years. According to current studies, 67 million Indians are affected with diabetes. By 2030, the prevalence of diabetes among Indians is projected to reach 87 million. Insulin remains the mainstay of treatment in diabetes and about 3.2 million Indians depend on insulin injections for the management of diabetes. With time, majority of people with type 2 diabetes eventually need insulin therapy for the optimal control of glucose levels. All people living with type 1 diabetes also need insulin for survival, and intensive insulin therapy is recommended in them. However, incorrect technique of injecting insulin may increase the risk of poor glycaemic control, due to mismatch of peak insulin effect and maximal glucose load.

As insulin injections are designed to deliver insulin into the subcutaneous tissue, it is important and crucial to make the right choice of appropriate needle length. Shorter needles are beneficial over longer ones as they avoid the risk of intramuscular administration even if injected at 90° angle to the skin surface. It has been demonstrated that the use of shorter needles provides equivalent glycaemic control compared to longer needles, without increasing the incidence of leakage events. Shorter needles also help in combating the psychological fear of needles in patients and hence improve their acceptance of insulin injection therapy.

Improper use, or reuse, of injection devices, such as needles, may lead to undesirable consequences including pain with bleeding and bruising, breaking off and lodging under the skin, contamination, dosage inaccuracy and lipohypertrophy. According to a study, correct injection technique and use of shorter needles (4 mm) are associated with improved glucose control, greater satisfaction with therapy and lower consumption of insulin after only a 3-month period.

Appropriate injection technique, thus, is an indispensable part of diabetes management. Although drugs such as insulin are prescribed frequently, rarely do HCPs* mention the appropriate devices in their prescriptions. Hence, specifying the injection device and needle length and gauge, along with the other instructions like prevention of reuse, is a mandatory part of an insulin prescription. These issues are too important to be left to the discretion of the retail chemist.

*Healthcare professionals.
Appropriate injection technique is crucial for the success of insulin therapy. Several factors influence the success of insulin injection therapy, injection technique being highly variable and operator-dependent. The factors influencing injection technique are classified in Box 4.0

4.0 Factors influencing injection technique health of a person with diabetes

**BIOMEDICAL**
- Manual dexterity
- Visual acuity
- Hearing acuity

**PSYCHOSOCIAL**
- Misconceptions about insulin
- Health literacy and numeracy
- Fear of pain/insulin
- Financial constraints

Several issues such as lack of knowledge, time constraints of HCPs, and scarcity of local recommendations may contribute to such factors. Physicians’ awareness and willingness to convey basic information such as the dosage, injection site selection, depth of injection and the correct method of injection go a long way in preventing faulty injection technique. The physician should also assess and clear misconceptions of the patient, thereby reducing fear, and thus easing adherence to medication. These are methods of modulating modifiable factors so as to enhance the success of insulin therapy.

However, there are some factors like dexterity, visual and hearing impairment, and learning skills which at times cannot be modified. These factors can be addressed, however, by choosing appropriate insulin devices, suited to the individual. For example, modern pens with magnified dose display, audible clicks to inform dose increments, and lower pressure requirements for plunging, can be helpful in differently abled individuals. Recommendations are needed to optimise the factors listed above and to ensure appropriate practice of insulin injection technique by both HCPs and people with diabetes.

Recommendations or consensus statements on insulin technique that suit the local needs of developed countries are available. Such documents have not addressed certain issues relevant to developing countries such as India. Hence, a need for Indian recommendations for best practice in insulin injection technique was felt.
5.0 Materials and Methods

The first draft of the FIT India recommendations, 2012, was prepared by a core writing group of three endocrinologists. A psychiatrist was co-opted into the core writing group to provide expert opinion on the psychological aspects of injectable therapy.

The methodology of literature search, medical writing strategy and evidence grading were finalised after consensus approval and validation by a board of 13 HCPs from various medical disciplines, including endocrinologists, diabetologists, diabetes educators, psychiatrists and psychologists. Simultaneously, the draft was also reviewed by 76 clinicians from India and 6 experts from South Asia (South Asian referral group). Another three eminent members were added to the FIT India advisory board in November, 2014.

These recommendations are based on the evidence collated from published literature, specific to the subject of injection technique. The grading method followed by Frid et al. (2010), which includes an ABC scale for the strength of recommendation and 123 scale for scientific support, has been used to grade the evidence (see Fig. 1). Certain recommendations which are supported by manufacturer advice or by drug authority guidance have been ranked 1 in scientific support.

An abridged version of the recommendations was published in Indian Journal of Endocrinology and Metabolism. An addendum was published in 2013 to cover certain issues which had not been included in the original FIT India document. An expert on insulin pump therapy was co-opted while writing the addendum.

**ABC Scale:**
- **Strength of recommendation**
  - A: Strongly recommended
  - B: Recommended
  - C: Unresolved issue

**123 Scale:**
- **Scientific support**
  - 1: At least one randomised controlled study
  - 2: At least one non-randomised (or non-controlled, or epidemiologic) study
  - 3: Consensus expert opinion based on extensive patient experience

Fig. 1: Grading criteria (Frid et al., 2010).

**FIT India Recommendations**

Each section of the FIT India recommendations contains a background and introductory information, followed by the actual recommendations stated in separate boxes.

In general, these recommendations apply to the majority of injecting patients; however, there will inevitably be individual exceptions for which these rules must be adjusted.

Another addendum has been published in 2014, with the aim of making FIT India more comprehensive. The revised FIT India recommendations, 2015, have been prepared carefully, to ensure that no relevant information is omitted, and no superfluous information added. It is hoped that FIT 2.0 India Recommendations 2015 will be used as a reference text by diabetes care professionals, as well as an easily readable source of information by people with diabetes.
6.0 Injection Technique Recommendations

6.1 Pre-injection assessment

Recommendations

- Patients should be encouraged to discuss their injection-related concerns. B3
- Pre-injection measures should include a complete history and physical examination of the patient, including assessment of manual dexterity, cognitive capacity, health literacy, numeracy skills, visual acuity, anxiety, local infections, ulcers and scars. B3
- Type of insulin and type of device prescribed, storage conditions, method of refilling of injection supplies and disposal facilities should also be assessed. B2
- If cold storage facilities are inaccessible, prefer insulin pens over vials. C1

6.1.1 Clinical assessment

A thorough patient assessment should precede therapy initiation. Concerns with regard to limited manual dexterity, injection anxiety, misconceptions, denial of the benefits of timely injections, visual and hearing impairments, and other barriers should be assessed and addressed. Optimisation of injection technique with respect to individual patient needs is critical for the success of injectable therapy.14

6.1.2 Environmental assessment

The use of correct type and device of insulin should be ensured. As insulin is sensitive to extreme temperatures, it is essential to inquire about storage conditions of injection supplies. Availability of stock for at least 1-3 months should be ensured so that no dose is missed. If injection cold storage facilities are not readily available, insulin pens can be used instead of vials.

6.1.3 Sociocultural sensibilities

Sociocultural sensibilities of the community should be respected. It is advised to discuss the site of injection beforehand in Indian women so that their sensibilities are not offended.

6.2 Pre-injection counselling

More than one-fourth of patients may refuse insulin therapy after prescription.15 This phenomenon is often termed as psychological insulin resistance (PIR). The most pronounced reasons associated with PIR are personal failure, anticipated pain, low self-efficacy and lack of awareness about the benefits of insulin. It is thus essential to encourage shared decision-making with active participation of the patient. Giving the patients a sense of control over their treatment plan improves acceptance and enhances adherence to therapy. Specification of pain-minimising devices, such as pens requiring low pressure for injection, in the doctor’s prescription, could help in insulin therapy initiation.14

6.2.1 Children

In the early stages of diabetes, especially in childhood, the diagnosis of diabetes creates a sense of distress and anxiety in both parents and children. This hinders parents’ ability to administer insulin or encourage
6.2 Psychological challenges of injections

**Children**
- Parents themselves have to be calm and composed before any injection. This is comforting for the child. A1
- Divert the attention of child or if required, cognitive behavioral therapies (relaxation training, guided imagery, graded exposure, active behavior rehearsal, modeling and reinforcement and small incentives) have to be employed. A2
- The threshold of pain is lower in children, so show your concern about the pain to the child. A2
- Choose your words carefully. A2

**Adolescents**
- Emphasise the long-term benefits of treatment adherence. B1
- Provide options of flexible injection schedule during weekends and holidays. B3
- Be aware of the apprehensions of weight gain and skipping injections while monitoring blood glucose levels and finding unexplained weight loss. B2
- Counsel adolescents about the fear, anxiety and frustrations of taking injections. A2
- Clinicians should reflect on their own perceptions of therapy. They should avoid use of terms which might show that such a therapy is a failure, a form of punishment, or used as threat. A3

**Adults**
- Share the goals of therapy with respect to short- and long-term advantages of controlling blood glucose levels. A3
- Healthcare professionals have to be assertive about the need to start insulin therapy. A3
- Pen therapy might have psychological advantage over a conventional syringe. A2
- Discuss benefits of injectable therapy. A3
  - Improved blood glucose control
  - Reduced risk of long-term complications

It is important to include the child and the parents as important partners in diabetes care. Their role as key stakeholders in the administration of insulin should be emphasised. This added sense of responsibility helps build their confidence and ensures their active participation.

Initially, to overcome anxiety, it may help to allow parents and children to administer saline, insulin diluent or one unit of insulin themselves. Explanation of role of insulin in diabetes management and the need for regular injections allays misconceptions and concerns. Spending some time on explaining these issues using simple and clear words helps. One may demonstrate injection technique on one self, or on a toy doll. Play therapy is a useful method of explaining injection technique.

6.2.2 Adolescents

Adolescents may exhibit sub-optimal compliance to insulin injection schedule due to several factors such as peer pressure, lack of seriousness, pain, and frustration. Adolescents, especially girls, may skip insulin injections because of the fear of weight gain. It is important to help them overcome any possible misconceptions related to insulin by sharing information with them. Age-appropriate information should be provided. Re-emphasising the benefits of insulin administration helps increase acceptance of insulin injection among adolescents. Positively reinforcing their commitment to diabetes care helps them realise their key role and ensures their active participation.
6.2.3 Adults

Managing diabetes in adults may be challenging in certain cases. All newly-diagnosed persons with diabetes should be educated about the course of diabetes and the need to start insulin therapy at some time in the future. Certain concerns which may hinder acceptance of insulin are:

• Perceived interference with the quality of life
• Worsening of diabetes condition
• Guilt or feeling of failure of self-management
• Daily injection burden
• Risk of hypoglycaemia

Clinicians should be aware of these potential barriers. It is important to explore and acknowledge these concerns of the patients. Helping the patient understand that having such concerns is not unusual encourages them to discuss these issues and find solutions.

6.2.4 Elderly

Counselling geriatric patients for self-injection can be a challenging task. Unlike their younger peers, they may have certain age-related difficulty in executing instructions properly. Functional disability, depression and lack of self-motivation, impaired cognitive function, inflammatory arthropathy and motor system disorders can considerably affect the ability to administer insulin, monitor blood glucose and manage hypoglycaemia. Limited dexterity, visual impairment, and hearing impairment are of utmost importance in this vulnerable group of patients.

The importance of modern pen devices is reflected best in the field of geriatrics. Their discreetness, simplicity and convenience of use, dosage accuracy and being less painful to inject allows for widespread acceptability amongst the elderly. Easy pre-selection of the prescribed insulin dose has also been well-documented. Various recommendations for diabetes management in the elderly have discussed these points and suggested some practical remedial steps. It has been suggested that the physician should not use age as an excuse to avoid usage of insulin.

Technical superiority of a product (analogue vs. conventional) or an injection device (pen vs. syringes), should be given due consideration. Along with insulin initiation, all elderly patients should be taught a structured self-monitoring and algorithm-based insulin dose titration. Healthcare providers must ensure the involvement of responsible family members/attendants during the selection of insulin and explanation of injection technique, in case of frail and very old patients.

6.3 Injection Storage

It is recommended that specific storage recommendations provided by the manufacturer be followed. Insulin should be stored in a cool and dark place. Insulin pens and vials, which are not being used, should be refrigerated, but not frozen. If frozen, insulin should be discarded. Insulin being used can be kept at room temperature to limit local irritation at the injection site, which may occur when cold insulin is used. The insulin vial should be taken out and kept at room temperature for at least 30 minutes before use. Pens should never be stored with needles on, because the higher risk of air entering through the needles may clog them and hence affect dosage delivery. In rural areas or in places where a refrigerator is not available, it is advisable to put the vial in a plastic bag, tie a rubber band and keep it in a wide-mouthed bottle or earthen pitcher filled with water. Insulin should be kept out of reach of children.

6.3.1 Travel: Surface

While travelling, insulin should be stored in a flask with ice, or in a hand bag, or in a proper container if the outside temperature is >30°C. Insulin should never be kept in the glove compartment of a car, or left in a locked car with closed windows.
6.3 Injection storage: Recommendations

- Store insulin in use at room temperature (15–25°C) and discard 30 days after initial use or follow manufacturer’s instructions. A1
- **Currently unused vials/refill cartridges (meant to be used in future) should be refrigerated.** A1
- **Never freeze** (frozen insulin should be thrown away). A1
- Storage recommendations specific to the insulin formulation according to the manufacturer’s instructions (package insert) are to be checked before use. A1
- When storing pre-filled insulin syringes, store them with the needle pointing up. A3
- **Never use insulin beyond the expiration date stamped on the vial, pen, or cartridge that is supplied by the drug manufacturer.** A1
- **Avoid extremes of temperature such as:** A3
  - Direct sunlight
  - Kitchen
  - Closed cars
  - The top of a radiator
  - The top of a television
  - Green houses

6.3.2 Travel: Air

While travelling by air, one should ensure that:

- Physician should be consulted if travelling to a place with a time-zone difference of 2 or more hours because it may require a change in insulin injection schedule. A3
- Insulin should not be placed in the baggage hold of the plane due to the risk of exposure to extreme temperatures. A3
- Extra insulin pen or vial should be carried so that insulin therapy is not interrupted in the event of device breakdown/malfunction.

6.4 Device selection and use

Prior to injection, the patient must verify expiry date and the dose, and whether injection with the correct type of insulin is being prepared. Depending on the type of insulin, significant variations in the expiry dates of insulin vials or pens after opening may be reported. Re-suspension of cloudy insulin is important to ensure proper absorption of injected insulin, and to maintain appropriate concentrations of the remaining insulin in the vial or pen (see Fig. 2).

![Fig. 2: Cloudy insulin resuspension.](image)

**6.4.1 Syringe and vial compatibility**

**Dose**

Both U-40 and U-100 insulin concentrations are available in India. **While initiating insulin therapy, the patient should be informed that U-100 vials should be used with U-100 insulin syringes, and U-40 vials with U-40 insulin syringes only.** Insulin syringes of U-100 have an orange cover and black scale markings denoting two units each, while U-40 syringes have a red cover and red scale marking denoting one unit each. A3, A25

**Needle size**

Insulin syringes with three different needle lengths 6, 8 and 12.7 mm are available. Also, three gauge sizes, 31, 30 and 29, are available in insulin syringes. The higher the needle gauge, the thinner the needle. A 31-gauge syringe is available in both 6- and 8-mm needle lengths. A25
6.4 Injection device and insulin verification

- Emphasise the choice of injection device, needle length and gauge, and type of insulin syringe in the prescriptions. A1
- Ensure that the pharmacist has dispensed the prescribed insulin. Check for: A1
  - Name and type of insulin
  - Expiry date
- Prior to use, it is critical to examine the insulin bottle and ensure there are no changes in insulin (e.g. clumping, frosting, altered colour or clarity). A1
- Clear insulin must be clear and cloudy insulin should be cloudy. A1
- Resuspension of cloudy insulin is essential to ensure proper absorption. Vials and cartridges must be gently rolled and/or tipped (not shaken) for 20 cycles until the crystals go back into suspension (solution becomes milky white). A2
- Correct resuspension technique has to be regularly evaluated. A2
- International colour codes can be used as an aid to identify insulin B3

6.4.2 Pens and pen needles

Insulin pens carry insulin in a self-contained cartridge. A7 Different brands and models of insulin pens are available. A7 Insulin pens are of two types: reusable insulin pens, where cartridge can be reloaded; and disposable insulin pens, which are disposed once emptied.

Certain aspects need to be considered while selecting an insulin pen. Different types and brands of insulin are available for the pen. One should consider the number of insulin units the pen can hold when full and the largest dose that can be injected with it. Certain features of the insulin pen such as adjustments of the dose by the pen based on the markings (two-, one- or half-unit increments) and indications on the pen to make sure whether or not there is enough insulin left in it for the entire dose, have additional benefits to the patient.

The design and material of the pen, numbering on the pen dose dial and its magnification and the amount of strength and dexterity needed to operate the pen should be checked. Also, one should check whether corrective measures are available if a wrong dose is inadvertently dialed into the pen. A8

Pen needles

Pen needles are available in 4, 5, 6 and 8 mm sizes and are of 32, 31 and 30 gauge. The shorter needles alleviate the risk of intramuscular injections while avoiding intradermal delivery as well. They are long enough to pass through the skin into the fat layer but are short enough not to reach the muscle tissue. A9

6.5 Needle length

A subcutaneous injection aims to deliver medication directly into the subcutaneous tissue without any discomfort or leakage. Ultrasound measurements reveal a mean skin thickness of about 2.2 mm. Multivariate analyses (of age, BMI, ethnicity and gender in adults with diabetes) demonstrate that variation in skin thickness is not clinically significant. A7 Hence, there is no medical reason to recommend needles longer than 4–6 mm to either children or adults. Extremely lean patients should be using a skin fold to inject even with a 4-mm and 5-mm needle.

Clinical studies have also reported equal efficacy and safety/tolerability of shorter needles (4 mm) in comparison to longer ones. A randomised trial compared the efficacy and tolerability of 4-mm and longer needles (5 and 8 mm) in adult diabetes patients. In addition to providing equivalent glycaemic control and alleviating the risk of intramuscular injections, a 4-mm needle resulted in less painful injections and did not increase leakage events compared to longer needles. This study also reported that shorter needles were
6.5 Needle length: Recommendations

**Children and adolescents**
- Children and adolescents should use a 4-mm needle with pens and the shortest needles available (currently 6-mm) with syringes. A2
- No clinical reason exists to recommend needles longer than 6 mm in children and adolescents. A2
- In children who are slim, when injecting into the limbs, a skin-fold is required: Especially when using a 5- or 6-mm needle. A1
- An injection angled at 45° with a 6-mm needle can be used instead of a skin-fold. A1
- If only an 8-mm needle is available, then they should lift a skin-fold and/or inject at 45°. A1
- Injection into the arms needs third-party assistance and a lifted skin-fold for needle length more than 5mm A3.

**Adults**
- Adults including obese patients can use 4-mm needle with pens, and 6-mm long needles with syringes. A2
- **Adults do not require the lifting of a skin-fold**, particularly for 4-mm and 5-mm needles. A1
- Shorter needles should be given in adults at a 90° angle to the skin surface. A1
- An injection into the limbs or a slim abdomen warrants the need for a skin-fold with needles longer than 5-mm. A2
- No clinical reason is available for recommending needles of length more than 6 mm in adults. A2
- Patients already using needles ≥8 mm should move to a shorter needle or lift a skin-fold and/or inject at 45° in order to avoid injecting into muscle. A2

preferred by patients. Thus, shorter needles may obviate psychological insulin resistance and thereby

**6.5.1 Needle length in children**

**Shorter needle length (4-mm) is considered safe and efficacious in children.** Currently, a 4 mm pen needle is

*For a very lean adult, a pinch-up may be required*
6.6 Seven-step injection site care process

- Prior to injection, the site has to be inspected and palpated for lipohypertrophy and inspected for wounds, bruises or blisters. A3
- If the injection site shows any signs of lipohypertrophy, inflammation, oedema or infection, a different site should be selected. A2
- Injection should be given at a clean site with clean hands. A2
- If the injection site is found unclean, it should be cleansed prior to injection. A3
- The injection site has to be inspected at every visit or at least every 6 months, or as part of investigation into sub-optimal or erratic blood glucose control. A2
- Rotate injection sites systematically. A2
- Ideally do not reuse needles. A2

6.7 Cleansing

- Ensure that injection site is socially (one should be willing to touch the skin) clean before injection. A3
- Recommend the use of alcohol swabs or cotton balls dipped in water for cleansing. A2

6.6.4 Buttock

The upper outer quadrant of the buttock should be used. The upper outer quadrant may be located by placing index finger on the iliac crest and making a right angle between the index finger and the thumb. This site is not used routinely in adults. It can be used in infants and toddlers.

The order of the rates of absorption at these sites is abdomen > arm > thigh > buttock. Presence of a fat layer and only a few nerves in these regions makes injections convenient. Proper care of the injection site should be taken, as poor hygiene can lead to local infections.
6.7 Cleansing

Cleanliness of the injection site should be ensured before giving the injections. **Cleansing is the single most important procedure for preventing healthcare-associated infections.** The injection site may be thoroughly cleansed either with cotton balls dipped in water or with alcohol swabs. Cleansing should be started in the middle and moving outwards in a circular motion, whole area of the injection site should be properly cleansed. Alcohol on the skin should be completely dry before injection. It is not necessary to use cleansing agents if the site is already ‘socially clean’.

6.8 Skin-folds

Injections into skin-folds are considered when the presumptive distance from skin surface to muscle is less than the length of the needle (see Fig. 4a). Lifting a skin-fold at the abdomen and thigh is relatively easier than in the buttocks, and is virtually impossible in the arm. Ideally, the thumb and index finger are used to lift a skin-fold properly (possibly with the addition of the middle finger, see Fig. 4b). Use of whole hand while lifting the skin risks lifting muscle and can lead to intramuscular injections. Use of skin-fold avoids soft-tissue compression and prevents the penetration of drug to a level deeper than intended.
6.8 Lifting skin-folds

- Injection site should be examined to decide whether lifting a skin-fold is necessary for the given length of needle. A3
- The recommendation should be provided to the patient in writing. A3
- People with diabetes and caregivers should be taught the correct technique of lifting the skin-fold from the onset of injectable therapy. A3
- The lifted skin-fold should not be squeezed so tightly as to result in skin blanching or pain. A3
- Indenting the skin should be avoided, as it makes needle penetrate deeper than intended. B3
- The optimal sequence to perform a lifted skin-fold should be: A3
  - Make a lifted skin-fold
  - Insert needle into the skin at 90° angle
  - Administer insulin
  - Leave the needle in the subcutaneous tissue for 10 sec after the plunger has been fully depressed
  - Withdraw needle from the skin
  - Release skin-fold
  - Dispose of the used needle or syringe safely

6.9 Systematic rotation of injection sites

Systematic rotation of the injection sites is important, as it:
- helps maintain healthy injection sites
- optimises insulin absorption
- reduces the risk of lipohypertrophy
A common and effective scheme is to divide the injection site into quadrants (abdomen) or halves (thighs, buttocks and arms) (see Fig. 4f). One quadrant or half should be used for one week and then move either in a clockwise or anticlockwise fashion to another quadrant or half next week. Proper and consistent rotation of the injection sites safeguards normal subcutaneous tissue. Dummy dolls and paper aids can be used to explain proper rotation techniques.

### 6.9 Rotation of injection sites

- An easy-to-follow rotation scheme should be taught to the patients from the onset of injection therapy. A2
- Dividing the injection site into quadrants (or halves when using thighs or buttocks), using one quadrant per week and moving always in the same direction, either clockwise or anticlockwise, has been proven to be effective. A3
- Injections within any quadrant or half should be spaced at least 1 or 2 cm apart to avoid repeat-tissue trauma. A3
- Rotation scheme should be audited during every visit and advice is to be provided where needed. A3

### 6.10 Injection technique

#### 6.10.1 Syringe and vial

A syringe is the primary injecting device commonly used in India. While injecting insulin, one should confirm the following points:

a. Ensure that the insulin is at room temperature; it should be taken out of refrigerator 30 minutes prior to injection. Before use, insulin bottle should always be inspected for expiry date, possible damage to bottle, and possible spoilage of insulin.

Twelve steps are to be followed while injecting insulin:

**Step one**
Wash your hands.

**Step two**
If you are taking cloudy insulin, inspect the contents for any changes, such as clumping, frosting, or precipitation. Roll the bottle between your hands until it is uniformly cloudy. Never shake a bottle of insulin

**Step three**
Wipe the top of the insulin bottle with an alcohol swab

**Step four**
Draw air into the syringe equal to the dose of insulin you wish to take.

**Step five**
Pierce the rubber stopper of the insulin vial in the middle at a 90° angle and push the air in.

Avoid touching the metal rim on the bottle with the needle tip.

**Step six**
Holding the bottle upside down, slowly and steadily draw the dose into the syringe. Once the required dose is drawn into the syringe, the syringe and the vial should be turned back over. Holding the syringe by the barrel, the needle should be carefully removed.
Step nine
Clean the injection area with an alcohol swab. Start in the middle of the area and then moving outward in a circular motion, clean the whole area.

To reduce any stinging, be sure that the alcohol on the skin is completely dry before you inject.

Step ten
Next, gently pinch up the area of the skin between your thumb and the index finger.

Push the needle through the skin. Slowly push the plunger in to inject the insulin.

Step eleven
Count till 10 before pulling the needle out. Wait an additional while in case of larger doses.

Release the pinch-up (only after the needle is taken out of the injection site) and press an alcohol swab over the injected spot. Do not massage the area.

Press your finger or an alcohol swab over the spot you gave your injection.

Step twelve
Clip off the syringe needle with safe clip.

Put out the used syringe into a sharps collector or hard plastic or metal container with a screw-on or tightly secured lid.

Ideally, a needle should never be re-used.\cite{22,35}

straight out of the bottle (see Fig. 5).\cite{15}

While keeping the syringe in the upright position, air bubbles should be looked for. If present, air bubbles should be removed by drawing up several more units of insulin and re-injecting the bubbles into the vial by pushing the plunger back to the desired dose marking. If bubbles are still present, insulin should be slowly pushed back into the vial and the desired number of units should be again drawn by pulling the plunger very slowly. The process should be repeated until no air bubbles are present in the syringe.

Step seven
Ready for injection. Place the syringe on the table carefully without letting the needle touch the surface.

Step eight
Select the site.
6.10.1 The correct use of syringes

- Check insulin vial for type and expiry date. A1
- **Ensure that right insulin syringe is used with the right strength of insulin in use (e.g. U-100 vial with U-100 insulin syringe).** A1
- During initial step of drawing insulin, the air equivalent to the dose should be drawn up first and injected into the vial. A3
- If air bubbles are seen in the syringe, tap the barrel to bring them to the top and then remove the bubbles by slowly pushing up the plunger. A3
- Mix cloudy insulin by rolling between the palms 20 times till the solution is mixed uniformly, but do not shake. A3
- Syringes should ideally be used only once and never be reused. A2
- Dispose used syringes safely after use. A1
- **The injection site should not be massaged.** A3

6.10.1.1 Mixing insulins

For a mixed dose, care should be taken to follow the right sequence of mixing. Regular insulin should be filled first followed by NPH insulin. Reversal of this order can contaminate the regular insulin vials:

- Steps 1–12 would be similar for this too, however, care should be taken while mixing the insulins.
- One must ensure that right number of insulin units has been drawn, as the insulin cannot be pushed back into the vial.35

The following steps should be followed while mixing insulins (see Fig. 6):

**Step one**
Draw air into the syringe equal to the dose of cloudy insulin desired.

**Step two**
Insert the needle through the rubber stopper of the cloudy insulin vial, and inject the air into it; this will make it easier to draw back the insulin later. Then remove the needle without drawing up the cloudy insulin.

**Step three**
Pull the plunger back to the dose of regular insulin desired, inject the air into the clear insulin vial.

**Step four**
This time, leave the needle in the bottle, turn the vial upside down and slowly draw the desired dose of regular insulin. If you see air bubbles in the syringe, draw up several more units of insulin and re-inject the bubbles into the vial by pushing the plunger back to the desired dose. Now remove the needle from the vial.

**Step five**
Holding the bottle upside down, insert the needle through the rubber stopper of the cloudy insulin vial, and pull the plunger back to the marking that indicates the total dose of insulin. Be sure you have the right number of units because you cannot push any insulin back into the vial.

**Step six**
The mixed insulin is now ready to be injected. Follow the step-by-step procedure mentioned in the previous section to administer the insulin.

Fig. 6: Mixing insulin.
6.10.2 Mixing insulins Recommendations

Although a wide range of pre-mixed insulin preparations is available, preparing split-mix insulin, by mixing rapid- or short- and intermediate- or long-acting insulin, may be necessary at times. Admixture of such combinations is needed in some patients to maintain euglycaemia. The formulations and particle size distribution of insulin preparations vary, and on mixing, physicochemical changes may occur in the mixture either immediately or over time. This may result in variations in physiological responses to admixtures of insulin, as compared to both component insulins being injected separately.

- Human short-acting (regular) insulin can be mixed with intermediate-acting insulin (NPH) in the same syringe in any ratio, as desired.
- When rapid-acting (lispro, aspart and glulisine) and NPH are mixed, a slight decrease is seen in the absorption rate, but not in the total bioavailability. However, in clinical trials, postprandial blood glucose response was similar with this combination.
- It is advised not to mix glargine (which has an acidic pH) with any other insulin; the time/action profile of glargine may change and precipitation of the preparation may occur.

6.10.2 Correct use of pen devices

- Priming of pen devices is essential (observing at least a drop at the needle tip) and should be done according to the manufacturer's instructions before each injection.
- Pen devices and cartridges are for single person use and are never to be shared with others as this increases the risk of cross-contamination.
- Pen needles should ideally be used only once, and never be reused.
- Use of new needles each time reduces the risks of needle breakage in the skin, clogging of the needle, inaccurate dosing, and indirect costs.
- Hold for 10 seconds after pushing the thumb button in completely or before withdrawing the needle. This ensures delivery of full dose and prevents the leakage of insulin.
- Do not leave needles attached to the pen. This prevents entry of air and other contaminants into the cartridge. Moreover, leakage of insulin, which can affect the subsequent dose accuracy, is prevented.
- The injection site should not be massaged.

6.10.3 Pens

The method of device preparation is the same for both reusable and pre-filled disposable pens. In case pre-mixed insulin is being used, one should ensure that the insulin has been resuspended by rolling the pen. The edge of the pen should be cleaned with a swab, and a new pen needle screwed on. Insulin pen should be primed with two units of insulin as the first step. It should then be discarded and the actual dose should be dialed in. The appropriate dose dialed can be seen on the device’s display window and can be heard as audible clicks in many pen devices.

The selected injection site should be cleaned with an alcohol swab by starting in the middle of the area and then moving in a circular motion outwards. Stinging may be reduced by ensuring that alcohol on the skin
6.11 Injection–meal time gap: Recommendations

- Timing of insulin injection is critical for proper metabolic control. A1
- The appropriate injection -meal time interval should be followed to enhance the glucose-lowering effect. B2

The pen needle should then be removed from the pen and disposed safely. It is advised to release the pinch up only after the needle is taken out of the injection site. It is advised to remove and dispose the needle immediately after injection, instead of being left attached to the pen. This will prevent the entry of air into the cartridge as well as leakage of the medication, which can affect subsequent dose accuracy.

6.11 Injection–meal time gap

The efficacy of insulin may be affected by the time gap between injection and meal. Hence, the timing of injection with respect to meal is critical in controlling glycaemic levels. Patients should always follow physician’s advice.

6.11.1 Short- and rapid-acting insulins

Ideally, human short-acting (regular) insulin should be administered 30 minutes before meal as it has a delayed onset, whereas rapid-acting insulins (lispro, aspart, and glulisine) can be injected before or immediately after a meal. The efficacy of insulin may be accentuated or reduced by altering the time gap between insulin injection and meal, hence modulating the glucose-lowering effect. Such a strategy should be practiced only under a physician’s guidance.

6.11.2 Intermediate- and long-acting insulins

Intermediate- (NPH) and long-acting insulins (detemir and glargine) should be injected at the same time every day, but need not be related to meal times. The ultra-
long-acting insulin degludec can be injected at any
time, without regard to timing of meals, or timing of the
previous day’s injections.

6.11.3 Glucagon-Like Peptide-1 Receptor
Agonists (GLP-1RAs)

Various GLP-1RAs are now available, which are
administered by different injection techniques. Exenatide
is administered twice-daily, 30 minutes before meals.
Liraglutide is injected once-daily, without regard to meal
timings. Some physicians advise liraglutide at bedtime to
reduce gastrointestinal discomfort. Long-acting release
(LAR) exenatide is injected with a 23 gauge needle, once a
week, at any time of the day. Dulaglutide and albiglutide
are also injected once a week with 29 gauge needle.

6.12 Troubleshooting

6.12.1 Pain

Patient adherence to insulin therapy is often affected
by the pain following an injection. Pain due to insulin
injection is infrequent, unless the needle irritates the
nerve endings. Some patients exhibit needle phobia or
increased sensitivity to pain due to previous undesired
experiences. Good injection practices can minimise or
avoid injection-associated pain.\textsuperscript{14,42}

6.12.2 Local Site Reaction to Subcutaneous
Insulin Injection

- Lipodystrophy
  - Lipo hypertrophy (LH): A thick soft to firm
    swelling with ‘rubbery’ consistency
  - Lipo atrophy/Lipodystrophy: A scarring lesion
    with depression
- Amyloidosis
- Bruising and bleeding

6.12.2.1 Lipo hypertrophy

Lipo hypertrophy, often caused by repeated reuse of
needles, manifests as a localised lesion at the repeated
injection site. \textbf{Chronic reuse of needles and injections at}

\begin{itemize}
  \item Appropriate messaging: Convey the benefits of
    insulin in a positive manner
  \item Appropriate site selection and preparation
  \item Appropriate device selection
    \begin{itemize}
      \item Thin gauge needles
      \item Short needles
      \item Pens requiring less pressure
      \item New needle for each injection
    \end{itemize}
  \item Appropriate dose selection: Consider splitting
    doses in persons with high insulin requirement
  \item Appropriate insulin selection
    \begin{itemize}
      \item Consider U-100 insulin in persons with high
        insulin requirement
      \item Consider insulins with neutral pH if patients
        complain of pain with acidic pH insulins
    \end{itemize}
\end{itemize}

\begin{itemize}
  \item Allow insulin to reach room temperature before
    injecting
  \item Allow alcohol to dry before injecting insulin
  \item Do not raise a tight, blanched, or painful skin fold
  \item Inject slowly
  \item Avoid injecting at hair roots
  \item Avoid intramuscular and intradermal injections
  \item Avoid injecting over bruised or traumatised sites
  \item Do not move the needle while injecting
\end{itemize}

\begin{itemize}
  \item Follow a systematic rotation policy
  \item Release skin fold (if raised earlier) slowly
  \item Do not massage the injection site
  \item Feel happy; insulin is a life-saver.
\end{itemize}
the same site may result in localised lipohypertrophy, or degeneration and atrophy (see Fig. 9). Patients tend to inject frequently in the lipohypertrophic sites because of reduced pain sensation. Injecting into lipohypertrophic sites may result in significantly unpredictable and delayed absorption which can lead to hyperglycaemia and/or hypoglycaemia. Further, unnecessarily larger doses may be used in such cases.\textsuperscript{14,43} Thus, in patients with uncontrolled diabetes, the sites of insulin injection should be inspected and palpated before making significant changes to the dose or type of insulin.

A study showed that combined intervention of injection technique and injection site assessment by trained HCP followed by general and individualised injection technique education to avoid lipohypertrophy and use correct rotation along with switch to 4 mm needles lead to:

• Almost 0.6% (0.58%) mean fall in HbA1c in 3 months
• Mean fall in fasting plasma glucose of 14mg/dL
• Reduced insulin daily dose of 2 units

These results are highly significant to patients and clinicians as correct insulin technique can:

1. Reduce the risk of complications significantly
2. Support well-being and satisfaction of patient
3. Support treat to target Hb1Ac whilst minimising need for additional insulin\textsuperscript{12}

6.12.2.1 Lipohypertrophy (LH)

**Definition:** A thickened, soft, firm, ‘rubbery’ swelling

**Prevalence:** High
• Diagnosis: By inspection and palpation
• Raised swelling
• Swelling which cannot be pinched together

**Etiology:**
• Repeated trauma to same site (non-rotation)
• Repeated use of same needle (non-change)
• Insulin per se: anabolic effect

**Associated factors:**
• High daily insulin requirement
• Frequent insulin injections
• Basal-bolus therapy

**Clinical relevance:**
• Reduced absorption of insulin\textsuperscript{45}
• Erratic absorption of insulin—High glycaemic variability\textsuperscript{45}
• Sudden reduction in insulin requirement when injections are administered at normal sites

**Prevention/Management**
• Regular inspection and palpation of insulin sites\textsuperscript{45}
• Do not reuse needles\textsuperscript{45}
• Follow correct site rotation policy\textsuperscript{45}
• Use larger injection surface areas
• Do not inject into LH sites
• Reduce dose of insulin in habitual LH site injections when shifting to normal SC tissue
• Rule out LH as a cause of poor glycaemic control, hypoglycaemia and high glycaemic variability

6.12.2.2 Bleeding and bruising

Occasional bleeding or bruising may occur due to reuse of needles. A change in the needle length or other injecting parameters may not alter the frequency of bleeding or bruising. Clinical studies have reported that shorter needles are associated with less frequent bleeding and bruising incidents. Bleeding and bruising appear to have no adverse clinical consequences for the absorption or action of injectable therapies.\textsuperscript{14}

6.12.2.3 Amyloidosis

Amyloidosis is a systemic or local disease in which amyloid substances are deposited extra-cellularly and impair tissue function.\textsuperscript{44} It has been shown that local
Amyloid deposition very infrequently takes place at the site of repeated insulin injection in patients with insulin requiring diabetes.\textsuperscript{45-47}

The nature of amyloid in the insulin injection site is considered to be insulin itself or insulin-related substance and has been identified as amyloid insulin type (A Ins).\textsuperscript{46-50}

In reported cases of insulin-induced amyloidosis, it took from 8 to 17 years of insulin injection history for the discovery of a mass of 3–7 cm in size in either the thigh or abdominal wall.

Blood glucose control improves markedly shortly after resection of the tumour or after the change of the injection site. The presence of the amyloid mass itself, perhaps due to poor penetration of insulin, may contribute to insulin resistance.\textsuperscript{51}

### 6.12.3 Trypanophobia (Belonephobia)

The fear of self-injecting insulin compromises glycaemic control and emotional well-being. Similarly, the fear of pricking can be a source of distress and may seriously hamper self-management. Needle phobia may be associated with the following factors:\textsuperscript{11,14}

- A perceived loss of control over life
- A lack of confidence that the demands of insulin therapy will be handled
- A belief that insulin therapy equates to a personal failure
- A perception that the diabetes had become much worse
- Injection-related anxiety
- A perceived lack of personal gain.

### 6.12.2 Tips to prevent bleeding and bruising

- If bruising occurs persistently, injection technique must be reviewed. A2
- Sites with bleeding and bruising should be avoided until fully recovered. A2
- To prevent bleeding and bruising, avoid injecting into blood vessels and hair roots. B2
- Patients are to be assured that bleeding and bruising do not appear to have adverse clinical consequences for the absorption of insulin or for overall diabetes management. A2
- Do not reuse needles. A2

### 6.12.3 Tips to win over needle phobia

- Patient's personal obstacles should be identified and acknowledged. A2
- Patient's sense of personal control has to be re-established with a brief trial of insulin therapy if he/she opts to continue injections. A2
- Expeditious follow-up of dose adjustments is important once the injection has been restarted. A2
- Psychological counselling should be considered for patients who are really needle-phobic. A2

### 6.12.4 Needle-stick injuries

Needle-stick injuries commonly occur while recapping needles. Safety needles effectively protect health professionals against contaminated needle-stick injuries. Education and training are needed to ensure that safety practices are followed.\textsuperscript{14}
6.12.4 Clinical safety

- Safety needles should be recommended whenever there is a risk for a contaminated needlestick injury. B1

* Occupational Safety & Health Administration (OSHA) standards required healthcare facilities to “reflect changes and technologies that eliminate or reduce exposure to blood borne pathogens”. (https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051)

* In needle-based safety devices, safety mechanism is built into the needle to prevent needle stick injury in order to reduce or eliminate such a risk.

- Use of shorter needles without a skin-fold should be recommended as most safety mechanisms will not protect against needle sticks through skin-folds. A2

- Use of an angled approach rather than a skin-fold should be preferred if there is a risk of intramuscular injection. B3

6.12.5 Injection through clothing

Injection through clothing is a common practice among patients, especially when in hurry, or in a public place. This practice should, however, be firmly discouraged, as:

- The needle becomes unsterile and can cause infection.

- It is difficult to perform a pinch-up correctly when injecting through clothing.

- Injecting through clothing removes the lubrication in the needle, making injection more painful.

- Cleaning and inspection of the site before and after injection for bleeding, insulin leakage or injection are not possible when injecting through clothing.

- Fibres from the cloth may enter the skin and cause irritation.

6.12.6 Needle/Syringe hygiene

Needle reuse causes the blunting and bending of the needle tip, increasing the risk of:

- Bleeding, bruising or scarring
- Dosage inaccuracy
- Lipohypertrophy
- Healthcare professionals should create awareness in patients regarding the potential adverse effects of needle reuse, and discourage this practice. A2

6.12.5 Tips to prevent injection through clothing

- Injecting through clothing is not recommended. A3
- Injection practices are to be reviewed and addressed regularly. A3
6.12.6 Needle/syringe hygiene

The United States Food and Drug Administration (USFDA) recommends injection needles for a single use only. Syringes should ideally be used only once. On the contrary, in India, patients often reuse syringes and needles for economic reasons. It is advised to counsel such patients about the potential hazards of reuse while explaining the technique of single-handed scoop recapping the needle cover aseptically after each use [although against National AIDS Control Organisation (NACO) recommendations]. The importance of not sharing syringes between individuals should also be emphasised. HCPs should adopt a pragmatic approach on this issue.

Following aspects of reusing the needles should be discussed with patients:

- When reusing, the thin tip of the needles gets damaged, needles bend, and the silicone lubricant coating of the needles is also lost (see Fig. 10). All these contribute to a more painful injection, with bleeding and bruising. Repeat usage can also result in breaking off and lodging of the needles under the skin. Furthermore, there is a higher chance for insulin to get deposited within the needle with reuse, making it harder to press on the plunger and deliver proper insulin doses.

- Reuse of needles increases the risk of contamination and infection. In an attempt to be hygienic, some patients clean the needle with alcohol prior to reusing it. This practice removes the silicone lubricant and results in a more painful injection. This practice should be discouraged.

- Repeated use of insulin needles can also result in damage to the tissues and an increased risk of lipohypertrophy.

- Insulin pen delivery systems, when used properly, are extremely accurate. Improper use of pens with needles left attached after use bears more chance for air to pass into the insulin chamber and an increased risk of contamination. Furthermore, there is a higher chance for dosage inaccuracy due to air bubble formation. Hence, manufacturers recommend removing insulin pen needles immediately after use.

6.13 Recommendations for periodic clinical audits

- Periodic clinical audits should be performed to ensure that administration of injections is according to the prescribers’ instructions. A2
- Nurses and other HCPs should be aware of the actions, contraindications and side-effects of the drug. A2

Fig. 12: Safe disposal of injection devices.

6.13 Periodic clinical audits

A periodic audit of injection practices in diabetes patients by their clinicians is highly recommended. Such a practice helps in determining patient knowledge about the correct administration of insulin and ensuring that patients are using the correct injection sites and correct injection technique. Mutual audits can be performed in pairs by members of diabetes clubs or patient organisations.
6.14 Safe disposal of injection devices

- Awareness of local regulations should be created among patients and healthcare professionals. Legal and societal consequences of nonadherence should be reviewed. A3
- Patients should be educated about correct disposal right from injection initiation and this should be reinforced throughout the therapy. A3
- The patient’s family members, especially children, and service professionals (rubbish collectors and cleaners) should be made aware of potential risks. A3
- Sharp materials should never be disposed off in public trash bins or areas. A3
- Empty pen devices can be disposed in household refuse bins. B2

6.14 Injection device disposal

According to the recommendations developed by NACO, it is recommended to collect the used needles or syringes in a puncture proof box or safety box, labelled as ‘biohazard’. When filled, these boxes should be handed over to appropriate centres such as waste management agencies, medical colleges, or hospitals, wherein disinfection and disposal of sharps are carried out. Needle clipping devices that remove insulin syringe needle and pen needles safely and easily should be used (see Fig. 12). Many people in India do not have access to sharps disposal devices. An easy and practical method is to collect used sharps, including needles and lancets, in a strong cardboard/glass container, label and seal it, when full, and dispose it off at the nearest healthcare facility.

Public facilities should be encouraged to provide sharps disposal devices in restrooms and retiring areas.

6.15 Missing injections: Recommendations

- Patients should be made aware of the consequences of missing injections. A2
- If there is a change in the insulin, then the patient should be fully informed as to why there has been a change and the potential need for additional glucose monitoring. A3
- Insulin species, type or brand name should not be changed unless absolutely indicated. A2

6.15 Missing injections

Insulin injections may be missed by patients either by design or because of unavoidable circumstances. All patients should be counselled about the negative effects of missing injections. In case of extreme scarcity of insulin, insulin rationing may have to be resorted to. However, both physicians and patients should be made aware of the harmful effects of such a practice. No pharmacist or other HCP should make any change in the insulin species, type or brand without the approval of the prescribing physician. Any change in the insulin therapy should be conveyed to the patient. If a patient is admitted in hospital and there is uncertainty about his current insulin regimen, human insulin should be administered until further information is available. In case the patient-specific brand of insulin is not available, the same insulin formulation from another manufacturer can be substituted. This should always be done under medical supervision.

6.16 Special populations

6.16.1 Pregnancy

Insulin is required in about 10–20% of all antenatal women with diabetes, which complicates about one-sixth of all pregnancies. Patients should be reassured that insulin is not only safe in pregnancy, but also contributes to maternal and foetal well-being.

The abdomen is a safe site for insulin administration in pregnancy.
6.16 Recommendations in special situations

6.16.1 Pregnant women

- In pregnant women, injections should be given into the abdomen using a raised skin-fold. B2
- Alternative sites may be used during the last trimester in apprehensive patients C3

6.16.2 Elderly

- Assessment of dexterity and strength of cognition, vision, and hearing is recommended before therapy initiation and during follow-up. A2
- Encourage the use of insulin pens as elderly patients find them easier to use. A2
- Caregivers should be educated about the importance of injection technique as well as hypoglycaemia treatment and prevention. A2
- Caregivers should be aware of the important features of the pen device such as adequate length of the device, dial visibility and ease of recapping the pen. A3

6.16.3 Sensory motor impairment

- Use of injection devices with preset doses and easy handling features benefit patients with reduced dexterity. A2
- Pre-filled syringes may be recommended for patients who have both visual and dexterity impairment. A2
- For hearing-deficit patients, instructions should be given in a well-lit and noise-free room. A2

6.16.4 Immunocompromised individuals

- Never reuse needles, syringes or lancets as there is a high risk of transmission of blood-borne pathogens (HIV and hepatitis). A2

First trimester: Women should be reassured that no change in insulin site or technique is needed.

Second trimester: Lateral parts of the abdomen can be used to inject insulin, staying away from the skin overlying the fetus.

Third trimester: Insulin can be injected over the abdomen while ensuring the skin fold is properly raised. Apprehensive patients may use the thigh or upper arm to inject themselves.

6.16.2 Dermatological Disease

Insulin injection should be avoided at sites of active or recently healed infection or inflammations, such as skin and soft-tissue infections and psoriasis. Injection should not be administered into keloids or scars. However, stable vitiligo is not a contraindication for insulin injection. Acanthosis nigricans is also not a contraindication.

6.16.3 Surgical Disease

In patients with recent surgical wounds or open fistulas/ileostomies/colostomies, a different quadrant of the abdomen should be used for insulin injection. Adequate pre-injection cleansing must be done.

Apprehensive patients with recent abdominal surgery may use the thigh or upper arm for injection.

6.16.4 Elderly

Impairments in dexterity, cognition, vision and hearing are common in elderly patients. It is recommended that elderly patients should be assisted by a caregiver and the importance of injection therapy as well as prevention and treatment of hypoglycaemia should be emphasised.
6.16.5 Sensory motor impairment: Visual, tactile and lack of manual dexterity

In visually impaired patients, non-visual insulin measurement devices, syringe magnifiers, needle gauges and vial stabilisers help ensure accuracy and aid in insulin delivery. In patients with both visual and dexterity impairment, pre-filled syringes may be helpful. Pens which require low pressure for plunging should be preferred.

In patients with low hearing and those who use hearing aids, therapy-related discussions should be conducted in a noise-free environment or at a place with very low or no background noise. The instructor should face the person with sufficient light falling on his/her face which facilitates lip-reading. In addition, speaking slowly and clearly with normal intonation will also be a benefit. In people with dexterity problems, use of injection devices with preset doses and easy featuring devices may be beneficial.

6.16.6 Immunocompromised individuals

Hypoglycaemia is a major concern in some immunocompromised patients, including those with HIV and hepatitis. Hence, early initiation of insulin therapy should be considered in immunocompromised patients, as it improves therapeutic outcomes. Personnel giving injections and those handling the sharp material are at high risk of exposure and transmission of blood-borne pathogens (HIV and hepatitis) through injections and finger-sticks administered to affected patients. Therefore, needles, syringes or lancets should never be reused.

6.16.7 Indoor patients/Nursing home patients

Patients who share their cold chain facilities, such as refrigerators, with others, as in hospitals, nursing homes and old age homes, should label their insulin vials and pens with their names and/or bed numbers.

6.17 Insulin Pump Infusion

The insulin pump is a pager-sized device, which provides continuous subcutaneous delivery of rapid-acting insulin with the help of an infusion set. One end of the infusion set connects to the reservoir, which is filled with insulin and is kept inside the insulin pump and the other end of the infusion set is connected to the needle placed subcutaneously.

In India, unlike in the Western world, pumps are more commonly used in type 2 diabetes. As an alternative delivery system, insulin pumps are a replacement for syringes/pens, provided the subject fulfills the essential criteria for a pump candidature. Since there are no reimbursement policies for pump users in India, most of the subjects have innovated and improvised their own ways and means of reducing the cost by prolonging the use of infusion sets and reusing reservoirs.

Such peculiar circumstances have created an urgent need for formulating insulin pump infusion recommendations. These need to be customised for the Indian subcontinent, considering education, ethnicity, dressing styles, resources and weather, while at the same time ensuring clinical efficacy and avoidance of infections.

6.17.1 Infusion site

The preferred infusion site for pumps is the abdomen, while the upper arm and thighs are alternate sites. Select a site in the abdomen 5 cm away from the umbilicus and every new site should be 2.5 cm away from the previous site. Following a systematic pattern will help ensure that the longest possible time will pass before using the same site again. In pregnancy, the outer thigh or hip may be used.

6.17.2 Cannula selection

Plastic cannulae are preferred by almost all doctors recommending an insulin pump. Steel needle infusion
sets are recommended in pregnancy, for patients who have reactions to plastic cannulae and who have frequent kinks in plastic cannulae. Short length cannulae (6 mm for 90° sets, 13 mm for 30–45° angled infusion sets) are most preferred. Shorter tubing is recommended for most patients while longer tubing is preferred by patients who feel comfortable keeping the pump in the socks or underneath the pillow while sleeping.

6.17.3 Angle of insertion
Insertion angle 90° is widely used by pump users. 30° to 45° angles are preferred by dexterous lean or muscular patients and pregnant women.

6.17.4 Selection of infusion sets
The most popular infusion set is a 90°, soft cannula infusion set. Variable angle, soft cannula infusion sets are also available for patients who are lean or lead an active lifestyle. Steel needle infusion sets and 90°, soft cannula infusion sets that combine the infusion set and insertion device into one unit are also available.

6.17.5 Troubleshooting

6.17.5.1 Adhesive tape allergy
This is extremely rare in Indian scenario and the use of oral antihistaminics for a few days usually suffices. Though there is a possibility of acquiring alternative adhesive materials, in practice, only few patients will require them.

6.17.5.2 Infusion site infection prophylaxis
The infusion site must be clean and dry before insertion of the cannula. Washing the site with an anti-bacterial soap or solution is sufficient. Changing the infusion set once in every 2–3 days is recommended. In India, most of the pump users retain the same infusion set for 5–7 days due to the high cost of consumables. With this practice, the potency of insulin will be lost; there are chances of the site getting infected as well. Customised advice and recommendations are to be made based on affordability, work pattern and level of education.

6.17.5.3 Lipohypertrophy
Lipohypertrophy has been described in the earlier part of the recommendations.

6.17.5.4 Loss of Insulin potency
If patients use the same reservoir and insulin for more than the recommended 3 days, the potency of insulin may be compromised. If patients fill the reservoir with fresh insulin without changing the infusion set, adequate instructions have to be given by the diabetes care team. For subjects living in extremely hot environments, pump may not be a suitable option.

6.17.5.5 Pump occlusion
If there is any block in the pump, the smart pumps will give out an alarm. The newer cannula rarely kink and block. If occlusion persists, the cannula and infusion set have to be changed.

6.18 Disaster management

6.18.1 Recommendations
• Patients should be educated about the importance of disaster management. A2
• Supplies adequate for 30 days should be kept ready in the disaster kit. A2
• The disaster kit should be personalised for each patient. B3
• The disaster kit should be kept in a handy spot, ready to go. A3

Avoiding or missing insulin therapy in persons with type 1 diabetes can be life-threatening. Hence,
disaster planning is essential and should include the precautionary steps to be taken if a disaster strikes. A portable, insulated and water-proof diabetes disaster kit should be kept handy. The kit should have a supply of insulin syringes for at least 30 days and insulin vials or pens and needles along with cold packs. In addition, it should also contain blood-testing supplies including lancets, test strips and a glucose metre (preferably two) with extra batteries. A separate sharps container for the disposal of lancets and needles should also be included. At least a three-day supply of nonperishable food and bottled water is also recommended.11

6.19 Barriers to insulin therapy

Patient-related barriers

- Several myths, misunderstandings and negative approaches act as barriers in the use of insulin among type 2 diabetes patients.9
- Clinicians may help patients discuss their concerns by asking open-ended and nonjudgmental questions: Effective solutions can thus be found and implemented.
- Encouraging shared decision-making with active participation of the patient is important.
- Giving patients a sense of control over their treatment plan improves acceptance and enhances adherence.

Physician-related barriers

- Physicians are often concerned about the patient-related barriers in early initiation of insulin therapy.
- Physician-related barriers include concerns about adherence and the patient’s perceived adverse effects of hypoglycaemia and weight gain, lack of supporting staff and counselling/motivational skills, and the desire to prolong non-insulin therapy.
- Physicians have a misconception that insulin therapy is expensive; however, insulin therapy actually reduces costs by decreasing complication rates and management burden.

Health care system-related barriers

- Lack of resources also acts as an important barrier in insulin therapy. A financial barrier exists for patients who lack insurance.
- For HCPs, lack of trained diabetes educators is an important issue.
- This can be linked to the lack of resources, ability and/or facilities for training diabetes educators.
- Use of reusable insulin pens; providing training to HCPs; and hiring a diabetic educator and setting up an educational programme may be helpful in increasing the availability and lowering the cost of insulin therapy.54

6.20 Pharmaceutical factors influencing adherence to insulin

Drug-related factors

- Appropriate insulin regime
- Appropriate insulin dose
- Efficacy
- Safety (no or minimal hypoglycaemia)
- Tolerability (no weight gain)
- Flexibility (in timing of injection)
- Consistency (in action profile)

Device-related factors

- Ease of use
- Ease of carrying
- Social acceptability
- Ease of maintenance

Barriers to initiating and adhering to insulin therapy include a comprehensive range of obstacles relating to patients, physicians and healthcare systems. Success of self-management of diabetes largely depends upon careful identification and correction of such barriers (see Box 6.20).
6.20 Improving adherence

Counselling forms an integral part of diabetes management. Counselling about drug-, patient- and physician-related factors can improve adherence to injection therapy. These factors are listed in Box 6.21.

The attributes of a good insulin injection technique counsellor are listed in Box 6.21.1.

Encouraging patients to ask questions and clarify doubts is important. Patient’s concerns should be acknowledged as they indicate active patient participation in the treatment process. Arranging periodic refresher sessions with patients is helpful in addressing any new issues that arise during the course of therapy. Additionally, motivational interviewing should be conducted in an individualised manner keeping in mind the unique make up of a particular patient. The message should be personalised and information relevant to the patient’s perspective should be provided.

The WATER approach, explained below, has been suggested to fulfill the purpose (see Table 6.21.2).

• The patient must be Welcomed Warmly in the clinic, from the outpatient counter on wards.

• The clinicians should Ask and Assess carefully making use of various cues and sequencing the questions appropriately.

• They should Tell Truthfully making use of metaphors analogies, keeping in mind both the verbal as well as non-verbal cues from the patient.

• They should Explain with Empathy, making use of experience sharing, practical demonstration and imparting coping skills training.

• Finally, the Clinicians must Reassure the patient and tell him/her to Return for any clarifications.

• Optimisation of insulin-related and device-related factors can help improve adherence to insulin therapy.

6.21 Ongoing patient and physician education

Educational sessions can be individualised or may be conducted in a group setting. Patients may not retain the information if they are anxious at the time of education sessions. It is essential to revisit all aspects of injection technique regularly. Enough time has to be provided to meet individual learning needs and the learning style of each individual has to be assessed beforehand. Information given in short sessions and regularly reinforced is more easily retained. Education content and the style of teaching have to be adjusted to individual needs.
6.20.1 Attributes of a good diabetes counsellor

- Confident competence
- Accessible authenticity
- Reciprocal respect
- Expressive empathy
- Straightforward simplicity

6.20.2 WATER approach

- Welcome warmly
- Ask and assess
- Tell the truth
- Explain with Empathy
- Reassure and return

6.21 Therapeutic education

- Before starting the injection therapy, the healthcare provider should ensure that patients understand each of these essential topics. A3
  - The injection regimen
  - The choice and management of the devices used
  - The choice, care and self-examination of the devices used
  - Proper injection techniques (including site rotation, injection angle and possible use of skin-folds)
  - Injection complications and how to avoid them
  - Optimal needle lengths
  - Safe disposal of used sharps

- Healthcare professionals should spend ample time exploring patient anxieties and other concerns about the injecting process and insulin itself. A3

- A quality management process should be put in place and made sure that the correct injection technique has been practiced regularly by patients and is also documented in the record. A3
Conclusion

The FIT India recommendations 2015 have been designed to address the needs of people with diabetes and HCPs in India. Their relevance, however, is glocal. i.e., global as well as local. These recommendations provide a reader-friendly, yet comprehensive, source of information for all stakeholders connected with injectable therapy for diabetes. It is hoped that the FIT India recommendations will contribute to improved glycaemic control in people with diabetes, in India, and across the world.

Duality of interest

The authors are members of FIT India advisory board, who have helped develop the Indian Insulin Injection Technique Recommendations 2015. FIT India is supported by Becton Dickinson India Private Limited (BD), a manufacturer of injecting devices. Members of the FIT advisory board have not received any honorarium from BD for their contribution to the recommendations. The Indian insulin injection technique recommendations 2.0 developed by FIT is a copyright of BD and shall be considered proprietary to BD India Private Limited, therefore limited to be disclosed or published solely by BD India Pvt Ltd.
Top 10 insulin injection recommendations

<table>
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<tr>
<th>Category</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>Needle length</td>
<td>1. All injectors including children, adolescents, adults and obese patients are recommended to use the shortest available needle length of 4 mm with insulin pens. A2</td>
</tr>
<tr>
<td></td>
<td>2. All injectors including children, adolescents, adults and obese patients are recommended to use the shortest available needle length of 6 mm with insulin syringes. A2</td>
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<td></td>
<td>3. An easy-to-follow injection site rotation scheme should be taught to the patients from the onset of injection therapy. A2</td>
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<td>Needle/syringe hygiene</td>
<td>4. Ideally, do not reuse needles. A2</td>
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<td></td>
<td>5. Use a new needle for each injection. A2</td>
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<tr>
<td>Lipohypertrophy</td>
<td>6. Injection site should be inspected at every visit. Patients should be taught to inspect their own sites and should also be given training on how to detect lipohypertrophy. A2</td>
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<td></td>
<td>7. The best current strategies to prevent and treat lipohypertrophy are to rotate the injection sites with each injection, using larger injecting zones and non-reuse of needles. A2</td>
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<tr>
<td>Injection sites</td>
<td>8. Injection should be given at a clean site with clean hands. A2</td>
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<td></td>
<td>9. Prior to the injection, the site has to be palpated for lipohypertrophy and inspected for wounds, bruises or blisters. If the injection site shows any signs of these, then a different site should be selected until the problem has been resolved. A3</td>
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<td>Safety issues</td>
<td>10. Safety needles should be recommended whenever there is a risk for a contaminated needle-stick injury. B1</td>
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