Forum For Injection Technique (FIT), India Recommendations
The Need For FIT India Recommendations
India: Diabetes Capital of the world?

In India, Diabetes under-diagnosed & under-treated
- Delay in initiation of insulin therapy
- Psychological resistance to Insulin

- 61.23 Million People With Diabetes
  - (51% Diagnosed)
  - 30 Million People With Diabetes (27% Treated)
  - 8.1 Million People With Diabetes

1-2 years:
- Diet & Exe + 1OAD

3 years:
- Diet & Exe + 2OAD

2 years:
- Diet & Exe + 3OAD

After 7 To 8 yrs (20% on insulin):
- 1.4 Million Patients On insulin

* IDF Data
Why is Diabetes under-treated in India?

Patients have a psychological resistance to adoption of insulin therapy in India
- Fear of needles
- Insulin considered to be the last incursion for someone with diabetes

A survey conducted in 708 Type 2 diabetes mellitus (T2DM) patients revealed:

- ~50% participants believed that initiation of insulin therapy would restrict their lives
- Of these, 28% were unwilling to begin insulin therapy
- 51% cited anticipated pain as a reason for their unwillingness
- ~40% reported a lack of confidence in complying with the injection routine.
- Of the total, 38.4% equated it with personal failure.

Need for Early Initiation of Insulin in T2DM

- Insulin provides better control over HbA$_{1c}$ than the other existing therapies.
- Early use of insulin has been shown to improve β-cell function.
- Short-term insulin treatment may have long-lasting effects when introduced in the early stages of T2DM.

Injection technique is critical to the therapeutic success of insulin.
Injection technique is critical to the therapeutic success of Insulin!

Improper use or reuse of injection devices may lead to undesirable consequences:
- Pain
- Bleeding
- Bruising
- Breaking & lodging under the skin,
- Dosage inaccuracy → poor glycemic control
- Lipodystrophy

The first insulin injection ever given to a human being was followed by severe reaction

So, Injection Technique is critical from the word ‘GO’!
The FIT India Recommendations
The Forum for Injection Technique (FIT): Objectives

Developed by health care professionals working in the field of diabetes

- To establish and promote best practice in injection technique for all involved in diabetes care
- To raise awareness of existing and emerging research relating to injection technique and the impact this may have on health outcomes for those with diabetes that require subcutaneous injection therapy.

FIT is an autonomous body, committed to promoting safe and best injection practices worldwide, supported by BD.

Established following the 3rd International Injection Technique meeting (Athens 2009) after a consensus was reached to establish the international injection technique recommendations.
The FIT India Recommendations

Designed to address the ‘Indian’ perspective of Insulin Injection Technique.

- Initiated by a core group
  - three endocrinologists
- Developed by a board of
  - 13 clinicians (12 endocrinologists / diabetologists & 1 Diabetes educator)
- Reviewed by
  - 76 clinicians from India
  - 6 clinicians from other South Asian countries
Psychological Challenges
What happens when a Dr advises Insulin therapy to a patient?
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Patients refuse insulin therapy due to
- Sense of distress/anxiety/frustration
- Fear of Needles,
- Sense of life-long dependence on Insulin
- Sense of failure to manage one’s diabetes
- Fear of weight gain
- Low self-esteem
- Interference with quality of life

No!!
NOT ME?!!!
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FIT Recommends
Patient counseling is important. Encourage decision-making with active participation of patient and their care-giver as appropriate.
Minimizing Challenges

- Employ the WATER approach
  - **Welcome** warmly,
  - **Ask** and assess the patient carefully,
  - **Tell** Truthfully,
  - **Explain** with empathy,
  - **Provide** Reassurance

- Acknowledge fears, concerns and try to resolve through effective communication that offers clarification

- Discuss benefits of injectable therapy as a solution to reduce risk of long term complications.
Adequacy of teaching method

- During patient interactions, instructions are rarely given on proper injection technique.

### Titan ITQ results*

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Adequacy of teaching method

During patient interactions, instructions are rarely given on proper injection technique.

**FIT Recommends**
Clinicians must emphasize choice of injection device and related specifications (needle length, site rotation & prevention of reuse) in prescriptions.

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*Note: ITQ stands for Improved Technical Questions.
What to educate?

- Choice & Management of devices
- Choice of injecting regimen
- Correct injection technique
- Optimal needle length
- Rotation, care and self examination of injection sites
- Injection complications: Prevention, detection & management
- Safe disposal of sharps and clinical waste
Pre-Injection Counseling

Adequate care and counseling of patients of different age groups, children, adolescents, adults and extend an individualized approach

- Showing adequate concern about the pain
- Providing options for flexible injection schedule.
- Emphasizing the long-term benefits of treatment adherence.
- While counseling children, keep parents calm and composed before any injection.
- Adopt cognitive behavioral therapies and appropriate choice of words
- Counseling adolescents on fears of weight gain, and consequences of skipping injections.
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FIT Recommends
Patients should be encouraged to discuss their injection-related concerns.
The Prescription

- It is essential to record the appropriate details of the insulin therapy in the prescription.

- Specifications – such as
  - Needle length,
  - U100/40
  - Dosage
  - Administration technique
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  - Needle length,
  - U100/40
  - Dosage
  - Administration technique

FIT Recommends
Emphasize the choice of injection device, needle length and gauge, and type of insulin syringe in the prescriptions.
05

Insulin storage & Suspension
Insulin Storage

- Insulin and GLP-1 agonist
  - in use is to be stored at room temperature
  - not in use shall be refrigerated
- Discard 30 days after initial use or follow manufacturers instructions
- Avoid freezing; if found frozen, discard.
- Store pre-filled insulin syringes with needle pointing up.
- Avoid extremes of temperature. i.e direct sunlight, leaving in a car/on top of a radiator, as it will make the medication less effective
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FIT Recommends

Prefer insulin pens over vials if cold facilities are inaccessible
Before the Injection!

Check

- Name and type of insulin, and follow manufacturer’s instructions on storage.
- Expiry date before use.
- Whether the dispensed insulin is the same as that prescribed
- Insulin must be clear. There should be no discoloration, cloudiness or particles
- Cloudy insulin must be cloudy. i.e., uniformly cloudy when resuspended

It may be useful to carry an ID card stating the name of the insulin/ GLP-1 agonist as a reference or in case of an emergency
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FIT Recommends
Prior to use, it is critical to examine the insulin bottle and ensure there are no changes in insulin
Insulin Re-suspension

- **Studies conducted** to evaluate the completeness of insulin resuspension by users indicated that **only one patient** out of all those who were evaluated, **mixed insulin according to the recommendation.**

- In 58 out of the 146 pens or cartridges tested, the suspension prepared, **varied significantly** from the expected value of opacity.

- This study indicated that there is an immense scope for emphasis on teaching patients on the correct mixing and preparation of suspensions.

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**FIT Recommends**
Correct resuspension technique has to be regularly evaluated.

Correct Re-suspension technique for Cloudy Insulin

Cloudy Insulin Re-suspension

- Roll 10 times
- Tip 10 times
- Visual check

Injection Process - Considerations
DID YOU KNOW?

- ITQ results* showed
  - 24% of patients leave needle in skin for >10 secs
  - 55% of patients leave needle in skin for 5–10 secs
  - 18% of patients leave needle in skin for <5 secs
  - 3% no data

- When skin-fold used
  - 54% of patients released skinfold before completing injection
  - this increases risk of IM injection
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FIT Recommends
Leave the needle in the subcutaneous tissue for at least 10 secs after the thumb button/plunger is fully depressed
How can you make insulin injections LESS painful?
How can you make insulin injections LESS painful?

- Consider splitting larger doses
- Insert needle in a quick smooth movement through the skin
- Use a new needle for every injection
- Inject slowly ensuring plunger/thumb button is fully depressed
- Insert the needle at 90° to the skin
- Use short needles with fine gauge
- If using alcohol swabs wait until fully dry before injecting

Keep injectable therapy in use at room temperature
Factors affecting absorption

- Size of dose
- Physical activity
- Ambient and body temperature

Factors Affecting Absorption

- Massaging sites
- Age
- Needle length
Injection Process - Pens
Insulin Pens – Pen device preparation

1. Check expiry date and type of insulin
2. Ensure there is sufficient insulin for dose
3. Re-suspend insulin if required
4. Attach new needle
5. Prime the device observing drop of insulin at needle tip
6. Dial desired dose
Injecting with the pen device

1. Choose the appropriate site for injection
2. Push the needle through the skin at 90° keeping thumb away from dosage button
3. Push thumb button down completely and count to 10 or follow manufactures recommendations
4. Remove needle from subcutaneous tissue
5. Remove needle from pen
6. Dispose of needle safely
Never Leave the Needle Attached to the Pen!

- Temperature and pressure changes may cause
  - Air bubbles to form in cartridge when cold
  - Insulin to leak out of cartridge when hot
- Leaking pre-mixed insulin can derange mixture ratio
  - This can lead to incorrect mixture and dosing

It is important to prevent the entry of air and other contaminants into the cartridge.

FIT Recommends
Always remove the needle from the pen device after injection
Correct Use of Pen Devices

FIT Recommends

• Following manufacturer’s instructions for priming the pen devices before each injection.

• Not sharing pen devices and cartridges with others.

• Not re-using pen needles.

• Not massaging the injection site.
Injection Process - Syringes
Correct Technique of Filling Insulin Syringes

Using a syringe: One insulin, one vial

1. Wash your hands
2. Wipe with alcohol swab
3. Draw air equal to the amount of insulin to be withdrawn
4. Push the needle through the stopper of the vial
5. Turn the insulin bottle and syringe upside down
6. Pull the plunger down slowly, to get the insulin into the syringe
7. Pull the syringe out of the bottle
Correct Technique for Insulin Injection

1. Make a skin fold using two fingers.
2. Hold the syringe at 90° and inject.
3. Count for 10 sec and release the pinch-up.
4. Turn the insulin bottle and syringe upside down.
5. Pull the plunger down slowly, to get the insulin into the syringe.
6. Pull the syringe out of the bottle.
Injection Site & Site Rotation
Insulin Injection Sites

- Anterior abdomen
- Anterior thigh
- Buttocks
- Upper arm
Systematic Rotation of Injection Sites

- Reduces the risk of lipohypertrophy
- Helps maintain healthy injection sites
- Optimizes insulin absorption
Importance of injection site rotation

- Studies reported that about 54.9% of children with Type I diabetes developed lipohypertrophy with repeated use of insulin injections in their arms.*

- Poor injection site care and inadequate site rotation could lead to malabsorption of insulin and can adversely affect glucose control.

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FIT Recommends
An easy-to-follow injection site rotation scheme should be taught to the patients from the onset of injection therapy.

What is Lipohypertrophy?

- Lipohypertrophies are thickened ‘rubbery’ lesions that appear over time in the subcutaneous tissue of injecting sites (especially insulin).

- Causes of lipohypertrophy
  - Long term insulin use
  - Improper site rotation
  - Improper care of injection site
  - Reuse of needles
Lipohypertrophy often develops slowly and insideously

ITQ Results showed that

- 54% of participants reported having lipohypertrophy at sometime in their life
- 47% in the adult group and 71% in the children and adolescent group
- 2.6% always inject into lipohypertrophy and 25.7% inject into them sometimes
- Only 46% of participants have their sites checked every visit
Risk Associated with lipohypertrophy

Implications of injecting into areas of lipohypertrophy

- Significant unpredictable and delayed absorption leading to possible hyperglycemia and/or hypoglycemia
- Malabsorption from lipohypertrophic sites may result in unnecessarily large doses of insulin use
Detecting Lipohypertrophy

Visual Check
Look for:
- Needle insertion points
- Small subcutaneous bruises
- Swellings/fatty lumps /depressions
- Hair loss

Palpation Check
Look for:
- Move finger across the injection site
- Feel for an irregularity of the skin and underlying tissue

FIT Recommends
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.
Self Examination

- Compare normal skin with lipohypertrophic tissue
- Self assessment to be done at least once every 4-6 weeks
- Lipohypertrophic lesions cannot be pinched tightly together
- Advise to avoid injecting into lipo site until tissue returns to normal, which could take at least few months to years

FIT Recommends
Switching injection sites from lipohypertrophied to normal tissue often requires a decrease in insulin dose. The amount of changes varies from one individual to another and should be guided by frequent blood glucose checks.
Tips to Prevent Lipohypertrophy

- Inspecting injection site for signs of lipohypertrophy.
- If present, recording the size of lesion.
- Rotating injection site every week.
- Monitoring glucose levels when the site is changed.
- Not injecting into damaged tissue.
- Considering dose modification with change of injection site: frequent glucose monitoring.
- Not reusing needles.
- Ensuring use of good quality insulin.
- Practice good site rotation
- Avoid needle reuse
- Use good quality purified insulin
Systematic Rotation of Injection Sites
Choice of Needle length
What would be your approach?

Three patients have come up to you for administering an insulin injection.

- One of them is a child aged 10 years,
- One of them is a middle aged obese female and
- The third one is a man aged 65 years.

Would you recommend a needle of the **same length** to all the three patients?
The sub-cutaneous layer

- **Intradermal Tissue**
  - Highly variable blood flow

- **Muscle Layer**
  - High general blood flow
  - Blood flow further increased with activity

- **Subcutaneous Tissue**
  - Stable, slow, reliable blood flow
Insulin injections are meant for subcutaneous delivery.

- The subcutaneous tissue has a stable, slow, reliable blood flow.
- The thickness of the subcutaneous layer should be greater than the needle length chosen.

**Subcutaneous tissue – the insulin injection site**

- Arms
- Thigh
- Abdomen
- Buttocks
Subcutaneous tissue – the insulin injection site

- Insulin injections are meant for subcutaneous delivery
- The subcutaneous tissue has a stable, slow, reliable blood flow
- The thickness of the subcutaneous layer should be greater than the needle length chosen

FIT Recommends
Use the correct needle length to ensure that the injection therapy is delivered into the subcutaneous tissue
DID YOU KNOW?

- **Skin thickness** does not vary significantly by
  - Age,
  - Gender,
  - BMI &
  - Ethnicity

- In a study, ultrasound measurements for skin thickness revealed a mean skin thickness of about 2.2 mm.

- Multivariate analyses (of age, BMI, ethnicity and gender in adult diabetics) revealed that variation in skin thickness is not clinically significant.

- There is no medical reason to recommend needles longer than 4–6 mm to either children or adults.

- Hence, **the shorter the needle the better it is!**

*Gibney MA. et al (2012) Skin and subcutaneous adipose layer thickness in adults with diabetes at sites used for insulin injections; Implications for needle length recommendations. Current Medical Research and Opinion 266, 1519-1530*
Selecting the Correct Needle Length

Longer needles may not be appropriate for all sites
Needle length considerations in Children, Adolescents, Adults, including Obese

- There is no clinical reasoning on recommending needles greater than 6mm.
- 4, 5, 6mm needles have been reported to be suitable for all regardless of BMI and may not require a lifted skin fold particularly with 4 mm.
- Majority of cases 4mm needles inserted at 90° require no lifted skin fold – hence no third party assistance required in injecting in the arm!
- If using needles >8mm, skin-fold may be required.
- A pinch up may be required in injections in the age group of 2-6 years.
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FIT Recommends
For children and adolescents, a 4, 5 or 6 mm needle should be used. Adults, including obese patients, can use 4, 5 and 6 mm needle length.
Use of Shorter Needles

- Alleviate the risk of intramuscular injections
- Provide equivalent glycemic control,
- Do not increase leakage events,
- Reduces psychological insulin resistance,
- Better patient compliance to insulin injection therapy

Shorter needles are beneficial over the longer ones!
Skin-fold
Why Skin-folds

- Skin-folds facilitate desired penetration
- Skin-folds may be considered when the subcutaneous tissue is thin or alternately, the distance between the skin surface and the muscle is less than the length of the needle
- The thumb and the index finger are to be used to lift a skin-fold properly
- Use of whole hand for lifting a skin-fold involves risk of intramuscular injections
When is a Lifted Skin Fold needed

- If the SC thickness is presumed to be lesser than the length of the needle
- To ensure predictable insulin absorption
- To minimize risk of hypoglycemia, erratic blood glucose levels
- To avoid soft tissue compression and IM injections
When is a Lifted Skin Fold needed

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- To ensure predictable insulin absorption
- To minimize risk of hypoglycemia, erratic blood glucose levels
- To avoid soft tissue compression and IM injections

FIT Recommends
Adults generally do not require the lifting of a skin-fold, particularly for 4 mm needles.
Interesting Revelations

ITQ survey showed

- 43% of responders release the skin fold too soon
- 17% of the participants lift skin-folds incorrectly

- Indenting skin with injecting device may lead to deeper injection than intended and therefore must be avoided.
- This MRI shows 2 areas of compression where SC thickness does not exceed 6mm.

FIT Recommends
An injection into the limbs or a slim abdomen warrants the need for a skin-fold
Skin Folds

Correct and incorrect ways of lifting a skin fold

When used with proper injection technique: 90 deg angle, no-pincho
Injecting into a Skin-fold

- Make a lifted skin-fold
- Insert needle into the skin at 90° angle
- Administer insulin
- Leave the needle in the subcutaneous tissue for 10 seconds after the plunger has been fully depressed
- Withdraw needle from the skin
- Release skin-fold
Injecting into a Skin-fold

- Make a lifted skin-fold
- Insert needle into the skin at 90° angle
- Administer insulin
- Leave the needle in the subcutaneous tissue for 10 seconds after the plunger has been fully depressed
- Withdraw needle from the skin
- Release skin-fold

FIT Recommends
People with diabetes and care-givers should be taught the correct technique of lifting the skin-fold from the onset of injectable therapy.
What would be your approach?

An obese patient with a BMI of 38 has to be initiated on an insulin pen & his choice of Injection site is abdomen & arm.

- What would be your choice of needle length

and

- Would you consider making a skin-fold to inject?
What would be your approach?

An obese patient with a BMI of 38 has to be initiated on an insulin pen & his choice of Injection site is abdomen & arm.

- What would be your choice of needle length
  - 4 mm
  - and

- Would you consider making a skin-fold to inject?
  - Would not require Pinch-up
Injection Site Care
Importance of Injection site care

- Regular site inspection is essential
- Poor injection site care can lead to malabsorption of insulin
- This in turn could adversely affect glucose control.
- Development of lipohypertrophy
Injection Site Inspection

- Always inspect the site before giving injection
- Inspect the site every visit or at least once in 6-months or as part of the investigation following blood glucose checks
- While doing so, patient should be standing, with clothes loosened and removed from the respective injection site area.
- Look for
  - Lipohypertrophy
  - Inflammation
  - Oedema
  - Infection

To avoid lipohypertrophy rotate injection sites with each injection and avoid needle re-use
Seven Step Injection Site Care Process

FIT Recommends

- Prior to the injection, inspect the site for wounds, bruises, or blisters, and palpate for lipohypertrophy.
- Select a different site for injection in case of signs of lipohypertrophy, inflammation, edema, or infection.
- Inject at a clean site with clean hands.
- If unclean, cleanse the site with soap and water.
- Inspect the injection site at every visit or at least every six months or as part of investigation into sub optimal or erratic blood glucose control.
- Rotate injection sites systematically.
- Ideally do not reuse needles.
Safety issues
What would be your approach?

According to you,

- Is an insulin syringe and a pen needle, a **single use** or a **single patient use device**?

- Would you consider using the same pen needle/insulin syringe to inject one more dose in the same patient.
What would be your approach?

According to you,

- Is an insulin syringe and a pen needle, a single use or a single patient use device?
- Would you consider using the same pen needle/insulin syringe to inject one more dose in the same patient.

Both are single use devices and FIT recommends not to reuse the same pen needle/insulin syringe to inject more than 1 dose on the same patients.
Needle/Syringe Hygiene: Do Not Re-use

Needle reuse causes damage to the tip of the needle

New Needle

Needle used once

Needle used twice

Needle used 6 times

CAN THIS HARM YOUR PATIENT?
Hazards of needle/syringe reuse

- Pain
- Bleeding and bruising
- Lipohypertrophy
- Contamination
- Infection
- Dosage inaccuracy
- Breaking off and lodging under the skin
Needle/Syringe Hygiene: Do Not Re-use

Risks of needle reuse

FIT Recommends
Use a new needle for each injection & ideally, do not reuse needles.
Bleeding & Bruising

ITQ results show
34% of patients report witnessing bleeding or bruising at some time point at their injection sites

- Needles will on occasion hit a blood vessel on injection. This may cause bleeding/bruising
- Needle re-use is known to cause bleeding/bruising
- Needle length does not seem to impact frequency of bleeding / bruising
- Bleeding/bruising does not appear to have adverse effects on insulin absorption or overall diabetes management

FIT Recommends
Sites with bleeding or brushing should be avoided until fully recovered

Disposal of used syringes
Safe Disposal of Injection Devices

Never recap

Use needle clipping devices to cut needles

Use pliers Kocher & equivalent unscrew the needle pen.

Empty pen devices can be disposed in house-hold refuse bins.
Injection Device Disposal

FIT Recommends

- Educating patients and health care providers about correct disposal of injection devices.
- Alerting family members and service providers about potential risks.
- Not disposing sharps in public area bins.
- Disposing empty pen devices in household refuse bins.
- Collecting used needles in a puncture proof box labeled as “biohazard”.
BD Diabetes Care
Dedicated to Continuous Innovation and Improvement

For over 85 years, a Worldwide Leader in Diabetes Drug Delivery

The Result:
World’s finest injection devices and
A commitment to ensure that they are used properly
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Thank You