Eroding Barriers to Insulin Pens

Moving Toward a New Standard of Care

Improving Health at a Local Level: Action Today...Impact Tomorrow

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Eastern Idaho Public Health District
Idaho Falls, Idaho

Objectives of Slide Kit
• Review safety issues with insulin delivery
• Identify reasons why insulin pens may be preferred over syringes
• Demonstrate that health care costs can be improved with insulin pens

Insulin Injection, Syringes, and Pens

Evolution of Insulin Pens
• The first insulin pen was launched in 19851
  - Features included a cartridge containing 150 U of 100 U/mL short-acting insulin and a 27-gauge needle
• All pens meet criteria established by the International Organization for Standardization1
• Pens are available in 2 types2
  - Prefilled disposable
  - Reusable with replaceable insulin cartridge
• Currently, insulin pens account for over 50% of insulin use worldwide3

Insulin Pen Usage By Geographical Region

Evolution of Insulin Pens (cont)
• Key features of the current insulin pens include the following:
  - Small, slim, and easily portable size
  - Easy dose dialing and dose correction
  - Dose confirmation at end of injection
  - Higher maximum doses
  - Low injection force
  - Click-in/click-out cartridge change and larger cartridge capacity
  - Visual and tactile differentiation of pens with different insulin

ROW = rest of world.

Advantages and Disadvantages of Insulin Syringes

**Advantages**
- Disposable, with microfine needles, available in a wide variety of sizes and styles, and light in weight
- Injections can be quick, with practice
- Disposable syringes and needles are inexpensive

**Disadvantages**
- Fear of injections
- Inconvenience
- Painful injections
- Lack of social acceptance
- Dosing errors, particularly with self-mixed preparations


Benefits of Insulin Pen Use

**Simple administration**
- Improved dose accuracy
- Reduced risk of hyperglycemia and hypoglycemia
- Improved patient acceptability and adherence
- Ease of use
- Lifestyle friendly
- Cost-effective
- Less painful
- Easy to educate patients
- Appropriate for various patient groups (children, elderly)
- Overcomes patient dexterity and visual impairment
- Improves quality of life
- Avoids contamination of multiple-dose vials


Insulin Injection Patterns of US Adults: Results of an Internet Survey

- 57% of respondents (N=502) with T1DM or T2DM reported intentionally skipping insulin injections; 20% reported skipping them sometimes or often

<table>
<thead>
<tr>
<th>Independent Risk Factors for Insulin Omission (P&lt;0.001)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Younger age</td>
</tr>
<tr>
<td>Lower income</td>
</tr>
<tr>
<td>Having T2DM</td>
</tr>
<tr>
<td>Taking more injections</td>
</tr>
<tr>
<td>Interference with daily living</td>
</tr>
<tr>
<td>Embarrassment</td>
</tr>
</tbody>
</table>

77% of the patients had T2DM.


Safety Issues With Insulin Delivery

Safety Issues Reported With the Multiple Use of Syringes and Medication Vials

| Year | Reports of Contamination and Infections Associated With Syringes/Vials |
|--------------------------|
| 2000¹ | CDC confirmed that 3 patients contracted HCV from an MDV, and 35 patients died before investigation was completed |
| 2001² | Two patients died of meningitis caused by Pseudomonas aeruginosa in a German hospital due to contaminated contrast media used as an MDV |
| 2003³ | A 1,200-bed hospital study revealed improper storage for >50% of vials; 50% lacked opening date labels, and of 227 vials available, 1 vial and 1 needle were contaminated with Staphylococcus epidermidis |
| 2006⁴ | An endoscopy clinic in Nevada had 6 cases of acute hepatitis C caused by multiple use of syringes and vials to administer anesthesia. About 40,000 patients had to be notified that they were at risk for HCV, HIV, and HBV |

1. CDC = Centers for Disease Control; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; MDV = multiple-dose vial.

Needlestick Injury Among Nurses Caring for Patients With Diabetes

Retropective study involving 400 nurses working in a hospital setting for previous 12 months, 118 (30%) of whom experienced a needlestick injury.

Safety Needles

• The US General Accounting Office estimated that approximately 69,000 needlestick injuries in hospitals can be prevented each year by using needles with safety features.

• A safety needle is a single-use needle with an automatic shield feature that initially covers the needle, retracts during insulin deposition, and locks into place after use.

• Safety needles used with insulin pens offer several benefits:
  - Lower the risk of accidental needle puncture wounds for health care professionals and patients
  - Help reduce anxiety in patients with needle phobia, as needle remains invisible
  - Prevent reuse of the same needle

Safety Needle Preference

13.3% preferred safety needles over regular needles
(P<0.0001)

Nurse Preference for Safety Needles

• No needlestick injuries occurred among nurses using safety needles on insulin pens.

• Most preferred safety needles over regular needles.

Sharing Insulin Pens May Result in Transmission of Blood-Borne Pathogens

• The US FDA reported that insulin pens were shared among ≥2000 patients in one army hospital in the United States from 2007-2009 and among a smaller number of patients in at least 1 other hospital.

• The US FDA has issued the following alert to health care providers, health care facilities, and patients:

> Each insulin pen (and each insulin pen cartridge) is designed for single-patient use only and is never to be shared among patients. Insulin pens are not designed, and are not safe, for one pen to be used for more than one patient, even if needles are changed between patients because any blood contamination of the pen reservoir could result in transmission of already existing blood-borne pathogens from the previous user.

Patient-Reported Outcomes of Insulin Pens vs Vials and Syringes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Studies Found</th>
<th>Key Findings (Insulin pens vs vial and syringe)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preference</td>
<td>29</td>
<td>In 21 studies, &gt;65% of patients preferred pens or chose pens over syringes for treatment with pens</td>
</tr>
<tr>
<td>Acceptability</td>
<td>12</td>
<td>In 10 studies, &gt;73% of patients reported greater acceptance of pens</td>
</tr>
<tr>
<td>Pain</td>
<td>9</td>
<td>In 8 studies, &gt;50% of patients experiencing less pain while using pens</td>
</tr>
<tr>
<td>Quality of life</td>
<td>8</td>
<td>In 3 studies, quality of life improvement was greater among patients using pens</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>7</td>
<td>In 5 studies, &gt;76% of patients reported higher satisfaction with pens</td>
</tr>
<tr>
<td>Convenience</td>
<td>10</td>
<td>In 8 studies, &gt;50% of patients found pens to be more convenient</td>
</tr>
<tr>
<td>Handling and dosing</td>
<td>2</td>
<td>In 2 studies, 92% of patients considered pens to be easier to use, 92% considered handling to be easier, 88% found pens to be more reliable in drawing and dispensing insulin</td>
</tr>
<tr>
<td>Ease of use</td>
<td>9</td>
<td>In all 9 studies, &gt;83% of patients considered pens easier to use</td>
</tr>
</tbody>
</table>

Findings are based on aggregated evidence of patient-reported outcomes from 1980 to 2008 in patients with T1DM and T2DM.

Insulin Pen vs Vial and Syringe Use: Treatment Preference, Satisfaction, and Adherence

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of Patients, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Preference</td>
<td>Pen: 74%, Vial: 20%, No preference: 6%</td>
</tr>
<tr>
<td>Easier-to-Read Dose</td>
<td>Vial: 77%, Syringe: 15%, No preference: 8%</td>
</tr>
<tr>
<td>Confidence in Setting Dose</td>
<td>Vial: 66%, Syringe: 30%, No preference: 4%</td>
</tr>
<tr>
<td>More Discreet in Public</td>
<td>Vial: 63%, Syringe: 21%, No preference: 16%</td>
</tr>
</tbody>
</table>

**Patient Satisfaction With Insulin Treatment During Hospitalization**

<table>
<thead>
<tr>
<th>Survey Item</th>
<th>Insulin Pen (n=32)</th>
<th>Vial/Syringe (n=40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method used to give me my insulin in the hospital was simple and easy</td>
<td>31 (97)</td>
<td>38 (95)</td>
</tr>
<tr>
<td>I would like to continue taking insulin at home using the method used during my hospital stay</td>
<td>26 (74)*</td>
<td>18 (45)</td>
</tr>
<tr>
<td>I would recommend to other people with diabetes to use insulin by the method I used during my hospital stay</td>
<td>33 (94)*</td>
<td>29 (73)</td>
</tr>
</tbody>
</table>

Positive responses included responses of "agree" or "strongly agree." *P<0.05.

Prospective, randomized, controlled, parallel-group study. N=75 patients with T1DM (13%) and T2DM (87%).

**Preference Associated With Insulin Pens vs Prior Treatment Strategies**

Patients preferred the study pen to their prior treatment strategies.

<table>
<thead>
<tr>
<th>Preference</th>
<th>Insulin Pen</th>
<th>Pen Syringe</th>
<th>Vial/Syringe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convenience</td>
<td>3.1</td>
<td>2.7</td>
<td>2.3</td>
</tr>
<tr>
<td>Flexibility</td>
<td>3.0</td>
<td>2.7</td>
<td>2.4</td>
</tr>
<tr>
<td>Clinical Efficacy</td>
<td>3.1</td>
<td>2.8</td>
<td>2.5</td>
</tr>
<tr>
<td>Quality of Life</td>
<td>3.0</td>
<td>2.7</td>
<td>2.3</td>
</tr>
<tr>
<td>Overall Preference</td>
<td>3.0</td>
<td>2.7</td>
<td>2.3</td>
</tr>
</tbody>
</table>

**Insulin Pen Usage Is Associated With Changes in Glycemic Control and Quality of Life After 12 Weeks**

- Insulin pen usage improved the summary scale of physical components in the 36-item Short-Form Health Survey (P=0.037).

<table>
<thead>
<tr>
<th>Change in Fasting Plasma Glucose</th>
<th>Pen</th>
<th>Syringe</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/dL</td>
<td>-5.7*</td>
<td>0.08</td>
</tr>
</tbody>
</table>

*P<0.007 vs baseline.

**Satisfaction With Insulin Pens Among Hospital Nursing Staff**

<table>
<thead>
<tr>
<th>Survey Item</th>
<th>Response, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>More satisfied with preparing insulin in hospital by the method of insulin administration</td>
<td>69</td>
</tr>
<tr>
<td>More satisfied with administering insulin in hospital</td>
<td>63</td>
</tr>
<tr>
<td>Pens are more convenient</td>
<td>80</td>
</tr>
<tr>
<td>Pens are more simple &amp; easy to use</td>
<td>72</td>
</tr>
<tr>
<td>Felt more confident when giving the insulin dose using pens</td>
<td>39</td>
</tr>
<tr>
<td>Felt more comfortable administering insulin in hospital using pens</td>
<td>43</td>
</tr>
<tr>
<td>Took less time to prepare &amp; give insulin when using the method of insulin administration</td>
<td>70</td>
</tr>
</tbody>
</table>

**Medication Adherence and Hypoglycemic Events After Switching to an Insulin Pen**

- Pen use resulted in 50% fewer hypoglycemic events requiring health care resource utilization (odds ratio: 0.50; 95% CI: 0.37-0.68; P<0.05).

Prospective, longitudinal, pre-post study among a medical and pharmacy claims database. N=2,514 patients with T2DM previously using insulin and transferred to the study pen, 4,423 years after converting from a vial and syringe to an insulin pen.


Medication Adherence and Hypoglycemic Events After Switching to an Insulin Pen (cont)

- Pen use resulted in 60% fewer hypoglycemic events requiring third-party intervention (odds ratio: 0.40; 95% CI: 0.27-0.61; P<0.05)

Retrospective, longitudinal, pre-post analysis using a medical and pharmacy claims database. Bev-64 patients previously treated with insulin and followed up for at least 2 years after converting from a vial and syringe to an insulin pen.


Testing Procedures for Insulin Pens

- Dose accuracy
  - Consistent dose accuracy ensures that the pen, when used properly, will repeatedly deliver the dialed dose, facilitating the correct titration of insulin dose without increased risk of hypoglycemia or hyperglycemia
  - Insulin pens must meet dose accuracy criteria specified by the International Organization for Standardization

- Ergonomic
  - To recommend the most suitable basic dimensions of the pen
  - To establish relevant human strength data to identify the maximum operating force required to push the injection button
  - To gather information on the optimal dosage display window so that the needs of visually impaired users are taken into account

- Injection force
  - Performed to measure the force and force characteristics required to dispense a known volume of insulin within a fixed time period


Comparable Dose Accuracy Between 2 Commonly Available Insulin Pens

<table>
<thead>
<tr>
<th>Intended Dose, U</th>
<th>n</th>
<th>Mean Delivered Dose (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pen A</td>
<td>Pen B</td>
</tr>
<tr>
<td>5</td>
<td>1260</td>
<td>5.07 (0.15)</td>
</tr>
<tr>
<td></td>
<td>5.03 (0.21)</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>750</td>
<td>9.87 (0.16)</td>
</tr>
<tr>
<td></td>
<td>9.83 (0.14)</td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>270</td>
<td>29.70 (0.38)</td>
</tr>
<tr>
<td></td>
<td>29.45 (0.25)</td>
<td></td>
</tr>
</tbody>
</table>

A total of 60 pens were tested; 30 each for Pen A (FlexPen) and Pen B (Insuline). Penfornis A et al. Diabetes Technol Ther. 2008;10:359-362.

Health Care Costs With Insulin Pens

Commonly Used Disposable Insulin Pens Display a High Degree of Dosing Accuracy

Distribution of Actual Doses

- 1 U, 10 U, and 30 U
- 40 U, 60 U, and 80 U

A total of 30 pens from 2 lots of each pen model were used in this comparator study. Pens A = FlexPen; Pens B = Medtronic MiniMed Paradigm 754; Pens C = Iletop; Pens D = SoloSTAR.

Insulin Pens Associated With Reduced Health Care Costs vs Syringes

<table>
<thead>
<tr>
<th>Total Costs, Second Year, $</th>
<th>OAD to Syringe (n=1162)</th>
<th>OAD to Pen (n=168)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient</td>
<td>13,104</td>
<td>13,762</td>
</tr>
<tr>
<td>Hospital</td>
<td>7796</td>
<td>4,985</td>
</tr>
<tr>
<td>Total Diabetes Costs</td>
<td>21,900</td>
<td>18,747</td>
</tr>
</tbody>
</table>

P<0.05

Savings = $1590/patient

Savings = $1748/patient

OAD = oral antidiabetic drug.
Nonconcurrent, comparative, retrospective analysis of Medicaid-enrolled patients with T2DM. Total health care costs, excluding prescription costs, were $13,104 for patients switching to pens and $13,762 for those switching to syringes. Pawaskar MD et al. Clin Ther. 2007;29:1294-1305.

Insulin Pens May Reduce Costs Due to Insulin Wastage From Multidose Vials

The total insulin wastage rate for the 5 hospitals was 34.1%

Reducing Barriers to Timely Insulin Use

Delay of Insulin Addition to OAD Therapy Despite Inadequate Glycemic Control

By 24 mo, ~50% of patients never attaining A1C goal added insulin

By 60 mo, ~50% of patients attaining not maintaining A1C goal added insulin

Pens May Help Overcome Physician Barriers to Timely Insulin Use

Physician Barriers

- Difficulty and time spent educating the patient
- Concern that patients will not adhere to therapy

Benefits of Insulin Pen vs Vial and Syringe Therapy

- Insulin pens are easier for patients to use
- Pens can help reduce the complexity of administering insulin
- Studies have demonstrated significant increases in adherence with use of the pen

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St. Peter, Halldinand, Norfolk, Hotel Dieu, Victoria


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Six-week study on specific wards of 5 hospitals in Ontario, Canada. "Wastage" was defined as the insulin that was discarded due to expiry, patient discharge, insufficiency for dose, spoilage, or other. Variation in wastage was associated with the type of hospital ward (chronic or acute).

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OAD = oral antidiabetic drug.
Pens May Help Overcome Patient Barriers to Timely Insulin Use

### Patient Barriers

Belief that insulin will severely restrict their personal lives
- Patients overwhelmingly preferred the pen to their prior treatment strategies for reasons including convenience and flexibility.

Perception that insulin therapy is too hard to manage
- Patients using insulin pens rated them easier to use, easier to handle, and more convenient.

Fear of injection
- Disposable pen needles are often finer and shorter to increase patient comfort.
- Patient perception of pain is significantly reduced with pens.

### Benefits of Insulin Pen vs Vial and Syringe Therapy

- Patients with the ability to intuitively set/dispense 20-U insulin dose
- Patients with the ability to intuitively set/dispense 3 randomly selected insulin doses (4 U-50 U) after written instruction/demonstration
- Dose Accuracy and insulin Delivery

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Insulin Pen vs Syringe Among the Visually Impaired

<table>
<thead>
<tr>
<th></th>
<th>Pen</th>
<th>Syringe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients, %</td>
<td>64</td>
<td>27</td>
</tr>
<tr>
<td>0-20 min</td>
<td>42</td>
<td>31</td>
</tr>
<tr>
<td>20-60 min</td>
<td>39</td>
<td>61</td>
</tr>
<tr>
<td>60-100 min</td>
<td>31</td>
<td>15</td>
</tr>
</tbody>
</table>

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Practical Considerations When Switching to an Insulin Pen

- Patient’s lifestyle
- Patient’s insulin regimen (qd, bid, tid, basal-bolus)
- Patient’s blood glucose profile
- Factors that may interfere with ability to use a pen (eg, poor vision, manual dexterity, memory)
- Familiarity with previous pen devices
- Usability, design, and aesthetics

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Points to Consider When Selecting a Pen

1. Design
2. Usability
3. Patient Considerations

- Address the specific needs of different patient populations

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Usability of a Prefilled Insulin Pen: Health Care Professional–Oriented Survey

<table>
<thead>
<tr>
<th>Time Needed by HCPs to Train Patients</th>
<th>HCPs reported the following:</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5 min</td>
<td>Excellent or acceptable effect on participants’ reluctance to use insulin (65% of HCPs)</td>
</tr>
<tr>
<td>0-10 min</td>
<td>Excellent or good effect on participants’ confidence to manage their diabetes (99% of HCPs)</td>
</tr>
</tbody>
</table>

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Design, Usability, and Patient Considerations When Selecting an Insulin Pen

- Exterior design and styling
- Size and portability
- Tactile feel and features
- Ease of use
- Ease of setting the dose
- Ease of reading the dose
- Ease of correcting the dose if overdialed
- Auditory feedback
- Number of turns to set dose
- How far the dose button sticks out
- Effort required to inject the dose
- Ease of determining whether the dose was delivered
- Ease of determining the amount of insulin left in the cartridge

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Notes:
Educating Patients on Proper Pen Usage

- Review the pen manufacturer’s user guide
- Demonstrate the main steps in operating a pen. For example:
  
  - Attach the needle
  - Perform a safety test
  - Select the dose
  - Inject the dose
  - Remove the needle

Benefits of an Insulin Pen for Routine Hospital Use

- Is labeled by the manufacturer with the product name and strength\(^1\)
- Can be individually labeled with the patient’s name\(^1\)
- Provides insulin in a form ready for administration\(^1\)
- Lessens nursing time needed to prepare and administer insulin\(^1\)
- Associated with fewer dosing errors because of the dial-a-dose feature\(^2\)
- Reduces medication waste that can occur when dispensing full insulin vials for each patient\(^1\)
- Avoids contamination of multiple-dose vials\(^3\)

Switching to Insulin Pens in the Inpatient Setting: A Case Study

- Rationale
  - Adverse drug events related to insulin errors are among the top-reported errors in the United States health care system
- Goal
  - To reduce the occurrence of insulin errors
- Method
  - Minimize floor stock of insulin and use patient-specific devices
- Results
  - Full conversion of all formulary insulin from vials to patient-specific insulin pens was achieved

Switching to Insulin Pens in the Inpatient Setting: Practical Considerations

- Maintaining a multidisciplinary approach throughout the entire process\(^3\)
- Obtaining approval from governing bodies within the institution\(^1\)
- Providing extensive educational training for the nursing and pharmacy staff before and after the pen conversion\(^2\)
- Labeling devices when first removed for patient use with patient name and date; bar-code scanning and the use of cautionary labeling can be helpful\(^1\)

Switching to Insulin Pens in the Inpatient Setting: Practical Considerations (cont)

- Delivering each insulin device on a per-patient basis\(^1\)
- Storing pen in a nonrefrigerated, patient-specific medication drawer\(^4\)
- Conducting ongoing education on proper administration technique to ensure proper pen usage by nursing staff\(^2\)
- Developing an institution-wide policy describing proper usage procedures\(^2\)
- Ensuring continuous quality improvement through informal feedback methods\(^2\)

Eroding Barriers to Insulin Pens: Summary

- Insulin pens may be more accurate, convenient, and discreet, and less painful than syringes
- Switching to insulin pens may:
  - Be preferred by patients and health care workers
  - Improve adherence to therapy
  - Improve dose accuracy
  - Reduce health care costs
  - Help overcome physician and patient barriers to timely insulin use
- The clear and simple dose selection of insulin pens may be suitable for a wide range of patients, including the elderly, children, as well as those with hearing or visual impairment and manual dexterity issues
### Resources for Patients

- **ADA (American Diabetes Association)**
  - www.diabetes.org
- **Diabetes Life**
  - www.ldh.com
- **Insulin and device companies**
  - www.lillydiabetes.com
  - www.lillydiabetes.com
  - www.lillydiabetes.com
  - www.lillydiabetes.com
- **Diabetes in Control newsletter**
  - www.diabetesincontrol.com
- **Juvenile Diabetes Foundation**
  - www.jdf.org
- **Children with Diabetes**
  - www.childrenwithdiabetes.com
- **Diabetes Network**
  - http://www.diabetesnet.com
- **National Diabetes Education Program, a joint program of the National Institutes of Health and the Centers for Disease Control and Prevention**:
  - www.ndep.nih.gov
  - www.cdc.gov/diabetes/ndep/index.htm

### Resources for Health Professionals

- **ADA (American Diabetes Association)**
  - www.diabetes.org
- **Diabetes Care**
  - http://care.diabetesjournals.org
- **AADE (American Association of Diabetes Educators)**
  - www.aadenet.org
- **CADRE (Council for the Advancement of Diabetes Research and Education)**
  - www.cadre-diabetes.org
- **NDEI (National Diabetes Education Initiative)**
  - www.nnde.org
- **National Diabetes Education Program, a joint program of the National Institutes of Health and the Centers for Disease Control and Prevention**:
  - www.ndep.nih.gov
  - www.cdc.gov/diabetes/ndep/index.htm
- **American College of Physicians Diabetes Portal**
  - http://diabetes.acponline.org
- **Overview of medication adherence. Where are we today?**
  - www.adultmeducation.com/OverviewofMedicationAdherence.html