

Eroding Barriers to Insulin Pens

Moving Toward a New Standard of Care

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

Bob Fell, Pharm.D.
Sr. Regional Medical Liaison
US Medical Affairs, sanofi-aventis
Golden, CO

Friday, October 22, 2010
Eastern Idaho Public Health District
Idaho Falls, Idaho

1

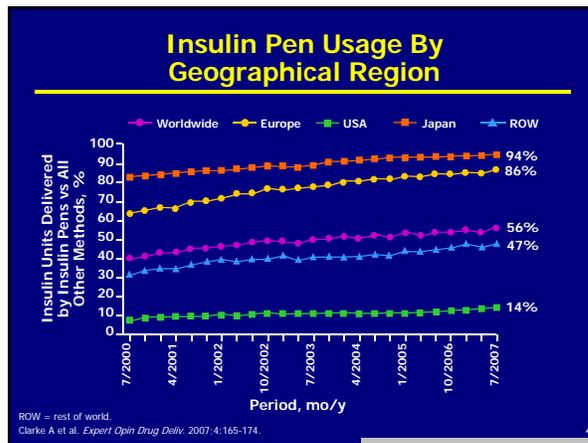
Objectives of Slide Kit

- 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

2

Insulin Injection, Syringes, and Pens

3



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 worldwide¹

5

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

6

Advantages and Disadvantages of Insulin Syringes

- **Advantages**
 - Disposable, with microfine needles, available in a wide variety of sizes and styles, and light in weight¹
 - Injections can be quick, with practice¹
 - Disposable syringes and needles are inexpensive¹
- **Disadvantages**
 - Fear of injections²
 - Inconvenience²
 - Painful injections¹
 - Lack of social acceptance³
 - Dosing errors, particularly with self-mixed preparations^{1,4}

1. Chauhan KG et al. *JPR*. 2009;2:1515-1520. 2. Clarke A et al. *Expert Opin Drug Deliv*. 2007;4:165-174. 3. Brunton S. *Am J Med*. 2008;121:S35-S41. 4. Bell DSH et al. *Arch Intern Med*. 1991;151:2265-2269.

7

Benefits of Insulin Pen Use

- **Simple administration¹**
- **Improved dose accuracy^{1,2}**
 - Reduced risk of hyperglycemia and hypoglycemia
- **Improved patient acceptability and adherence^{1,3}**
 - Ease of use
- **Lifestyle friendly¹**
- **Cost-effective¹**
- **Less pain⁴**
- **Easy to educate patients¹**
- **Appropriate for various patient groups (children, elderly)⁴**
- **Overcomes patient dexterity and visual impairment¹**
- **Improves quality of life²**
- **Avoids contamination of multiple-dose vials⁵**

1. Garg S et al. *Expert Rev Med Devices*. 2008;5:113-123. 2. Goldstein HH. *Postgrad Med*. 2008;120:172-179. 3. Spollett G. *Diabetes Educ*. 2008;34:957-960, 963, 967. 4. Bhargava A. *Insulin*. 2007;2:92-94. 5. DeBaum B. *Infection Control Resource*. 2008;3:1. Transmission of infection with multi-dose vials. http://www.infectioncontrolresource.org/Past_Issues/ICT1.pdf. Accessed April 29, 2010.

8

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**

Independent Risk Factors for Insulin Omission (P<0.001)

- Younger age
- Lower income
- Having T2DM
- Taking more injections
- Interference with daily living
- Embarrassment

77% of the patients had T2DM. Peyrol M et al. *Diabetes Care*. 2010;33:240-245.

9

Safety Issues With Insulin Delivery

10

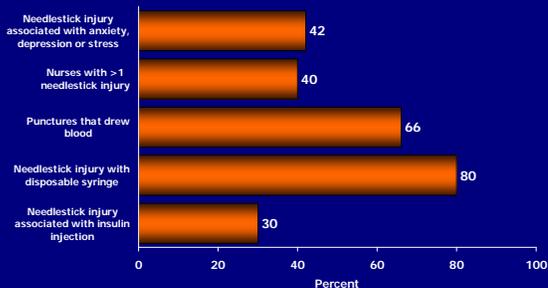
Safety Issues Reported With the Multiple Use of Syringes and Medication Vials

Year	Reports of Contamination and Infections Associated With Syringes/Vials
2000 ¹	CDC confirmed that 3 patients contracted HCV from an MDV, and 15 patients died before investigation was completed
2001 ²	Two patients died of meningitis caused by <i>Pseudomonas aeruginosa</i> in a German hospital due to contaminated contrast media used as an MDV
2001 ³	A 1300-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 <i>Staphylococcus epidermidis</i>
2006 ⁴	Bacterial contamination was found in 5.6% of vials in an Iranian teaching hospital; gram-positive bacteria (88.9%) with the highest frequency for <i>Staphylococcus epidermidis</i> (44.4%)
2008 ⁵	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 HBV, HCV, and HIV

CDC = Centers for Disease Control; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; MDV = multiple-dose vial.
 1. Pen safety movement calls for reexamination of multidose vial use. ISMP Website. <http://www.ismp.org/Newsletters/acutecare/articles/20000914.asp>. Accessed April 7, 2010. 2. Rich D. *Jl Comm Perspect Patient Safety*. 2006;6:10-11. 3. Mattner F et al. *Am J Infect Control*. 2004;32:12-16. 4. Motamedifar M et al. *Am J Infect Control*. 2009;37:173-177. 5. CDC. *MMWR Morb Mortal Wkly*. 2008;57:513-517.11

11

Needlestick Injury Among Nurses Caring for Patients With Diabetes



Retrospective study involving 400 nurses working in a hospital setting for previous 12 months, 110 (100%) of whom experienced a needlestick injury. Lee JM et al. *Curr Med Res Opin*. 2005;21:741-747.

12

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 features¹
- 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 use²
- Safety needles used with insulin pens offer several benefits²⁻⁴
 - 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

1. Occupational safety: selected cost and benefit implications of needlestick prevention devices for hospitals. Washington, DC: U.S. General Accounting Office; November 17, 2000. GAO-01-60R Needlestick Prevention. 2. Magnotti MA et al. *Insulin*. 2007;2:173-181. 3. Davis EM et al. *Diabetes Educ*. 2009;35:799-809. 4. Brown AW. *Clin Diabetes*. 2008;26:66-71.

Nurse Preference for Safety Needles

- No needlestick injuries occurred among nurses using safety needles on insulin pens
- Most preferred safety needles over regular needles

4-week, prospective, multicenter, observational study conducted at 52 hospitals in France involving 123 nurses who used safety needles, 122 of whom also used regular needles. Lautier O et al. *Insulin*. 2008;3:232-237.

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.

US FDA – US Food and Drug Administration.
FDA alert. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm133352.htm>. Accessed March 16, 2010.

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

Patient-Reported Outcomes of Insulin Pens vs Vials and Syringes

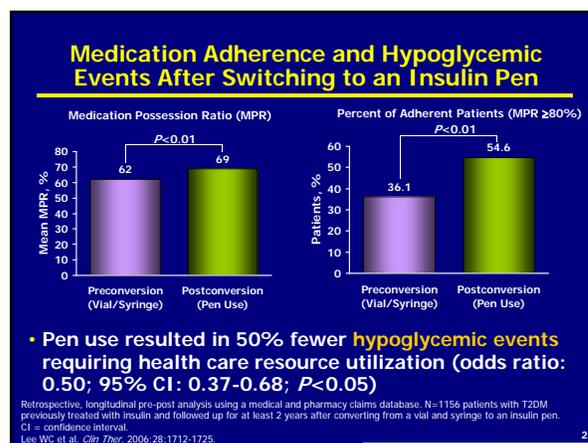
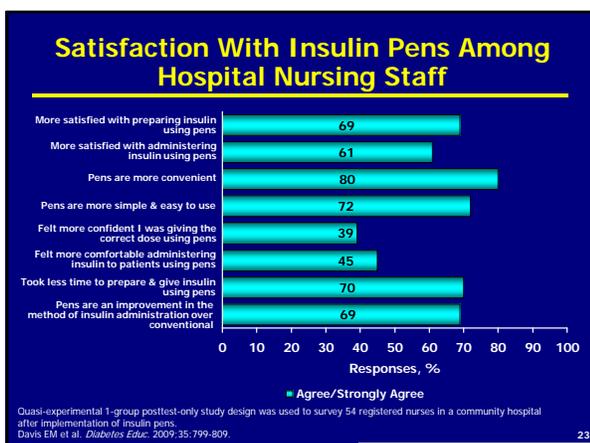
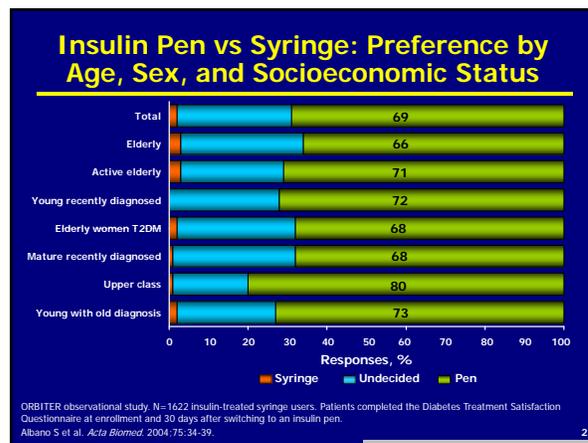
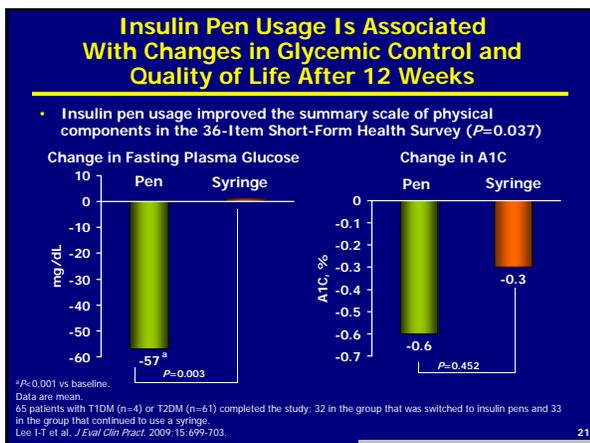
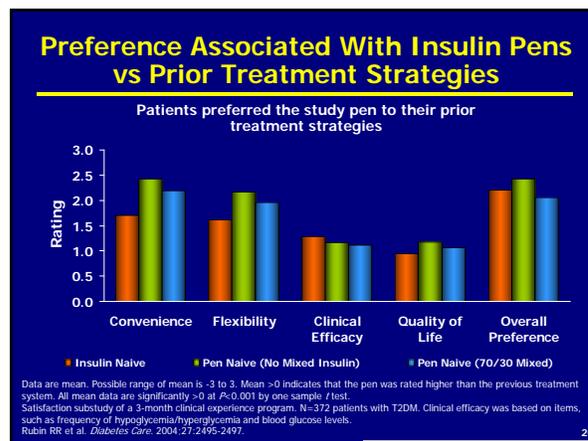
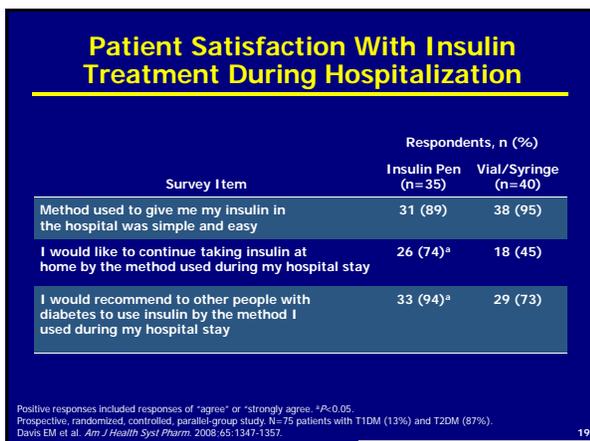
Outcome	Number of Studies Found	Key Findings (insulin pens vs vial and syringe)
Preference	29	In 28 studies, >66% of patients preferred pens or chose and/or were willing to continue treatment with pens
Acceptability	12	In 10 studies, >75% of patients reported greater acceptance of pens
Pain	9	In 8 studies, >50% of patients experienced less pain while using pens
Quality of life	8	In 3 studies, quality of life improvement was greater among patients who used pens
Satisfaction	7	In 5 studies, >76% of patients reported higher treatment satisfaction with pens
Convenience	10	In 8 studies, 56%-100% of patients found pens to be more convenient
Handling and dosing	2	In 1 study, 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
Ease of use	9	In all 9 studies, ≥61% of patients considered pens easier to use

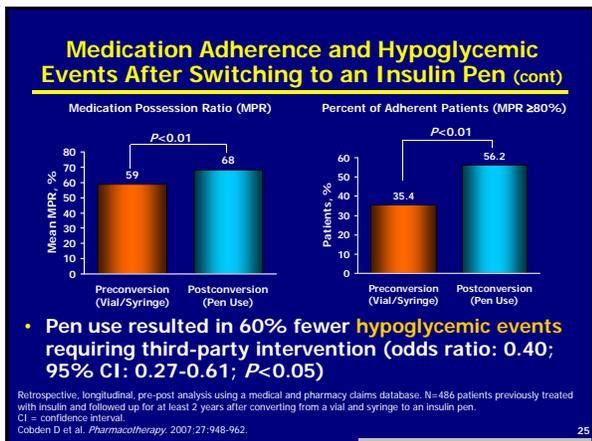
Findings are based on published evidence of patient-reported outcomes from 1980 to 2008 in patients with T1DM and T2DM. Molife C et al. *Diabetes Technol Ther*. 2009;11:529-538.

Patient Preference for Insulin Pens Over Vials and Syringes

74% patients preferred insulin pens, while 20% preferred vials and syringes

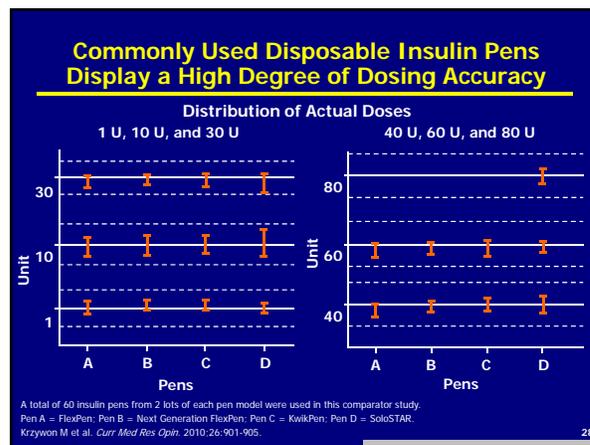
Randomized, open-label, comparative, crossover trial. N=105 patients with T1DM (12%) and T2DM (88%) who completed the questionnaire. Korytkowski M et al. *Clin Ther*. 2003;25:2836-2848.





Pen Technology

- ### 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 hypo- 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
- Clarke A et al. *Expert Opin Drug Deliv*. 2007;4:165-174.

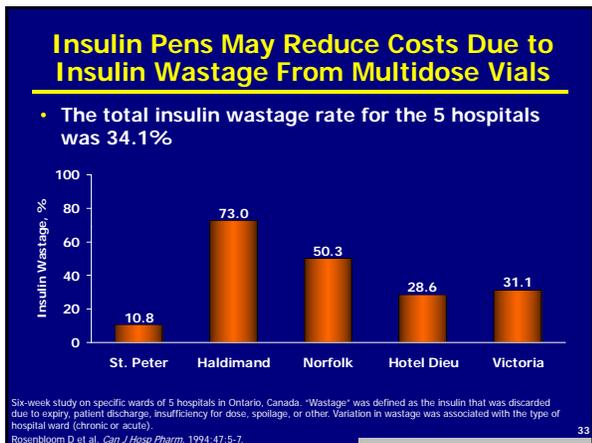
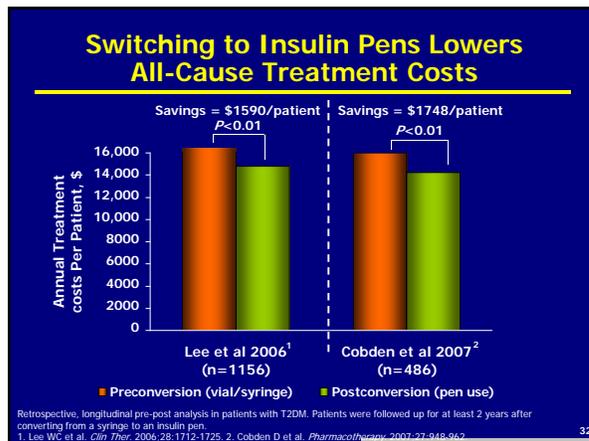
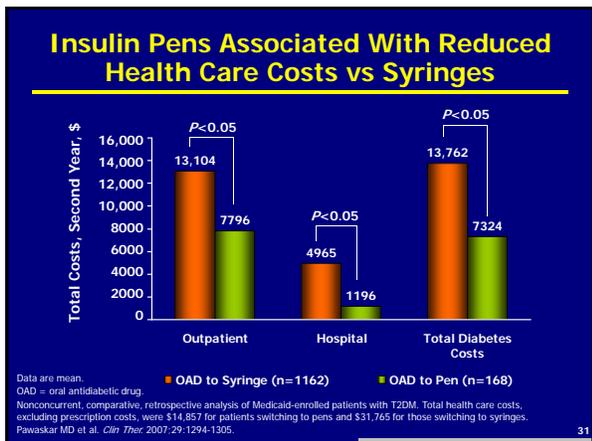


Comparable Dose Accuracy Between 2 Commonly Available Insulin Pens

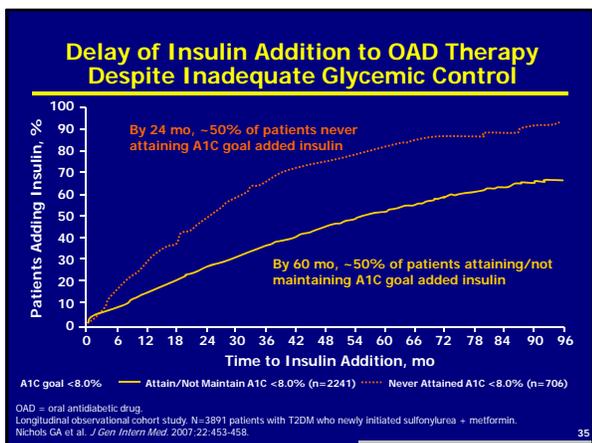
Intended Dose, U	n	Mean Delivered Dose (SD)	
		Pen A	Pen B
5	1260	5.07 (0.15)	5.03 (0.21)
10	750	9.87 (0.16)	9.83 (0.14)
30	270	29.70 (0.38)	29.45 (0.25)

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

Health Care Costs With Insulin Pens



Reducing Barriers to Timely Insulin Use



Pens May Help Overcome Physician Barriers to Timely Insulin Use

Physician Barriers ¹	Benefits of Insulin Pen vs Vial and Syringe Therapy
Difficulty and time spent educating the patient	Insulin pens are easier for patients to use ²
Concern that patients will not adhere to therapy	Pens can help reduce the complexity of administering insulin ¹
	Studies have demonstrated significant increases in adherence with use of the pen ^{3,4}

1. Brunton SA et al. *Clin Cornerstone*. 2006;8(suppl 2):S19-S26. 2. Polonsky WH et al. *Clin Diabetes*. 2004;22:147-150. 3. Cobden D et al. *Pharmacotherapy*. 2007;27:948-962. 4. Lee WC et al. *Clin Ther*. 2006;28:1712-1725.

Pens May Help Overcome Patient Barriers to Timely Insulin Use

Patient Barriers ¹	Benefits of Insulin Pen vs Vial and Syringe Therapy
<p>Belief that insulin will severely restrict their personal lives</p>	<ul style="list-style-type: none"> Patients overwhelmingly preferred the pen to their prior treatment strategies for reasons including convenience and flexibility^{2,3}
<p>Perception that insulin therapy is too hard to manage</p>	<ul style="list-style-type: none"> Patients using insulin pens rated them easier to use, easier to handle, and more convenient^{2,3}
<p>Fear of injection</p>	<ul style="list-style-type: none"> Disposable pen needles are often finer and shorter to increase patient comfort⁴ Patient perception of pain is significantly reduced with pens⁴

1. Brunton SA et al. *Clin Cornerstone*. 2006;8(suppl 2):S19-S26. 2. Rubin RR et al. *Diabetes Care*. 2004;27:2495-2497. 3. Korytkowski M et al. *Clin Ther*. 2003;25:2836-2848. 4. Korytkowski M et al. *Clin Ther*. 2005;27(suppl 8):S89-S100.

37

Insulin Pen vs Syringe Among the Visually Impaired

Dose Accuracy and Insulin Delivery¹

Ability	Syringe (%)	Pen (%)
Patients with the ability to intuitively set/dispense 20-U insulin dose	31	41
Patients with the ability to intuitively set/dispense 3 randomly selected insulin doses (4 U-50 U) after written instruction	27	61
Patients with the ability to intuitively set/dispense 3 consecutive insulin doses after written instruction/demonstration	64	85

Patients, %

- 3.6 million adults with diabetes in the United States reported visual impairment in 2008²

Multicenter, open, randomized, comparative study. N=86 patients with T2DM and visual impairment. 1. Fox C et al. *Pract Diabetes Int*. 2002;19:104-107. 2. Number (in millions) of adults with diabetes reporting visual impairment, United States, 1997-2008. Accessed April 7, 2010. CDC Website. <http://www.cdc.gov/print.do?url=http%3A%2Fwww.cdc.gov%2Fdiabetes%2Fstatistics%2Fvisual%2Ffig1.htm>.

38

Practical Considerations When Switching to an Insulin Pen

39

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

Time Needed by HCPs to Train Patients

Time	HCP, %
0-5 min	42
6-10 min	39
10+ min	20

- HCPs reported the following:
 - Training people with T1DM or T2DM to use an insulin pen was very easy (85%) or easy (15%)
 - Excellent or acceptable effect on participants' reluctance to use insulin (84% of HCPs)
 - Excellent or good effect on participants' confidence to manage their diabetes (99% of HCPs)

Single-group, open-label, nonrandomized, noninterventional, 3-month, observational survey involving 65 HCPs. HCPs = health care professionals. Carter J et al. *Curr Med Res Opin*. 2008;24:2741-2749.

40

Points to Consider When Selecting a Pen

- Patient's lifestyle¹
- Patient's insulin regimen (qd, bid, tid, basal-bolus)¹
- Patient's blood glucose profile¹
- Factors that may interfere with ability to use a pen (eg, poor vision, manual dexterity, memory)¹
- Familiarity with previous pen devices¹
- Usability, design, and esthetics²

bid = twice daily; qd = once daily; tid = 3 times daily. 1. Miles P. *Nurs Times*. 2006;102:53-54. 2. Spollett G. *Diabetes Educ*. 2008;34:957-967.

41

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

Design ¹	Exterior design and styling Size and portability How well the cap fits onto the pen Tactile feel and features
Usability ¹	Ease of use Ease of setting the dose Ease of reading the dose Ease of correcting the dose if overdialled 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
Patient Considerations ^{2,3}	Address the specific needs of different patient populations

1. Spollett G. *Diabetes Educ*. 2008;34:957-967. 2. Thurman JE. *Endocr Pract*. 2007;13:672-678. 3. Brunton S. *Am J Med*. 2008;121:S35-S41.

42

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

The LANTUS® SoloSTAR® Pen Step-by-Step Guide. sanofi-aventis Website.
http://www.lantus.com/solostar/how_to_use_solostar/solostar_insulin_injection_guide.aspx. Accessed April 7, 2010.

43

Benefits of an Insulin Pen for Routine Hospital Use

- Is labeled by the manufacturer with the product name and strength¹
- Can be individually labeled with the patient's name¹
- Provides insulin in a form ready for administration¹
- Lessens nursing time needed to prepare and administer insulin¹
- Associated with fewer dosing errors because of the dial-a-dose feature²
- Reduces medication waste that can occur when dispensing full insulin vials for each patient¹
- Avoids contamination of multiple-dose vials³

1. Considering insulin pens for routine hospital use? Consider this. ISMP Website. <http://www.ismp.org/Newsletters/acute/acute/articles/20080508.asp>. Accessed April 7, 2010. 2. Cornell S. *Health Policy*. Epub ahead of print March 12, 2010. doi:10.1016/j.healthpol.2010.02.006. 3. DeBaun B. *Infection Control Resource*. 2006;3:1. Transmission of infection with multi-dose vials. http://www.infectioncontrolresource.org/Past_Issues/IC11.pdf. Accessed April 29, 2010.

44

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

Greenwood B et al. *Am J Health-Syst Pharm*. 2008;65:698-699.

45

Switching to Insulin Pens in the Inpatient Setting: Practical Considerations

- Maintaining a multidisciplinary approach throughout the entire process¹
- Obtaining approval from governing bodies within the institution¹
- Providing extensive educational training for the nursing and pharmacy staff before and after the pen conversion²
- Labeling devices when first removed for patient use with patient name and date; bar-code scanning and the use of cautionary labeling can be helpful¹

1. Greenwood B et al. *Am J Health-Syst Pharm*. 2008;65:698-699. 2. Pisupati R et al. *Hosp Pharm*. 2009;44:871-873.

46

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

- Delivering each insulin device on a per-patient basis¹
- Storing pen in a nonrefrigerated, patient-specific medication drawer¹
- Conducting ongoing education on proper administration technique to ensure proper pen usage by nursing staff²
- Developing an institution-wide policy describing proper usage procedures²
- Ensuring continuous quality improvement through informal feedback methods²

1. Greenwood B et al. *Am J Health-Syst Pharm*. 2008;65:698-699. 2. Pisupati R et al. *Hosp Pharm*. 2009;44:871-873.

47

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

48

Resources for Patients

- ADA (American Diabetes Association)
 - www.diabetes.org
- Diabetes Life
 - www.dlife.com
- Insulin and device companies
 - www.Lantus.com
 - www.Apidra.com
 - www.goinsulin.com
 - www.lillydiabetes.com
 - www.mononordisk-us.com
 - www.bddiabetes.com/us
 - www.healthforwardus.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 and www.cdc.gov/diabetes/ndep/index/htm

49

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.NDEI.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 and www.cdc.gov/diabetes/ndep/index.htm
- American College of Physicians Diabetes Portal
 - <http://diabetes.acponline.org>
- WHO. *Adherence to Long-term Therapies: Evidence for Action*. Geneva, Switzerland: World Health Organization; 2003
 - www.who.int/chp/knowledge/publications/adherence_report/en/
- Overview of medication adherence. Where are we today?
 - www.adultmedication.com/OverviewofMedicationAdherence.html
- NCPiE. Enhancing Prescription Medicine Adherence: A National Action Plan [report]. Rockville, MD: National Council on Patient Information and Education; August 2007
 - http://talkaboutrx.org/documents/enhancing_prescription_medicine_adherence.pdf

50