Infusion Pumps: The Delivery Mechanisms for Your Compounded Products

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Infusion Pumps: The Delivery Mechanisms for Your Compounded Products

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Featured Speaker: Seth Eisenberg, RN, ASN, OCN®, BMTCN™
Professional Practice Coordinator, Infusion Services
Seattle Cancer Care Alliance

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Infusion Pumps:
The Delivery Mechanisms for Your Compounded Products

Seth Eisenberg, RN, ASN, OCN®, BMTCN™
Professional Practice Coordinator, Infusion Services
Seattle Cancer Care Alliance

July 2016
Objectives

• Identify different types of infusion pumps
• Discuss the relationship between compounded IV medications and IV tubing
• Identify common difficulties experienced by healthcare providers working with infusion pumps
• Describe the role of “smart pumps” in enhancing patient safety

Why pumps?

• Gravity infusions have been successfully used for more than 100 years

Cosnett, JE (1989)
Gravity infusions are subject to error:

- Volume of IV bag and relative height of bag above patient
- Length of tubing
- Diameter of tubing
- Plastic “creep” under roller clamps
- Ambient temperature
- Gauge of the IV catheter
- Anatomic location of the IV catheter
- Size of the vein
- Patient movement / position
- Venous blood pressure

Macklin, D (1999); Cosnett, JE (1989); Phillip, JH (1992)

Bag volume and relative height

500mL 50mL 36”

More volume = more pressure

Macklin, D (1999); Cosnett, JE (1989); Phillip, JH (1992)
Tubing length and diameter

- Longer tubing = more resistance
- Smaller inside diameter = more resistance

\[
\text{FLOW} = \frac{\text{Resistance}}{\text{Pressure}}
\]

Macklin, D (1999); Cosnett, JE (1989); Phillip, JH (1992)

Plastic dynamics (creep and expansion)

- Compression of plastic under roller clamp changes over time
- Tubing expands as temperature rises, decreasing resistance

Cosnett, JE (1989); Phillip, JH (1992)
Venous variables

- Location and gauge of IV catheter
- Size of the vein
- Patient movement / position

- Venous blood pressure
  - Increased BP = increased resistance

Cosnett, JE (1989); Phillip, JH (1992)

Controllers versus pumps

- 1970s: the age of electronic controllers
  - Able to regulate flow using a drip sensor on tubing drip chamber to count each fluid drop
  - Unable to produce positive pressure

- Pumps produce positive pressure, which overcomes most (but not all) resistance
- Some early devices were controller-pump combinations

Milam, DA (1990); Phillip, JH (1992)
Infusion pump definition

“External infusion pumps are medical devices that deliver fluids, including nutrients and medications ... into a patient’s body in controlled amounts.

An external infusion pump is a medical device used to deliver fluids into a patient’s body in a controlled manner.”

White Paper: Infusion Pump Improvement Initiative, Accessed June 23, 2016; http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm205424.htm#background

Early pumps

Flow meter for counting drops

Flow meter for counting drops
Classifying pumps: broad categories

- Mechanical (elastomeric)
- Implantable
- Subcutaneous
- Electromechanical IV

Major players: the field is small

**Pole Mounted Infusion Devices**

- Carefusion/Alaris: Spun off from Cardinal. Current market leader
- B Braun: German company, with large European base
- Smith’s Medical: Syringe-only pump
- Hospira: Spun off from Abbott in 2004
- Baxter/Sigma: Purchased Sigma in 2012
- Zyno Medical: Chinese manufacturer, FDA approval 2007
Major players: the field is small

Ambulatory Infusion Devices

- Smith’s Medical (Purchased Sims Deltec, original manufacturer of CADD Prizm)
- Moog/Curlin (Purchased Curlin)
- B Braun (Markets CME Bodyguard ambulatory pump (Israel))
- Hospira (Markets Q Core Sapphire ambulatory pump (Israel))
- Zyno Medical

Pole-mounted pumps

- AC with limited battery backup
- Ability for sophisticated programming
  - Secondary piggyback infusions
  - Delay start
  - Dose titration
  - Automated flushing of tubing
- Can connect with EMR
- Accuracy rated at ± 5%
Ambulatory pumps

- Portability is top priority
- Battery operated
- Can infuse for 4-96 hours, depending on pump and IV rate
- Can be “locked” to prevent patient tampering
- Simple user interface
- Accuracy rated ± 5-7%*
- Uses include home TPN, hydration 5FU infusions, antibiotics, analgesia

*Sapphire accuracy ± 2.5%

Syringe pumps
Syringe pumps

**Advantages**
- Accuracy (± 2 - 5%)
- Can deliver small amounts of drug
- First choice for pediatric/neonatal
- Can infuse at very slow rates
- Inexpensive microbore tubing
- Low priming volume

**Disadvantages**
- Drug must be compounded for syringe
- Syringe size limited to ~3mL-60mL
- No piggyback option
- Must be positioned so that nothing interferes with syringe barrel travel

Syringe pump examples

- **Excelsior**
  - Battery operated
  - Inexpensive
  - Easy to use
  - Only 3 rate options (low, medium, high)
  - Rate based on size of syringe
  - Good choice for antibiotics, premedication, etc. – when volume is consistent and infusion time not critical
Syringe pump examples

• Programmable (e.g., Medfusion)
  • Extremely accurate (± 2%)
  • Can infuse at very slow rates
  • Programmable for mg/hr or mL/hr
  • Can be set for different syringe manufacturers
  • Available with “smart pump” software

PCA pumps

• Available as inpatient (pole mounted) or ambulatory
• Deliver metered amount of drug via patient-operated button, with timed lockout
• Can deliver bolus and continuous infusion
• Have security locks to prevent/decrease drug diversion
Pump mechanisms

- Two methods of moving fluid from bag to patient:
  - Peristaltic
    - System used on all IV pumps except two
  - Cassette membrane mechanism
    - System used on Hospira Plum pumps and B Braun Outlook

- Note that some pumps use a “cassette” for tubing securement (e.g. CADD), but are still considered peristaltic

Peristaltic versus cassette

**Peristaltic:**
- Inexpensive tubing
- Easy to prime
- Easy gravity infusion in emergency situations
- Height of primary bag above pump influences pump accuracy
- Requires positioning height of piggyback well above height of primary
- Unable to control both primary and piggyback independently

**Cassette:**
- Tubing more expensive
- More difficult to prime
- Pump accuracy not affected by bag height
- Piggyback bag can be same height as primary
- Potential to infuse both primary and piggyback concurrently
- Potential to remove air and prime piggyback without opening system
Peristaltic design

Two types: Can be rotary or finger actuated. Fluid is squeezed and pushed through the tubing

Cassette diaphragm design

• Membrane or diaphragm is built into cassette housing
• Allows pump to manage primary and secondary infusions independently
Cassette examples

Hospira Plum A+ and 360  B Braun Outlook ES 400 (single channel only)

Bag height liabilities

• Actual warning noted in a pump operating manual:

NOTE: To minimize or prevent fluid flow from the primary container during a Piggyback infusion (sympathetic flow), it may be necessary to lower the primary bag more than 8 inches or clamp off the primary tubing. Sympathetic flow increases significantly when the Piggyback rate is greater than 125 ml/hr, and clamping the primary tubing is recommended at rates greater than 125 ml/hr.
Tubing

- Most manufacturers require specific tubing that is usually not compatible with other brands.
- Design of tubing depends on type of pump mechanism.
- IV tubing can require as much as 25mL to prime.
  - Major consideration for pediatric population and patients in phase I research studies.
  - Volume must be taken into account when priming tubing for ambulatory pumps (may require additional volume to compensate).

- The smaller the IV bag (e.g., premix 50mL ceftriaxone), the more residual drug is in the tubing when the bag is empty.
  - Depending on tubing, 50% of drug can remain in the tubing when bag is empty.
- Appropriate flushing protocols must be in place.
- Special tubings are necessary for certain medications (e.g., drugs containing Kolliphor® EL [formerly Cremophor® EL]).

Gelderblom, H. et al 2001; Paclitaxel prescribing information, Bristol-Myers Squibb 2011
Primary versus secondary tubing setup

Pump evolution: complexity and recalls

- Pumps have progressed from simple “set rate only” to microprocessor-controlled programmable devices
- Allows programming of:
  - Rate
  - Volume
  - Time
  - Other options
Infusion pump hazards

• Increased complexity = increased opportunity for errors
• From 2005 through 2009, approximately 56,000 pump-related adverse events have occurred (injuries and deaths)
• 87 recalls due to safety issues
  • 14 posing a risk of serious harm or death

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm205424.htm#causes

Infusion pump hazards: causes

• Software design
  • Alarms that fail to go off or trigger inappropriately (creates alarm fatigue)
  • Key bounce
• Hardware design and failures
  • Confusing data-entry steps
  • Breakage of commonly used components
  • Free-flow hazards
  • Air sensor issues
It’s a recall world

**Alli (60 mg orlistat capsules) by GlaxoSmithKline: Recall - Product Tamper**

(Posted 03/28/2014)

**AUDIENCE:** Consumer

**ISSUE:** GlaxoSmithKline (GSK) Consumer Healthcare is voluntarily recalling all alli-weight loss products, and Puerto Rico residents as the company believes that some packages of the product were tampered with in a manner that is not authentic. Alli.

GSK received inquiries from consumers in seven states about bottles of alli that contained tablets and did not alli. A range of tablets and capsules of various shapes and colors were reported to be found in bottles. Additionally, some bottles included the center carton were missing labels and had tamper-resistant seals that were not authentic. These tampered products were purchased in retail stores.

**BACKGROUND:** Alli is for weight loss in overweight adults, 18 years and older when used along with a reduced-calorie diet and regular exercise. The weight loss is achieved by blocking a portion of dietary fat from being absorbed in the intestines. Alli is packaged in a labeled bottle that has an inner foil seal imprinted with the words, “Sealed For Your Protection.”

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**Total recall**

- FDA responsible for safety and recalls
- Every pump manufacturer has had pump recalls
- Some have required modifications and/or user warnings
- Some have required permanent removal from the marketplace
Class I FDA recalls

- **Class I recall**: a situation in which there is a reasonable probability that the use ... will cause serious adverse health consequences or death.

http://www.fda.gov/safety/recalls/ucm165546.htm

Baxter / Sabratek 6060

- Several major safety concerns
- Obsolescence in design made retrofitting impractical
- Removed from market in 2005
Baxter Colleague

• Defects dating back to 1999
• 206,000 distributed in US by 2005
• Problems included:
  • Battery swelling, power loss, data issues, software glitches
• FDA required remedies
• Lawsuit for fraudulent repairs
• On April 30, 2010, the FDA ordered Baxter to destroy all pumps

Lawsuits happen

• B Braun Infusomat recall for unexpected free-flow
• Device that had not been taken out of service was blamed for a morphine overdose resulting in patient death
• Legal action against VA system

Biomedical departments have a responsibility to notify users of recalls and to act accordingly.
The FDA gets more involved

• In 2010, FDA issued a white paper (Infusion Pump Improvement Initiative) to:
  • Require manufacturers to include additional design and engineering information as part of their premarket submissions
  • Conduct additional testing of their devices
  • Work with manufacturers to address problems
  • Assist in diagnosing software interface issues

White Paper: Infusion Pump Improvement Initiative, Accessed June 23, 2016; http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm205424.htm#background
Smart pumps

“... intravenous (IV) infusion devices that provide computerized dose error reduction software with IV therapy libraries and corresponding administration rate limits.”

- **Examples:**
  - Alaris “Guardrails”
  - Hospira “Mednet”
  - B Braun “DoseTrac”

- Smart pump usage in US is 77%

[Harding, AD (2013); Pedersen, CA (2012)]

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Smart pumps

- **Prevent:**
  - Programming of rates outside allowable range for a given IV (drug library)
  - Use of incorrect units
  - Decimal point errors
  - Key bounce errors

- **Provide:**
  - Soft limits require confirmation prior to continuing, creating a “mental time out”
  - Hard limits cannot be exceeded
  - Automated reporting for QI
  - Communication with EMR

[Harding, AD (2013); Fairbanks, RJ (2014) www.ppmag.com]
Smart pumps

- Can be used with or without bar code medication administration (BCMA)

Harding, AD (2013)
Smart pumps

• When used without barcode medication administration
  • Nurse checks patient ID
  • Nurse checks medication label against order
  • Nurse finds medication in pump library and programs rate/volume
  • Infusion is started

Harding, AD (2013)

Smart pump challenges

• Expensive to implement with BCMA and EMR integration
  • Requires dedicated server, scanning equipment, Barcode printers, integration with pharmacy systems (e.g., DoseEdge™)
  • Custom drug “library” must be built
  • Library maintenance for new drugs added to formulary
  • Pharmacy and nursing education

Harding, AD (2013)
Not-so-smart pumps

- Nurses may be able to bypass library (a.k.a. “dumb pump mode”)
- Library may not be able to account for different rates depending on drug dose
- If BCMA not fully implemented:
  - Nurses could select wrong drug in library
  - Increased nursing time to initiate an infusion, which may impact overall compliance
- May not be compatible with EMR

Smart pump learning curve

- To be successful, smart pump implementation requires:
  - A multidisciplinary approach
  - Emphasis on a culture of safety within the organization
  - Sufficient resources (staff, $$, technology)
  - Annual education
Summary

• Electronic infusion devices (pumps):
  • Have evolved over the past 40 years
  • Can be used in a variety of settings
  • Can greatly reduce medication errors
  • Are subject to recalls
  • Do not all work and behave the same way
• Smart pump technology is becoming increasingly more important