The AAMI Foundation’s National Coalition to Promote the Safe Use of Complex Healthcare Technology Presents:

Go with the Flow: Insights into Complex Infusion Delivery Systems

July 20, 2018
**Vision:** Health technology enhances healthcare providers' abilities to improve patient outcomes.

**Mission:** The AAMI Foundation drives reductions in preventable patient harm and improvements in outcomes with complex health technology.

Current National Patient Safety Coalitions:
A Special Thanks

CLINICAL EXPERTISE
NURSING PRACTICE
SYSTEMS INNOVATION

NACNS
National Association of
Clinical Nurse Specialists

AAMI FOUNDATION
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Without their financial support, we would not be able to undertake the various initiatives under the National Coalition To Promote the Safe Use of Complex Healthcare Technology. The AAMI Foundation and its co-convening organizations appreciate their generosity.

The AAMI Foundation is managing all costs for the series. This seminar does not contain commercial content.
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Speaker Introduction

**Bob Butterfield**
Becton-Dickinson Engineering Fellow (retired)
Principal - RDB Medical Instrument Consulting

**Nathaniel Sims, MD**
Cardiac Anesthesiologist & Physician
Advisor to Biomedical Engineering,
Massachusetts General Hospital (MGH)
Assistant Professor of Anesthesiology,
Harvard Medical School
Go with the Flow: Insights into Complex Infusion Delivery Systems

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Disclosures

Bob Butterfield

• **Serves as expert on Standards Committees**
  • AAMI Infusion Devices
  • IEC 60601-2-24 Infusion Devices
  • ISO 7886 Disposable Syringes

• **Serves as advisor/invited lecturer and industry liaison**
  • Harvey Mudd College
  • University of San Diego
  • UC San Diego

• **Serves currently as a consultant to Ivenix, Inc.**
Disclosures

Nathaniel Sims, MD

• Cardiac Anesthesiologist at Mass General Hospital
• “Smart Infusion Pump” inventor - patent in public domain
• AAMI - Standards Organization - Board of Directors
• ASHP & ASA Initiatives on “Standardized Concentrations”
• “Micro-Infusion” Syringe Pumps in Surgery & Critical Care
• Closed Loop Control of Anesthesia - EEG signal
• Education: Infusion Pump Basic Principles & Best Practices
• No financial disclosures
Overview

Learning Objectives

• Understand large volume pump (LVP) technology and its use in typical clinical environments

• Identify external conditions that impact LVP flow accuracy

• Examine the impact to patient safety when flow variations occur

• Describe how hospitals teach about infusion safety, basic principles, and best practices
Case 1: The Long Long Infusion
Long-term Mean Flow

- Oncology Unit
- 1,000 mL infusion to be delivered over 24 hours
- Infusion Complete
- 100 mL remains in the bag
  - ~2.4 hours over expected infusion time

What’s going on?
What IS a "Large Volume Pump (LVP)?"

- LVP's act like a conveyor belt to transport fluid from a container to the patient continuously
- LVP's do not apply 'pressure' to the fluid, rather they 'displace' the fluid
- Most LVP's do not sense flow or volume but depend on accuracy of tube and mechanism

*graphics courtesy Dr. Nat Sims & Chris Colvin
"Drug Administration & Mixing Decisions"
Massachusetts General Hospital 2018
The human heart and most IV pumps behave remarkably similarly. In general, the greater the intake pressure, the greater the flow.
Filling Phase: Fluid (Head Height) Too Low

optimum fluid elevation over pump

actual level

“pump chamber” under-filled
Delivery Phase: Fluid (Head Height) Too Low

optimum fluid elevation over pump

actual level

“pump chamber” under-filled
Filling Phase: Fluid (Head Height) Too High

actual level

optimum fluid elevation over pump

“pump chamber” OVER-filled
Delivery Phase: Fluid (Head Height) Too High

- Actual level
- Optimum fluid elevation over pump
- "pump chamber" OVER-filled
Filling Phase: Fluid (Head Height) Level Correct

“pump chamber” OPTIMALLY-filled

optimum fluid elevation over pump
Delivery Phase: Fluid Level Correct

optimum fluid elevation over pump

“pump chamber” OPTIMALLY-filled
Effect of Output Pressure on Pump Flow

The heart regulates its flow automatically. IV pumps are much simpler - their flow is often reduced by output pressure.
Delivery Phase: High Backpressure (Elevation)

Back pressure causes the “pump chamber” to be slightly overfilled, resulting in some fluid NOT going to patient
Delivery Phase: High Backpressure (Resistance)

Back pressure causes the “pump chamber” to be slightly overfilled, resulting in some fluid NOT going to patient.
When the intake 'valve' opens, the “pump chamber” expels excess fluid UPSTREAM into the drip chamber
Summary: Effects of Intake and Output Pressure on Mean Flow Rate

User manuals offer some data - but it's not interpreted
±5% is the *typical* mean accuracy variation of set & pump under laboratory test conditions - 0 backpressure, nominal head height of source fluid

**Low intake pressure** -3% to -6%

**High back pressure** -10% to -25%

- Low fluid elevation
- Restricted vent
- Kinked tubing
- Viscous fluid
- Fluid filter

- High flows
- Viscous fluids
- Small bore - long catheters
- Manifolds
- Anti-siphon valves
- Needle-free valves
Impact of Mean Flow Error: Delivery Time and Volume

Volume infused vs Time

- Red: 10.0%
- Green: 0.0%
- Blue: -10.0%

100 mL short

2.4 hours LATE
Case 1: The Long Long Infusion
Long-term Mean Flow

- Oncology Unit
- 1,000 mL infusion to be delivered over 24 hours
- Infusion Complete
- 100 mL remains in the bag
  - ~2.4 hours over expected infusion time

- Today’s LVPs don’t actually measure flow
- Real world conditions are always different
- Head height, catheter size, and other factors impact flow
- Standardize on practices that optimize YOUR hospital’s equipment
Case 2: An Unstable Blood Pressure

Short-term Flow

- PICU
- Post open-heart surgery patient
- Vasopressor & Inotrope infusions
- Epinephrine concentration changed in order to decrease flow rate of pump
- Patient’s blood pressure becomes more varied

What’s going on?
Short-Term Flow Behavior
Flow from Pumps – Discrete “Shots”

Most pumps use "stepper" motors. This may result in non-continuous delivery - especially at low flow rates!
Importance of Continuity & Uniformity

Continuity

Lack of interruption of flow

Uniformity

Consistency of individual units of flow delivered (aliquots or 'shots')

*Device Standards* describe the discrete flows produced by pumps as “SHOTS” … so we will also..
Flow Continuity & Uniformity

Poor Continuity Good Uniformity

Drug level in body

low rate
high rate

One shot cycle

One shot cycle

time

minutes seconds
Flow Continuity & Uniformity

Good Continuity
Poor Uniformity

One pump cycle
Flow Continuity & Uniformity

Good Continuity (small shots)
Good Uniformity (equal shots)

Drug level in body

high rate

low rate

time

minutes

seconds
Case 2: An Unstable Blood Pressure
Short-term Flow

• PICU
• Post-heart surgery
• Vasopressor & Inotrope infusions
• Epinephrine concentration changed in order to decrease flow rate of pump
• Patient’s blood pressure becomes more varied

• Due to the nature of LVP & syringe technology, there can be various types of irregularities in flow
• Depending on flow rate and infusion site, this variability can be more pronounced – carrier solutions may help resolve
• Mix drugs thoughtfully for best balance between fluid restriction and pump capabilities
• MGH has created on-line, interactive educational modules
Case 3: The Piggyback that stayed home..
The challenges of Secondary infusions using check-valve sets and elevation

- Oncology unit
- Frequent Secondary mode gravity infusions
- Common occurrence of medication remaining in Secondary container although pump indicates infusion is complete

What’s going on?
Beginning Secondary Flow

Gravity pressure keeps one-way valve closed

Pressure lost due to flow through Secondary / Primary connection

Sec. Volume

Sec. Flow Rate
Completing Normal Secondary

Gravity pressure is now too small to keep valve closed.
Slow Secondary

Gravity pressure is now too small to keep valve closed.

Pressure lost due to high flow through connection.

Primary and Secondary run simultaneously (sympathetic flow).

High rate.
No Secondary at ALL

Will the un-delivered Secondary be noticed?

Roller clamp accidentally left closed

All the Secondary infusion has drawn from the Primary
Over Delivery of Secondary

"...the order is for 125 mL, why can't I just set the Secondary VTBI to 125 mL ?.."

ALL the Secondary volume will be delivered...but at different flow rates!
Case 3: The Piggyback that stayed home..
The challenges of Secondary infusions using check-valve sets and elevation

- Oncology unit
- Frequent Secondary mode gravity infusions
- Common occurrence of medication remaining in Secondary container although pump indicates infusion is complete

- Secondary infusions are complicated and require careful attention to set-up and manage
- Caregivers need to thoroughly understand basic principles of secondary infusions--
- -- particularly back-check valves, setting the VTBI, and how to observe the drip chambers to confirm equipment
- *MGH has created on-line, interactive educational modules*
Summary

• Under real-life operating conditions, LVP flow/volume error can be as much as negative 20-30%

• The way medications are mixed should take into account the pump’s performance characteristics (continuity & uniformity)

• Secondary infusions are complex to set up and assure intended delivery

• Choice of materials including secondary sets, needle-free valves, and vents all impact performance

• Risks of both over and under delivery of medication exist with each application

Clinical impacts range from inconvenience to serious under-medications
Series of online modules aimed at teaching key concept for understanding safe drug infusion practices.

Modules use:

- Graphic and animated content
- Interactive questions to practice applying the concepts
- Professional audio narration

https://druginfusionsafety.massgeneral.org
Syringe Infusion Pumps – Operation & Safety Considerations

2-part series. Topics include:

- Mitigating startup delays due to slack
- Limiting delays in occlusion detection and avoiding a post occlusion bolus
- The impact of changes in pump height on medication delivery
- What to think about when selecting the syringe volume and tubing set

https://druginfusionsafety.massgeneral.org
Delivery of Life Supporting Drugs: Dead Volume

2-part series. Topics include:

- What is dead volume?
- Explaining the implication of dead volume on drug delivery
- How to minimize the impact of dead volume

https://druginfusionsafety.massgeneral.org
Drug Administration & Mixing Decisions

Topics include:

- Selecting the optimal standardized concentration and flow rate based on pump limitations and a patient’s fluid tolerance.
- Key considerations when selecting between a large volume pump and syringe pump.
- Thinking about the container/mix volume.

https://druginfusionsafety.massgeneral.org
Basic Principle of Secondary Infusions

Topics include:

- Key setup elements of secondary infusions
  - Height difference
  - Back-check valve
  - Secondary roller clamp

- Back priming

https://druginfusionsafety.massgeneral.org
Conclusion & Call to Action

• **Going with the flow...** requires significant insight into the design and behavior of your pump
  - Determine how your LVP will meet the clinical needs of all the patients in your hospital
  - Work with your pump vendor to understand how your LVP behaves under real-life operating conditions

• **Participate in improving the design and performance of medical devices you use**
  - AAMI is developing new methods of evaluating flow performance of pumps
  - Get involved: AAMI National Coalition to Promote the Safe Use of Complex Healthcare Technology
Thank you!

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Polling Questions

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Coming Next!

The challenges of ensuring a safe and competent workforce in the use of medical devices in healthcare

David Williams RGN
Medical Devices - Clinical Lead
Clinical Engineering
Medical Physics & Clinical Engineering
NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST
QMC Campus
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We hope that you will support this important mission

Why Support? Adverse events continue to be a troubling issue in healthcare and technology is a contributing factor. With complex technology being introduced at the point of care at a rapid rate there is a need to identify solutions to help care givers navigate this environment and mitigate the risks that are present. Your support will create essential tools to help reduce the risk of technology related incidents.

How to Support? It is easy! you make a tax deductible donation two ways:

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Thank you for attending the AAMI Foundation Complex Technology Seminar Series!

This concludes the presentation.