Improving Data Quality by Monitoring Gravity Infusions

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Proof of concept to explore options for connecting DripAssist and DFdiscover using the DFws API, DFattach, or other tools.

The long-term goal is to show how DFdiscover can be used to connect to medical devices to provide insight into data. What might be a unique value-add to our current data views?

Infusion as starting point because the first ever electronic monitoring tool for gravity infusion promises new data quality and insight.
Many studies perform infusions, but the data collected is very minimal.

Unless an infuser is used, infusion rate can be highly variable.

Calculated vs. actual rates may be different, affecting safety, efficacy and outcomes.
Background on infusion: Pumps vs counting drops

- Syringe or large volume infusion pumps require sophisticated infrastructure to operate correctly
  - Cost may also be an issue, but even if it is not, most sites outside the US lack the infrastructure required for pumps to operate correctly (calibration, consumables, dirty power, etc.)
  - IV drug dosing can be especially challenging in distributed sites. (home care in the US as analogous in challenges)

- Infusion pump deployment, calibration, and maintenance can be a weak point in protocol consistency.
Current situation:

- Sites often rely on gravity infusion as primary or backup mechanism for infusing IV drugs

- Delivering drugs via gravity infusion lacks accuracy and monitoring ability
  - Research demonstrates gravity infusion is highly variable, and inaccurate (4 out of 5 times, at least 20% dosing error rate)

- Accurate gravity infusion data is practically impossible to achieve
Data is often limited to...

1. Was the study infusion administered?  
   - Yes  
   - No  
   - Why not? [Blank]

2. Infusion start time: 13:50 24-hour clock

3. Start rate: 185

4. Infusion end time: 18:40 24-hour clock

Maybe some admin questions

Start and stop times
Manually recorded rate
Lack of detail makes anomalies hard to explain

Why is this zero?

Why is the rate so low?

Why did it take so long?
Let’s look at a “bad” example of an infusion

Demo gravity infusion data shows what realistically could happen at the site
The infusion was 7 bags total over 5 hours.
The first bag just drained out without being monitored or adjusted for flow
The second bag was monitored and drip rate adjusted, but there was a long time gap until the bag was changed.
4th, 5th, 6th bags were adjusted but still some gap in time
7\textsuperscript{th} bag started late and too high, with an attempted correction
Having the visual explains a lot

The bag was empty

Rate not adjusted correctly

Big gaps between bag changes
New DripAssist Infusion Rate Monitor technology provides uniquely accurate gravity infusion monitoring usable in any setting.
Why start with infusion?

- Because the manually collected data is notoriously inaccurate
- Only reason there has been complacency with status quo is because there have been no real options
Why gravity infusion is hard

(1) Multiply the rate of administration in ml/min by the type of tubing you're using:

\[ \text{gtt/min} = (\text{ml/min}) \times (\text{gtt/ml}) \]

(2) \( \text{gtt/min} = (\text{ml/hr}) \times (1 \text{ hr/60 min}) \times (\text{gtt/ml}) \)

(3) Remember there are four potential gtts: 10/15/20/60
Factors for consideration
- Temperature
- Venous pressure
- Fluid viscosity
- Patient movement
- IV catheter size
- Tubing creep

- Roller clamps - poorly designed for fine control
  - 1-2 drops = 10-20% error rate
  - Pumps 39% error rate
  - Gravity 21% error rate

Also, an exceedingly variable system…
It would be great to be able to really see what is going on with drug dosing and infusion rates
Typical unmonitored infusion pattern
Another typical scenario…
Potential future: Connect DripAssist data to DFDiscover

Would provide a first ever complete picture of gravity infusion data

#DFUG2018
Rate can be visually monitored.

Audible warnings to change bags and if the rate is out of spec.

By connecting to DFdiscover, a visual record can be captured.

With DripAssist.
The goal of our software is to connect people with their data.
As Eric Bosch said yesterday: “accurate, efficient data entry”

Next horizon: “Accurate, efficient data generation”

New connected devices to provide accurate data directly to DF/Net tools
- New kinds of data generation
- New opportunities for data analysis
Options:

- #1 CRF or eCRF with DripAssist Infusion Rate Monitor

- #2 (future) DripAssist Connect direct download to DF/Net tools

  - Why I’m here today: to learn what kind of questions do we want to ask about infusion rates?
    - Drug delivery rate correlated with patient vitals?
    - Drug delivery rates correlated with adverse effects?
    - Site-based QC? Retrospective or real-time.
    - Etc.
Continuous gravity infusion monitoring options
Getting the data into DFdiscover

Two options being considered:

1) If the tablet is visually graphing the results, perhaps it can send a pre-made graph to DFdiscover via the API and/or use DFattach.

2) The raw data can be sent to the DFdiscover server, a graph created, and attached with DFattach.
Here to learn what you and your research colleagues want to see in a study using IV drug delivery.

Outside the US sites are using gravity. How do we collect and analyze better data from those sites?

Seeking product development advice.
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