UMC Utrecht

Infusion current and best practices

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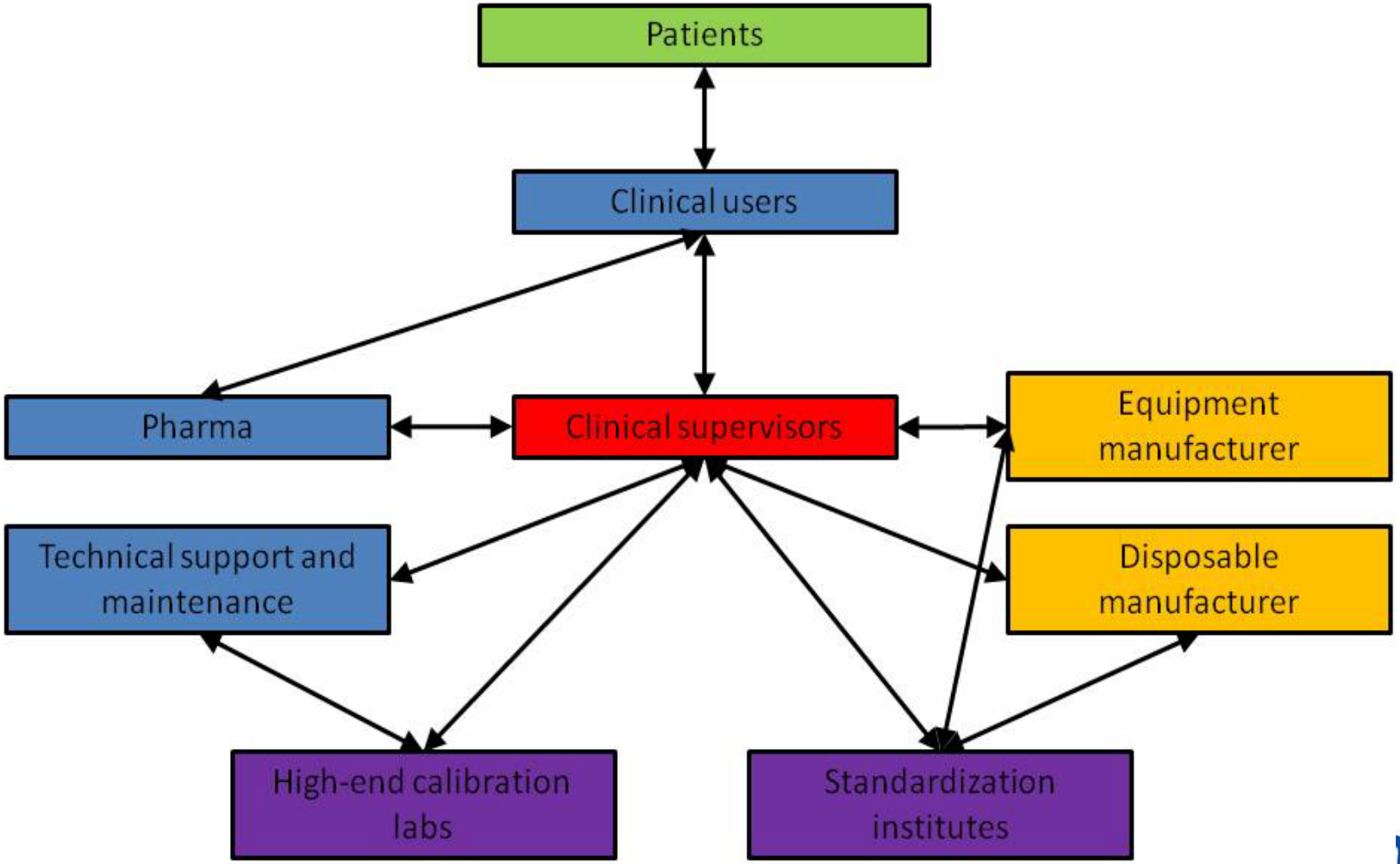
Outline

- Objective
- The parties involved
- Adverse events and risk analysis abstract
- Survey of current practice
- Infusion policies
- Education
- Conclusion and call for action

Procedures and protocols: the objective

- Create awareness on risks of multi- infusion
- Find best practices, make protocols and give practical solutions for safe use of infusion technology
- Method:
  - Analyse risks of (multi) infusion
  - Discuss solutions with clinical stakeholders
  - Make education programme

Parties involved in infusion technology application



Adverse events involving infusion pumps

2005-2010 USA

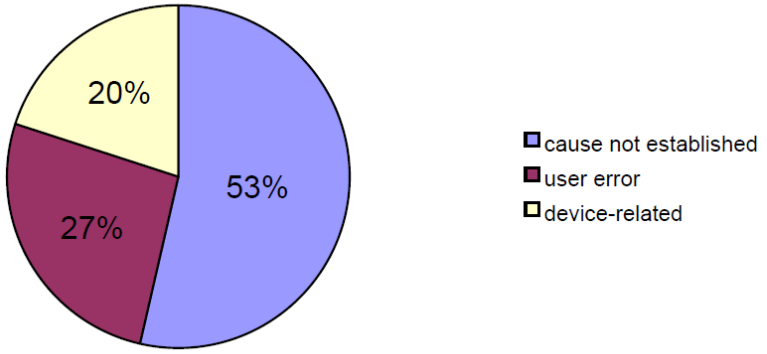
56.000 adverse events reported to FDA

- software defects
- user interface issues
- mechanical or electrical failures

1990 – 2000 UK

1.495 adverse events

- 20% Technology related
- 27% Human error
- 53% Cause unknown



Literature study risk inventory

Important conclusions

- Human and technical errors can be separated.
- Many of the errors were not exclusively human errors
- Most errors are also found in one pump infusion, but
  - Complexity in multi-infusion increases the probability
  - Higher risk of choosing wrong infusion pump
  - The consequences can be more severe.

Highest risks and preventative measures

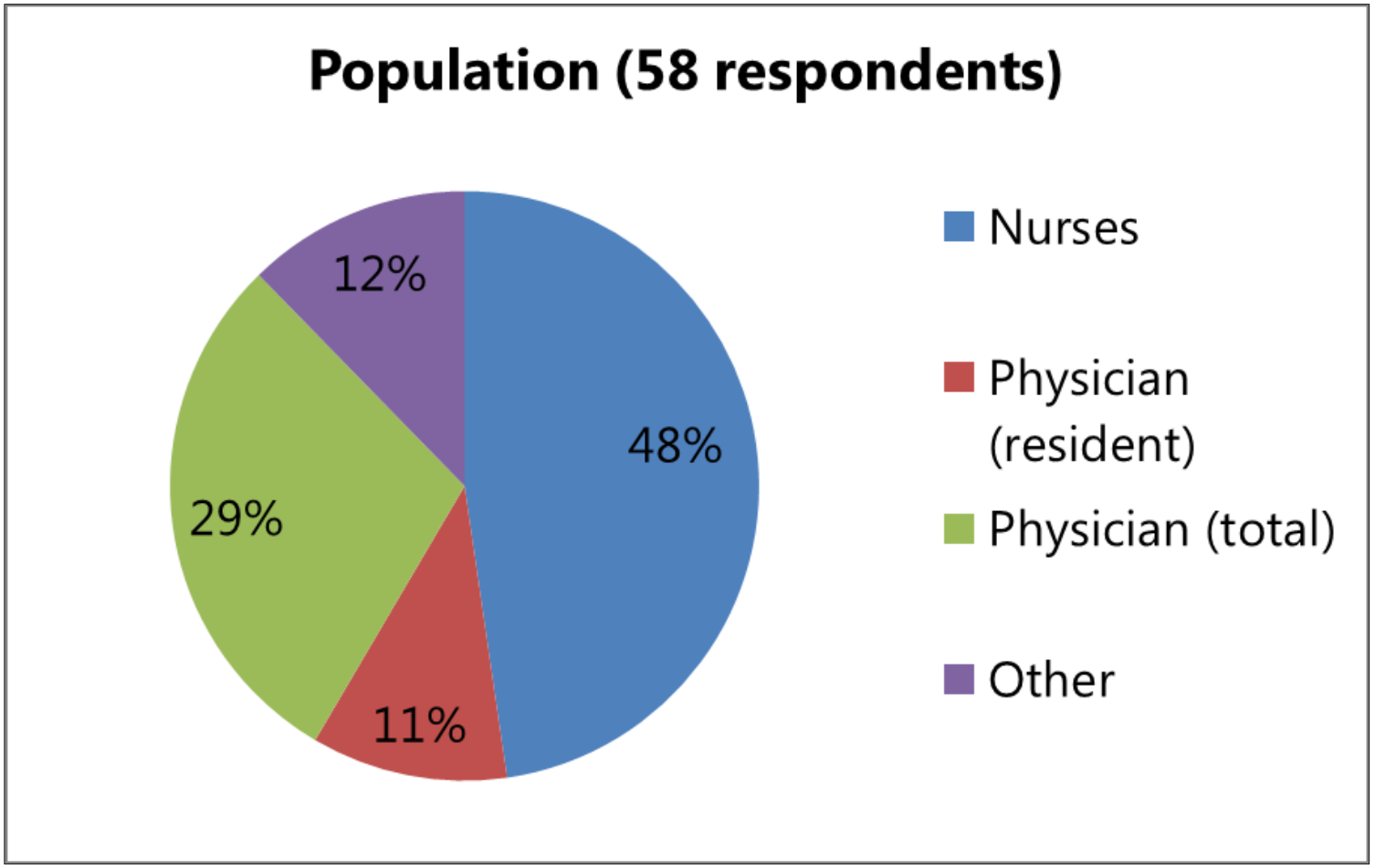
High risk	Preventative measures
• Alarm fatigue	• Alarm differentiation techniques and education
• Missed occlusion leading to extravasation	• Extravasation protocols and education
• Infection risks	• Infection protocols, instruction videos
• Errors in medication orders	• Protocols for double check, dose error reduction systems
• Poor interoperability of medication order systems	• Standardization

Who is responsible?

- Responsibility for administering correct dose is shared:
  - Doctors: integral patient therapy responsibility
  - Nurses: administering drugs
  - Pharmacists: preparation of drug solution, specified settings
  - Medical physicists and maintenance department
- Can responsibilities be met?
  - Lack of vital performance details
  - The drug delivery devices are checked regularly, typically once every 12/ 24 months
  - Recalibration requirements only in case of specific maintenance actions
  - Influence of disposable infusion medical devices on drug delivery are not included in key standards

Survey: Current practice

Survey of 30 questions.



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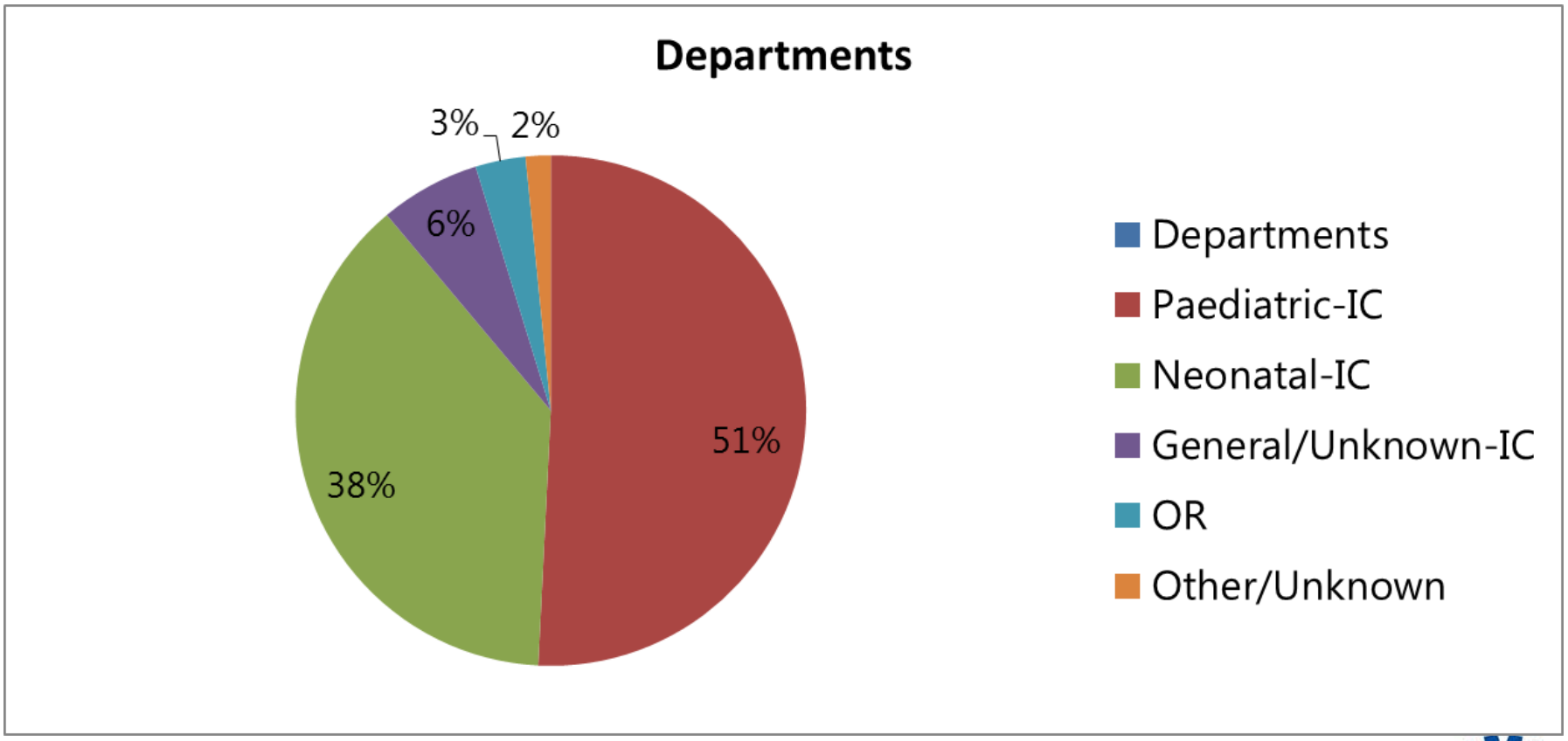
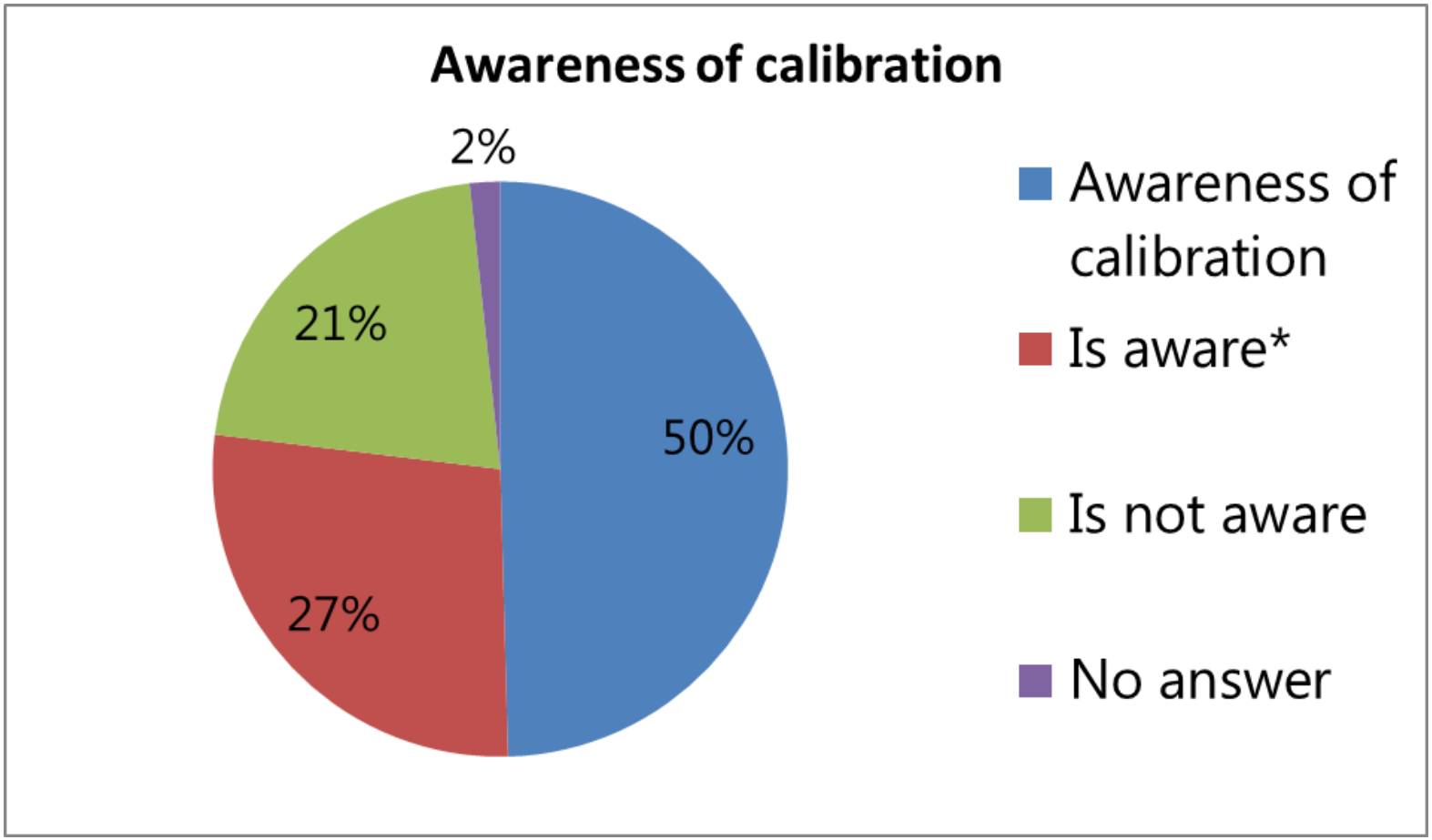
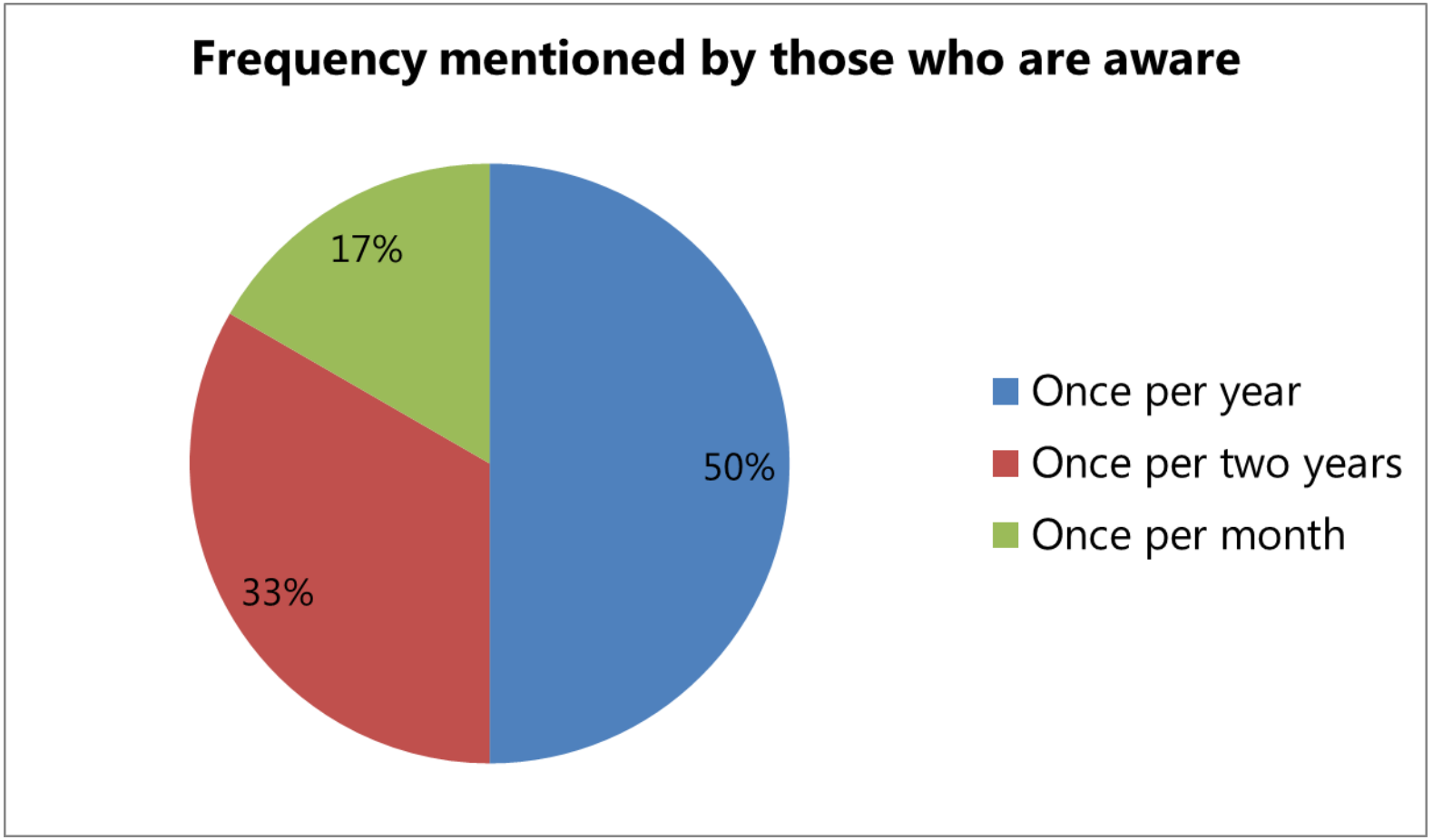


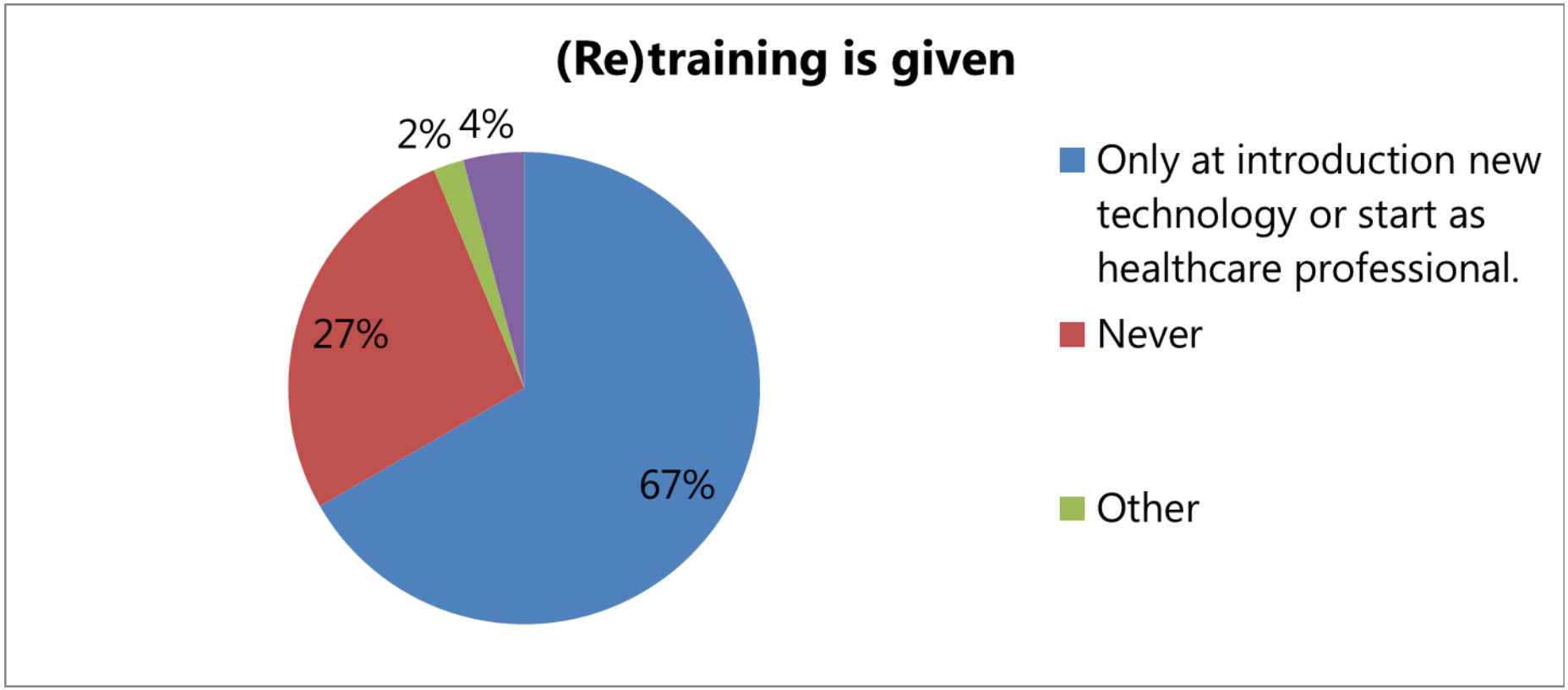
Awareness of pump calibration



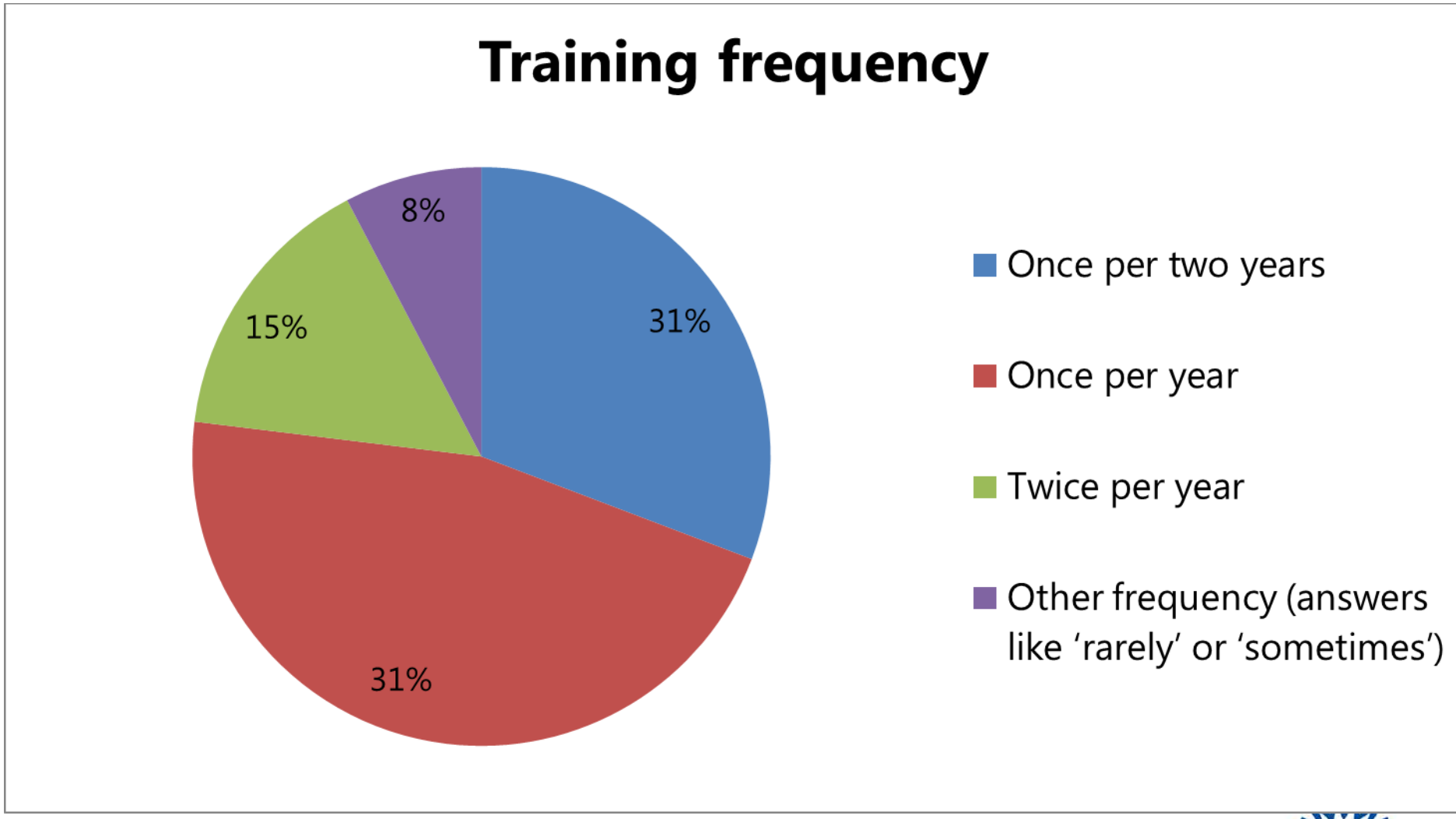
Awareness of pump calibration



Education


(Re)training is given
2%
4%
27%
67%
Only at introduction new technology or start as healthcare professional.
Never
Other

Education


Training frequency
8%
31%
15%
31%
Once per two years
Once per year
Twice per year
Other frequency (answers like 'rarely' or 'sometimes')

Survey of Current Practice: two interesting answers

- 41% clinicians is not aware about pump calibration
  - Is this just the responsibility of the clinician?
- 55% of clinicians only receive training with introduction of new technology.
- Some clinicians stressed the importance of more frequent training.
- 40% uses smart pumps

  These are pumps with advanced medication library software

Technical aspects

Response time of single pump infusion

- varies due to system mechanical compliance
- should be taken into account. Especially for low flow rates,
  - Pressure dependency
  - Temperature dependency
- Measurements help to assess quality
  - Specifications given by manufacturer
  - For critical applications in requirements

Dosing error at steady state

- Little influence of
  - Accessories
  - Pressures
  - Temperature
  - Viscosiy
- Large spread of results (flow from different syringes at <0,5 ml/h low flow rates), significant uncertainty

Standards and regulations

- Pumps: IEC/EN 60601-2-24
  - Describes “trumpet curve”
- Syringes: ISO 7886-2
  - Describes maximum compliance (compressibility)
  - Describes maximum “dead volume”

→ No specific regulations for low flowrate/ specific applications

→ No protocols describing maximum internal volume

→ No output measurements of entire system (pump+syringe+infusion line and catheter)

Clinical aspects and recommendations

Clinical aspect

- Start up time is important parameter. Two causes:
  - System compliance
  - System filling
- Dosing errors in multi-infusion on dose changes
  - sometimes acting counterintuitively.
  - Two causes:
    - System compliance, especially at low flow rates
    - System dead volume, especially at high flow rates and large flow rate differences

Recommendations

- Create user awareness by education
  - E-learning
  - on the job instruction
- Set up protocols for critical applications
- In infusion device procurement
  - Ask for system characteristics
  - Add requirements on compliance
- Add specific requirements to standards

User education

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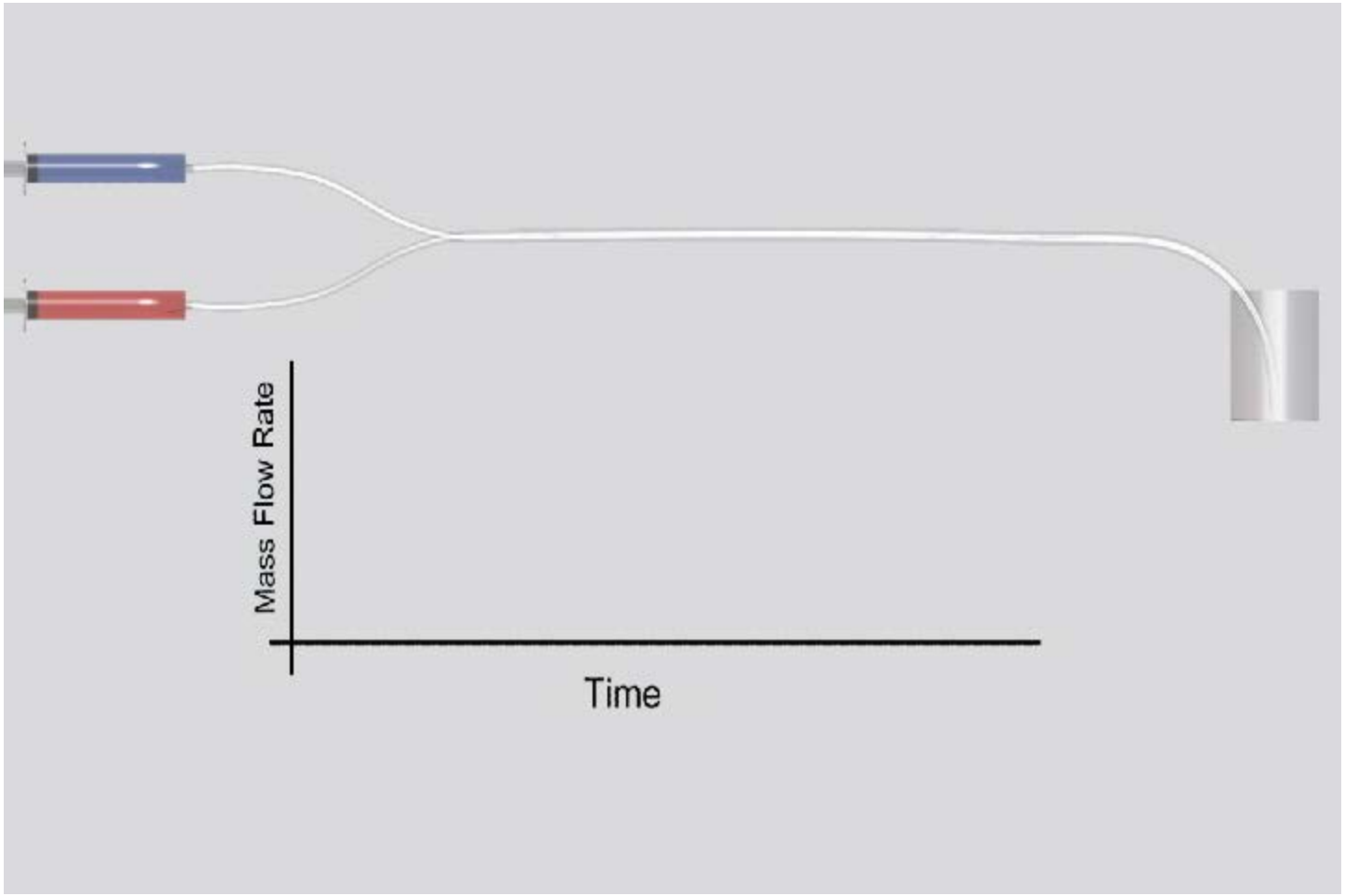
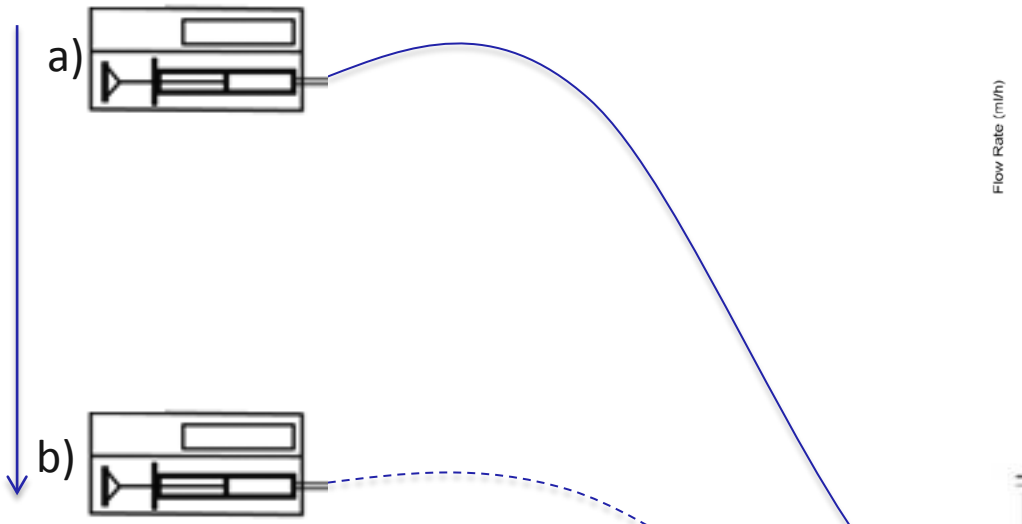
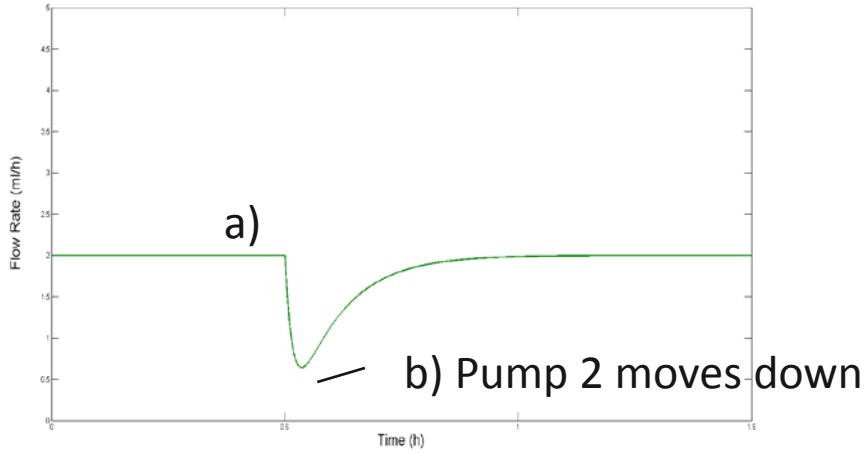
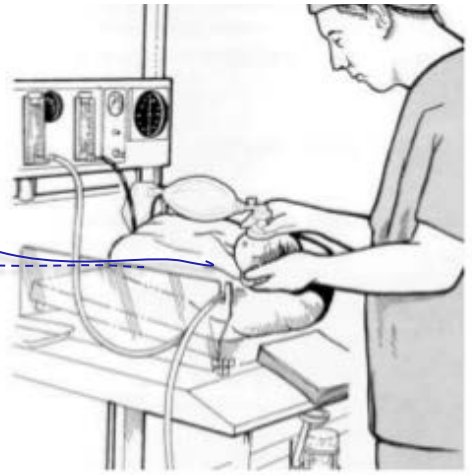


Height difference

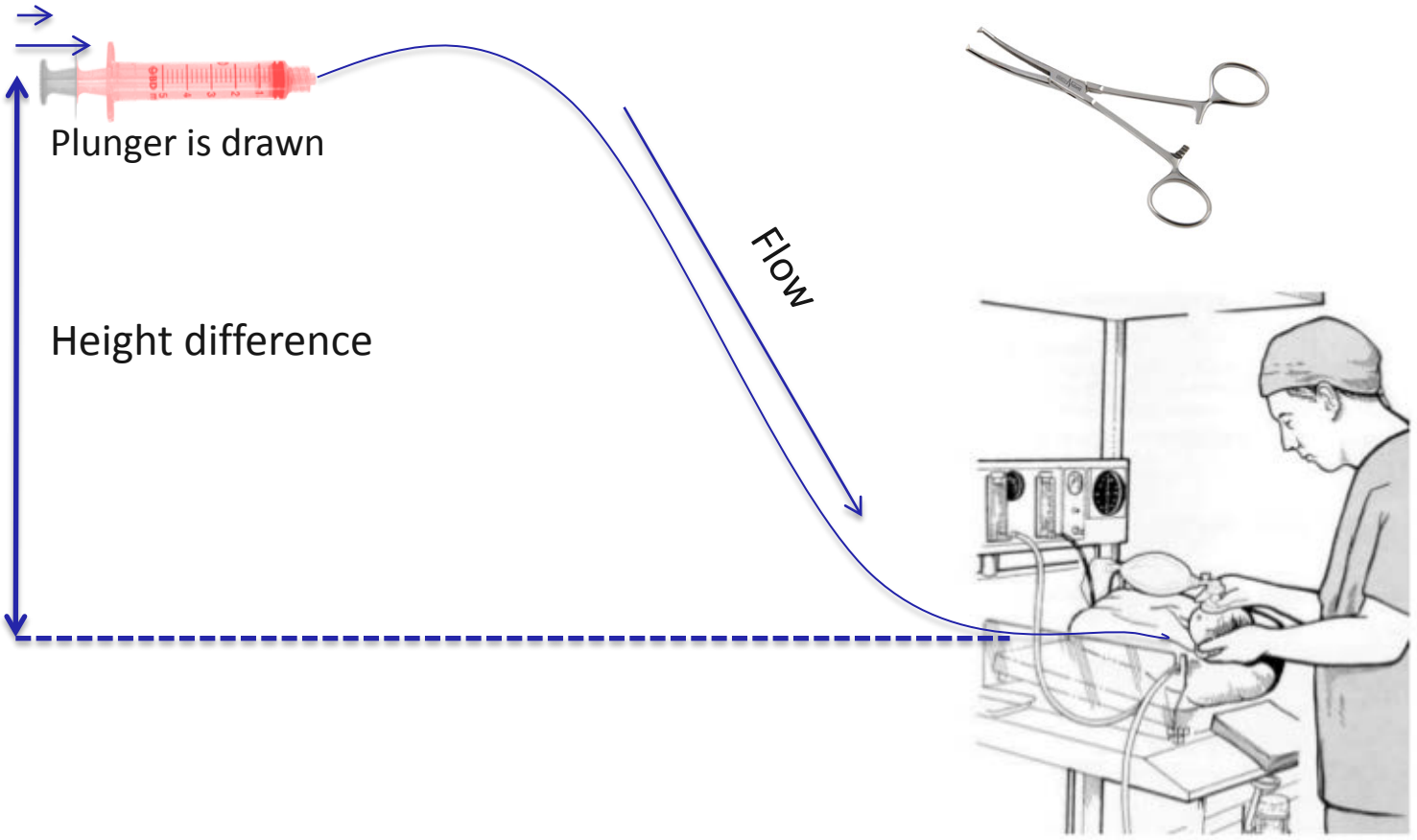






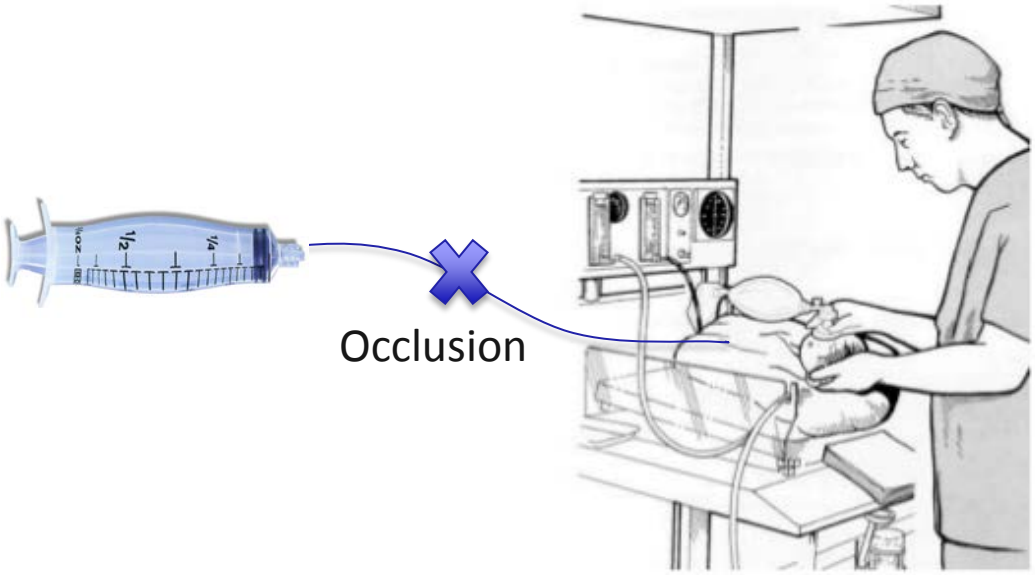
- Pumps are typically placed in different heights because users differ in height
- With the change of height of the pump, a transient pressure change may cause under- or overdosing
- This is only possible when the system is compliant or if the plunger is not clamped by the pump

Free flow



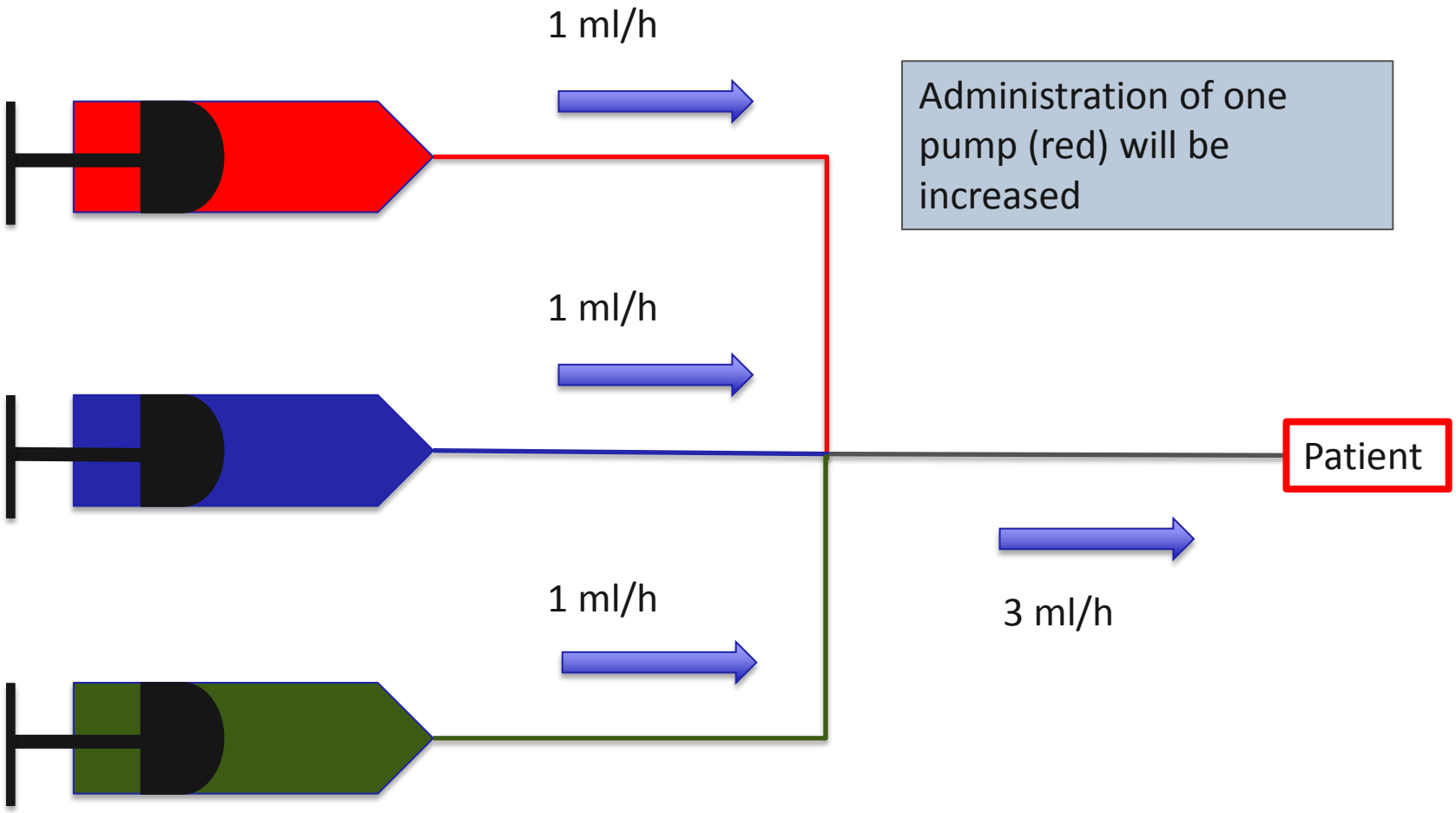
- Height difference between the syringe and the patient causes pressure difference
- Syringe replacement: the syringe plunger is drawn
- The syringe is emptied when not kept in place in the pump
- Prevention: line is blocked or clamped.

Occlusion

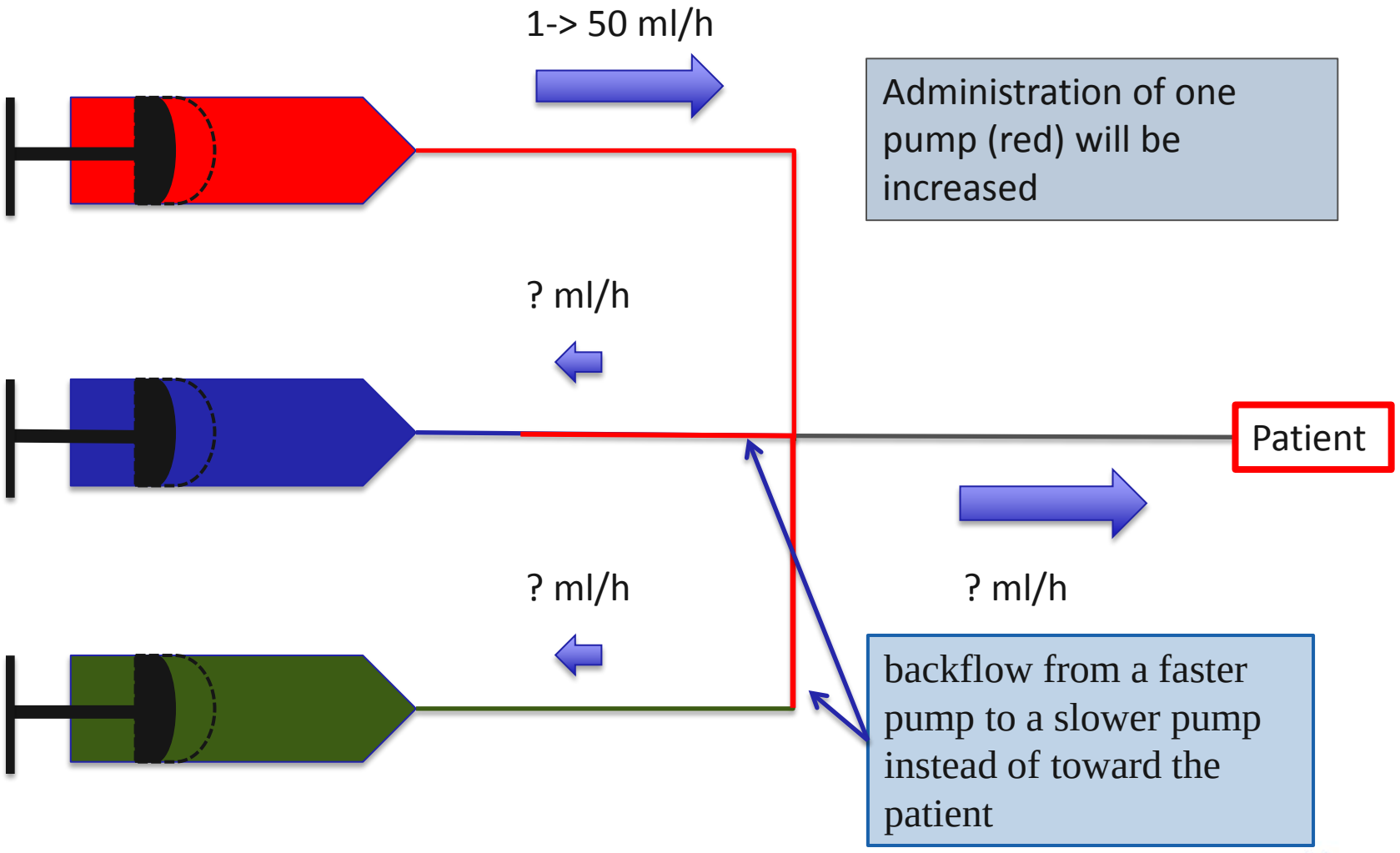


- The line is blocked. This is called an occlusion. No drugs ar administered.
- Because the components are elastic / compliant the pressure slowly increases
- The occlusion alarm sounds if the occlusion pressure is reached
- Dependent on the measuring system (in the line or on the syringe) this may take a long time because of the compliant components

Backflow


1 ml/h
Administration of one pump (red) will be increased
1 ml/h
Patient
1 ml/h
3 ml/h

Backflow


1-> 50 ml/h
Administration of one pump (red) will be increased
? ml/h
Patient
? ml/h
? ml/h
backflow from a faster pump to a slower pump instead of toward the patient

Conclusions

- A lot of variation in use of infusion technology.
  - Partly because of different applications
  - No clear consensus on best practice
- Best practices should contain technical aspects
  - Users should take variations in response time into account
  - Measurements add to quality assessment, especially at low flow rates a large spread in results exists
- Clinical best practices:
  - Dead volume requires longer waiting time
  - Avoid combining high and low flow rate on one line
  - Be extra careful when using potent drugs with low biological half time or small therapeutical range
  - Use low compliant syringes in low flow rate applications

Call for action

- This problem has been known for at least 20 years
- Action is needed to finally to finally realize the innovations needed to solve multi-infusion problems
- Infusion device manufacturers, hospitals, metrologists and scientists should work together
  - To innovate and create pressure independent infusion devices
  - To create adequate standards
- Join us for action!

Questions

Disclaimer

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