Closed-Loop Workshop

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M. Cannesson Disclosures
• Consulting for Edwards, Masimo, Covidien, Philips, Draeger
• Research funding from Edwards Lifesciences, Masimo
• Shareholder in SIRONIS®, Inc.

J. Rinehart Disclosures
• Consulting for Masimo, SurgiQuest
• Research funding from SurgiQuest
• Shareholder in SIRONIS®, Inc.

We intend to discuss investigational products
Closed-Loop: A Novel Idea?

Why a CL Workshop?

Medically-Relevant Articles with "Closed-Loop" in Title by Year
What Are People Working On?
Publications 2009-2012 relevant to our specialty

- Ventilation (most advanced area)
- Insulin (lots of active work)
- Propofol (± narcotic)
- Volatile anesthetics
- Fluid Administration
- Vasopressors
- NMB’s

What Guidance is out there?
International Standards

IEC 60601-1-10

INTERNATIONAL STANDARD

Medical electrical equipment –
Part 1-10: General requirements for basic safety and essential performance –
Collateral Standard: Requirements for the development of physiologic
closed-loop controllers

Update on Medical Device Interoperability
and recommendations from GHTF 10

- Evaluation under simulated use conditions may be
  necessary. Where possible, testing under unusual or
  stressful situations should be performed in order to
  increase confidence in the systems.
What Guidance is Out there?
Regulatory & Usability Standards

What Problems are Out There?
Internal vs. External Validation

Simulation & Engineering

Animal Studies

Human Studies

Published Work

Unpublished Work
Discussion - Practicality

• CL has been around for 30+ years and never really “caught-on”, is it different now or not?

Discussion - Practicality

• Should we be focusing on intelligent monitors and decision support instead of closed-loop?
Discussion - Practicality

• Where do closed-loop systems have the most potential to improve clinical care?

• Closed-loop versus open-loop?
Discussion – Development

• Should the STA/ASA/AMA/SPCA be providing guidance or recommendations for CL developers?

Discussion – Development

• Is there anything we can/should say about the expected R&D pathways for these systems?
Discussion – Safety & Reporting

• What standards of evidence of safety do we expect from closed-loop systems?

• How should safety be demonstrated to the clinical community?
Discussion – Safety & Reporting

• How do we deal with published vs. unpublished test results (especially in the context of “proprietary” data?), or is this just an issue for the FDA?

Discussion – Industry

• What role can industry play in the development of CL systems?
Discussion – Industry

• What role can industry play in the development of CL systems?

• Should we expect access to direct data from industry devices?

• What about control...?
Discussion - IP

- Does intellectual property in this area act as a barrier to development?