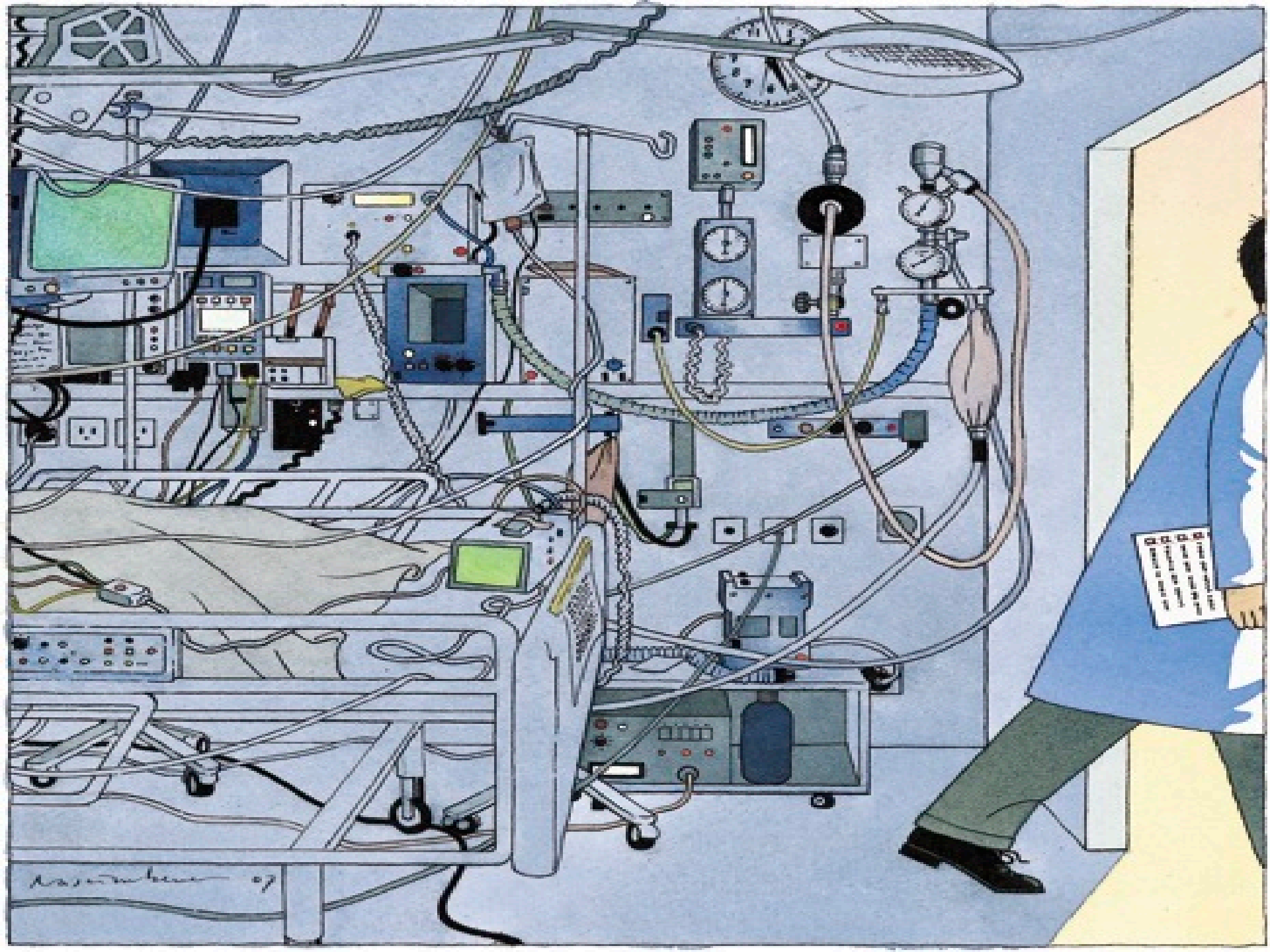
Medical Device Tubing [Mis]Connections

SCOTT COLBURN, USFDA

CONVENER – ISO TC210 JWG4

– SMALL BORE CONNECTORS



Background

In 2007, an international group of manufacturers, clinicians, and regulators began collaborating within ISO TC210 to develop a suite of new connector design standards, the ISO 80369 series of small-bore connector standards.

The group's goal was to establish global standards that would reduce the risk of connectors for two unrelated patient delivery systems being physically misconnected.

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FDA U.S. FOOD & DRUG ADMINISTRATION

Global vs. Regional vs. State Solutions

HOW A GOOD INTENTION CAN CREATE A GREATER PUBLIC HEALTH RISK.

Without a standard…..

…….what does that mean????

How does that effect a global market?

How does that reduce risk if done at the state/country level vs. globally?

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Aug. 28, 1988: Ramstein Air Show Disaster Kills 70, Injures Hundreds; By Daniel Dumas August 28, 2009

THE DISASTER REVEALED SERIOUS SHORTCOMINGS IN THE HANDLING OF LARGE-SCALE MEDICAL EMERGENCIES… MORE CONFUSION WAS ADDED-TO BY THE AMERICAN MILITARY USING DIFFERENT STANDARDS FOR INTRAVENOUS CATHETERS THAN GERMAN PARAMEDICS BEFORE A SINGLE STANDARD WAS CODIFIED IN 1995.

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Implementation efforts

Through the use of various forms of media, direct key constituent engagement and awareness campaigns bring to light the forthcoming changes in the use of specific small bore connectors to reduce associated medical device misconnection medication errors

- Prepare clinical constituents and users for the transition through the use of assessment tools
- Engage all key stakeholders in the integration process through the development of alignment tools and key messaging
- Integrate the new families of connectors with minimal disruption to the supply chain and clinical practice through a “best practices” conversion model
- Educate those critical constituents who will be responsible with enforcing & implementing the transition within the clinical setting

FDA Webpage on Misconnections

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm

Medical Devices

Home > Medical Devices > Medical Device Safety > Safety Communications > Reducing Risks Associated with Medical Device Misconnections

Reducing Risks Associated with Medical Device Misconnections

- Reducing Risks through Standards Development for Medical Device Connectors
- Information for Health Care Facilities
- Tips for Health Care Providers to Reduce Medical Device Misconnections
- Information for Home Use
- Examples of Medical Device Misconnections
- Information for Manufacturers of Small Bore Connectors and Medical Devices with Connectors
- Report a Problem to the FDA About Medical Device Misconnections

Reducing Risks Associated with Medical Device Misconnections

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- Background
- Medical Device Misconnections
- Reducing Risks
- The FDA's Role

Background

Patients in health care settings receive food, medication and other therapies through a variety devices, or delivery systems, such as syringes, catheters, and tubing sets that connect to each other. Connectors are the parts of devices that attach tubing, catheters and syringes to other medical devices.

Medical devices are often packaged together in tubing sets or co-packaged with another device (e.g. feeding set and enteral feeding tube). These sets comprise all the parts needed to use the tubing for its intended purpose, including the connectors that attach tubes to the other parts of the set or to other devices.

Driven by Industry, Supply Chain, Clinician/Patient Partnership and Regulatory

A sampling of some key organizations involved in the US. Additionally, several industry members, the USFDA, as well as state, regional and national hospital organizations also contribute to the current efforts.

AAMI Advancing Safety in Medical Technology

aspen

ISMP INSTITUTE FOR SAFE MEDICATION PRACTICES

HEALTHTRUST

The Joint Commission

Novation

PREMIER

NSF

AVA

NPSF National Patient Safety Foundation®

The Oley Foundation Help along the way

AHRMM Association for Healthcare Resource & Materials Management Advancing the Healthcare Supply Chain

GEDSA Unite. Connect. Deliver

Questions/Comments?

Thank you!