Leveraging Existing Standards to Enable Innovation

Dave Osborn

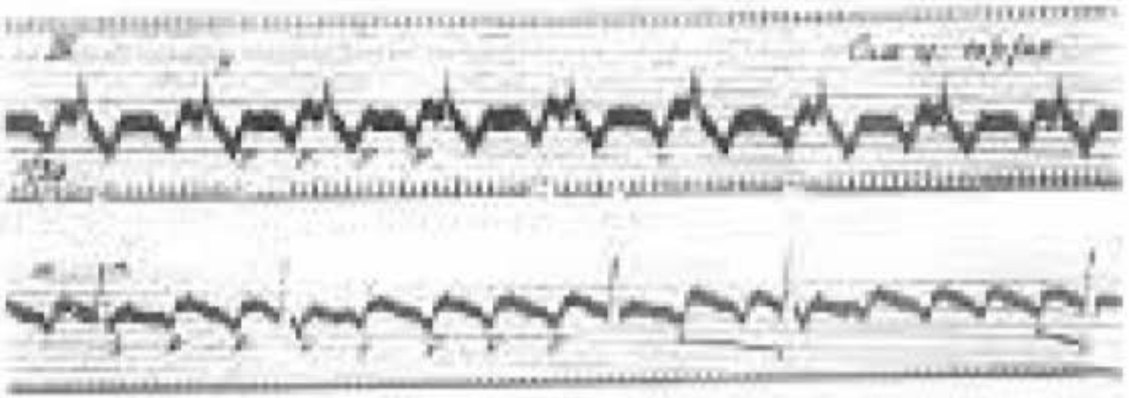
Sr. Manager of Global Regulations & Standards, Regulatory Science and Policy
Philips

2024-06-06

Introduction

- Standards historically—Looking to the past
  - Risk controls for known problems
- Some standards are forward looking
- How changes will impact the future

The first ECG…

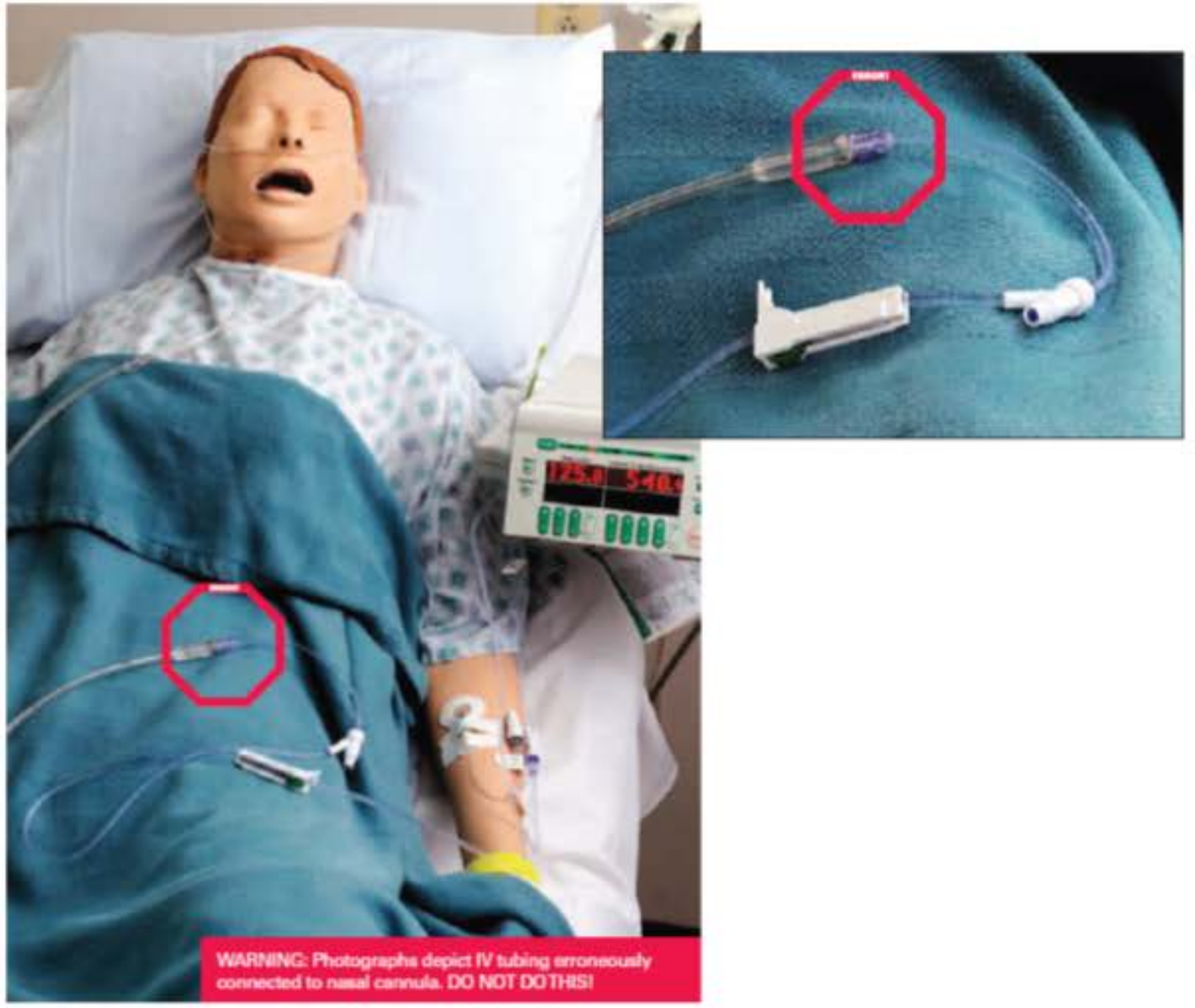


The ICU

Look.Check.Connect.

SAFE MEDICAL DEVICE CONNECTIONS SAVE LIVES

U.S. Food and Drug Administration



WARNING: Photographs depict IV tubing erroneously connected to nasal cannula. DO NOT DO THIS!

EVENT

IV tubing erroneously connected to nasal cannula

POTENTIAL FOR HARM

High

CASE STUDY

- A nurse's aide inadvertently connected a patient's IV tubing to the nasal oxygen cannula upon transfer to the step down unit
- The misconnection was not noted until 4 hours later, when the patient complained of chest tightness and difficulty breathing
- The patient was treated for congestive heart failure and survived

THE JOINT COMMISSION SAFETY TIP

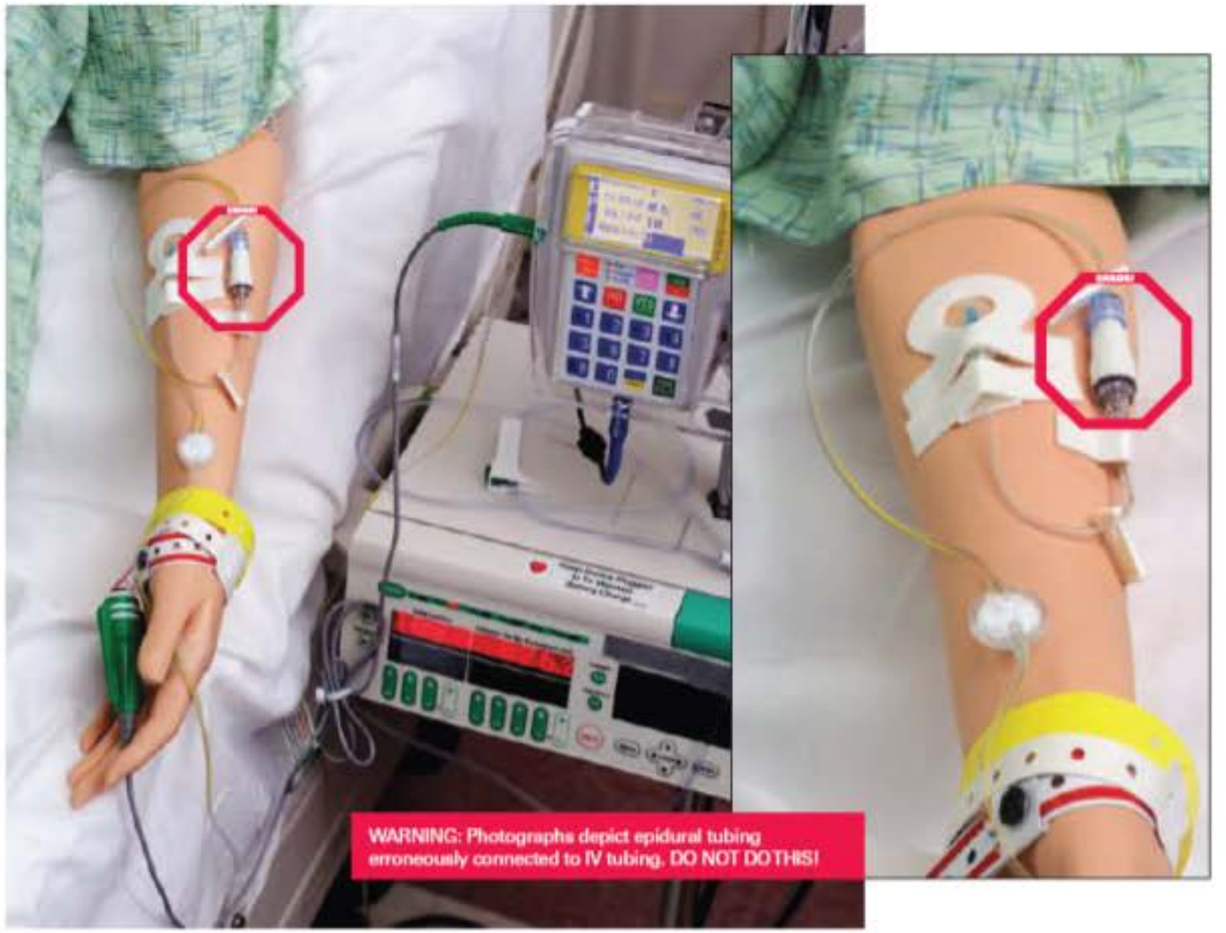
Recheck connections and trace all patient tubes and catheters to their sources upon the patient's arrival in a new setting or service as part of the hand-off process. Standardize this "line reconciliation" process.

IEC ISO

Look.Check.Connect.

SAFE MEDICAL DEVICE CONNECTIONS SAVE LIVES

FDA
U.S. Food and Drug Administration



EVENT

Epidural tubing erroneously connected to IV tubing

POTENTIAL FOR HARM

High

CASE STUDY

- An anesthetist and a midwife mistakenly connected an epidural set to the patient's IV tubing
- The epidural medication was delivered to the IV
- The patient died

THE JOINT COMMISSION SAFETY TIP

For certain high-risk catheters (e.g., epidural, intrathecal, arterial), label the catheter and do not use catheters that have injection ports

IEC ISO

Look.Check.Connect.

SAFE MEDICAL DEVICE CONNECTIONS SAVE LIVES

U.S. Food and Drug Administration

EVENT

IV tubing erroneously connected to enteral feeding tube

POTENTIAL FOR HARM

Moderate

CASE STUDY

- A child had both a gastric feeding tube for nutrition and an IV for medication and hydration
- When the child's gown was changed, a family member inadvertently attached the IV tubing to the gastric feeding tube
- The medication was delivered through the feeding tube into the stomach
- There was no patient harm since the event was noted in a timely manner

THE JOINT COMMISSION SAFETY TIP

Inform non-clinical staff, patients and their families that they must get help from clinical staff whenever there is a real or perceived need to connect or disconnect devices or infusions

IEC ISO

Other examples

- Integrated clinical environment (ICE)
- Physiological closed-loop control
  - Vasopressor blood pressure therapy (the past)
  - Artificial pancreas (the present)
  - Many more being worked on today (the future)
- Smart & autonomous medical systems

Education and research

Thank you