INCOSE Healthcare Working Group

5th Annual Systems Engineering in Healthcare Conference

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Human Factors Testing of Medical Devices: Best Practices & Lessons Learned

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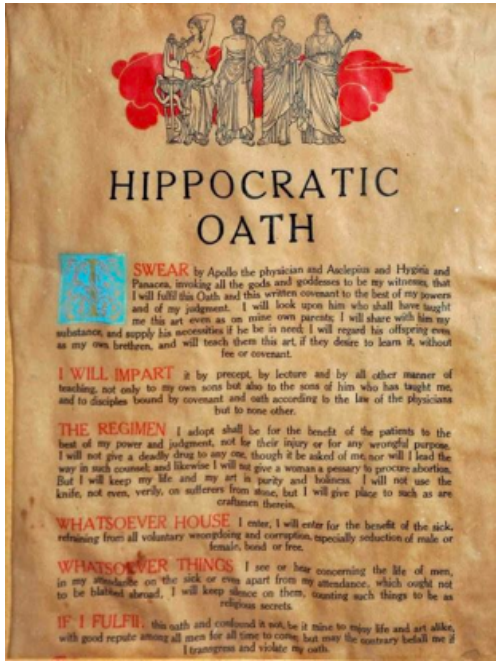
Balanced Experience, LLC

Human Factors & The FDA



HIPPOCRATIC OATH

I SWEAR by Apollo the physician and Asclepius and Hygeia and Panacea, invoking all the gods and goddesses to be my witnesses, that I will fulfil this Oath and this written covenant to the best of my powers and of my judgment. I will look upon him who shall have taught me this art even as on mine own parents; I will share with him my substance, and supply his necessities if he be in need; I will regard his offspring even as my own brethren, and will teach them this art, if they desire to learn it, without fee or covenant.

I WILL IMPART it by precept, by lecture and by all other manner of teaching, not only to my own sons but also to the sons of him who has taught me, and to disciples bound by covenant and oath according to the law of the physicians but to none other.

THE REGIMEN I adopt shall be for the benefit of the patients to the best of my power and judgment, not for their injury or for any wrongful purpose. I will not give a deadly drug to any one, though it be asked of me, nor will I lead the way in such counsel; and likewise I will not give a woman a pessary to procure abortion. But I will keep my life and my art in purity and holiness. I will not use the knife, not even, verily, on sufferers from stone, but I will give place to such as are craftsmen therein.

WHATSOEVER HOUSE I enter, I will enter for the benefit of the sick, refraining from all voluntary wrongdoing and corruption, especially seduction of male or female, bond or free.

WHATSOEVER THINGS I see or hear concerning the life of men, in my attendance on the sick or even apart from my attendance, which ought not to be blabbed abroad, I will keep silence on them, counting such things to be as religious secrets.

IF I FULFIL this oath and confound it not, be it mine to enjoy life and art alike, with good repute among all men for all time to come; but may the contrary befall me if I transgress and violate my oath.

- First do no harm…
- From the FDA's perspective, human factors is all about reducing the risk of harm to patients.

Human Factors @ FDA

- Other standards pertain to earlier design
  - IEC 62366-1:2015 (https://www.iso.org/standard/63179.html)
  - ANSI/AAMI HE75:2009/(R) 2013 (http://my.aami.org/aamiresources/previewfiles/he75_1311_preview.pdf)
- FDA only gets directly involved at the end (testing)
  - Centers for Disease and Radiological Health (CDRH)
  - Center for Drug Evaluation and Research (CEDR)

The Trouble with Scopes

Safety & Ease of Use

Deadly bacteria on medical scopes trigger infections

Peter Eisler, USA TODAY Published 6:21 p.m. ET Jan. 21, 2015 | Updated 3:06 p.m. ET March 19, 2015

The deadly pattern of illnesses began to emerge in 2012 at hospitals in Seattle, Pittsburgh, Chicago. In each case, the culprit was a bacteria known as CRE, perhaps the most feared of superbugs, because it resists even "last defense" antibiotics — and kills up to 40% of the people it infects.

DIRTY SCOPES, DEAD PATIENTS

Muscarella has identified at least a half-dozen U.S. outbreaks of CRE and related superbugs since 2012 that were linked to contaminated duodenoscopes — findings he published in a peer-reviewed medical journal in October. The biggest cases involved dozens of patients and multiple deaths, but as in the Seattle outbreak, not all of the fatalities were attributed conclusively to CRE because some patients had multiple ailments.

Even when the devices are cleaned strictly in accordance with manufacturers' FDA-approved guidelines, "they have a lot of intricate mechanisms and pieces that are very difficult to disinfect," says Alex Kallen, an infectious-disease physician at the CDC who helped direct the investigation. "There definitely is a risk of (disease) transmission with these scopes."

REGULATORY ISSUES

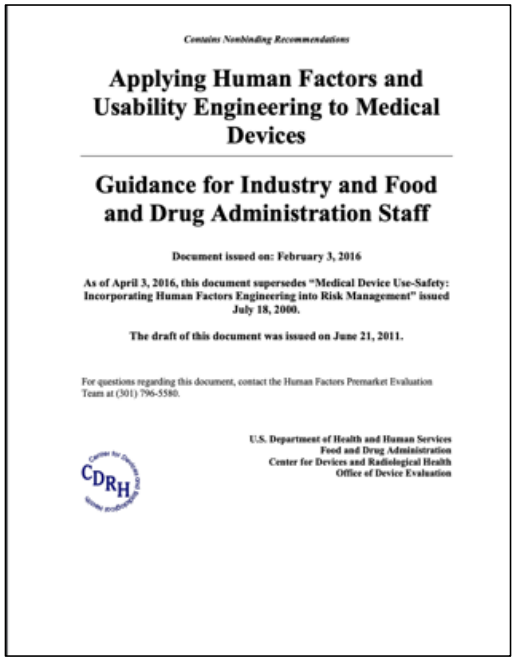
The FDA says it is working with all three major manufacturers of duodenoscopes — - to assess potential design changes and determine whether new disinfection processes can ensure the scopes' safety in their current configuration.

The Problem

"The problem was, the manufacturers did a great job of designing for the procedures, but they never designed the scopes to be cleaned."

- FDA

Mandated Human Factors Testing



Contains Nonbinding Recommendations

Applying Human Factors and Usability Engineering to Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on: February 3, 2016

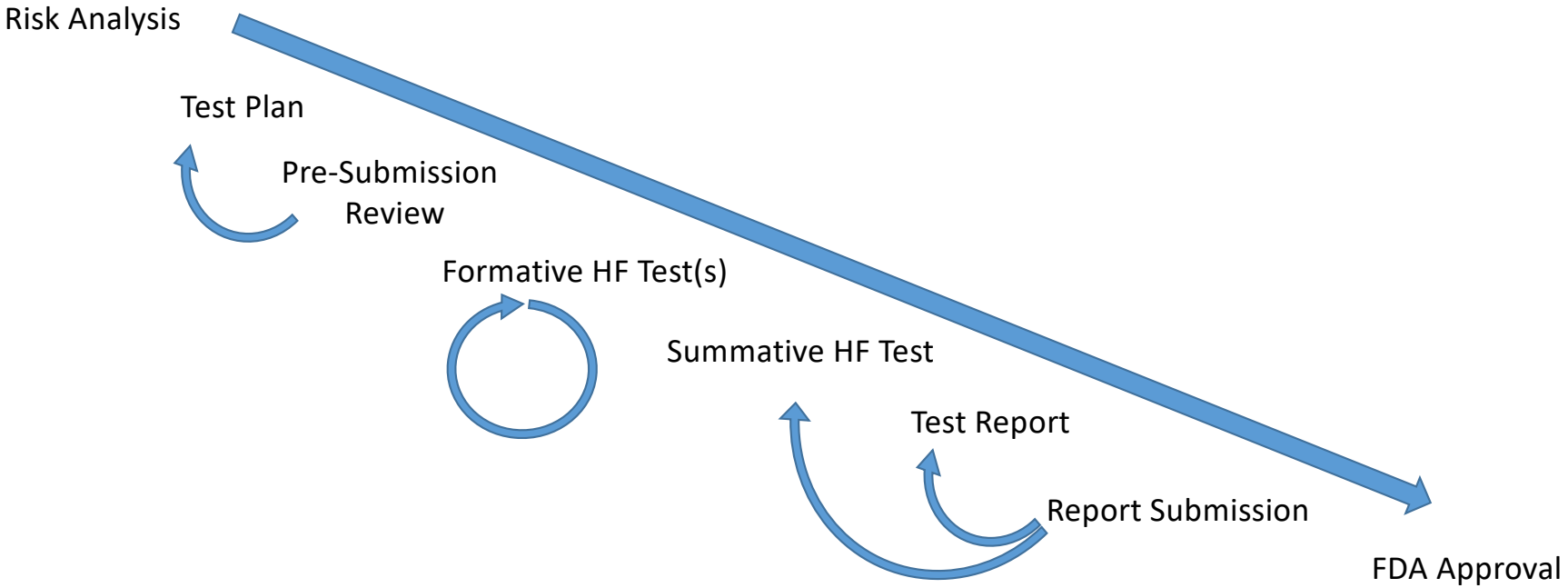
As of April 3, 2016, this document supersedes "Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management" issued July 18, 2000.

The draft of this document was issued on June 21, 2011.

For questions regarding this document, contact the Human Factors Premarket Evaluation Team at (301) 796-5580.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

HF Flow/Roadmap



Risk Analysis

Human Factors Testing

- Formative Test #1 – Training
  - 2 user groups
    - GI Nurses (8)
    - Reprocessing Techs (8)

- Formative Test #2 – Test
  - Same users

Human Factors Testing

- Summative (Validation) Test
  - Reviewed risk analysis
  - Updated training
  - Updated IFU (instructions)
  - 2 user groups
    - GI Nurses (16)
    - Reprocessing Techs (16)

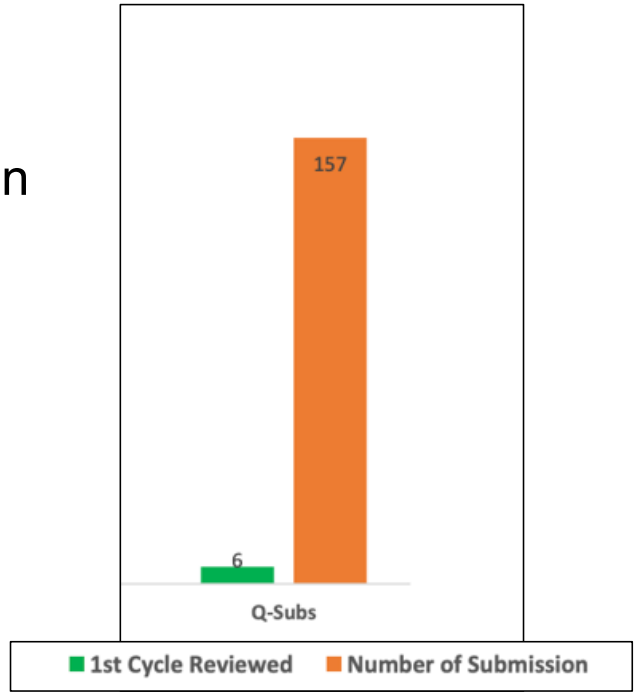
Planning & Scheduling

- Allow enough time – it takes a while

Q-Submission Type	Meeting	Timeframe for Meeting/Teleconference/Feedback (from receipt of submission)	Applicable Submissions
Pre-Submission	Upon request	70 days or 5 days prior to a scheduled meeting, whichever comes sooner	All applications
Informational Meeting	Yes	90 days	All Application
Study Risk Determination	No	N/A	N/A
Agreement Meeting	Yes	30 days or within time frame agreed to with sponsor	Mostly IDE
Determination Meeting	Yes	Scheduled within 30 days of request	Mostly IDE
Submission Issue Meeting	Yes	21 days	All Applications
Day 100 Meeting	Yes	100 days (from filing of PMA)	PMA

Planning & Scheduling (cont)

- Talk to the FDA – plan for a pre-submission (Q-sub) meeting
  - Only 4% are accepted on first submission
  - Better to get feedback before, not after



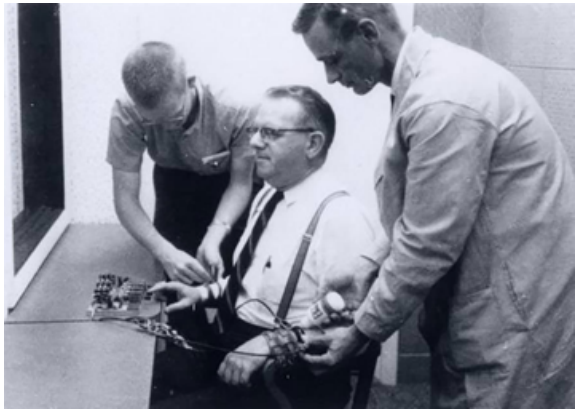
Planning & Scheduling (cont)

- Participant availability
  - Recruiting takes time (2-4+ weeks)
  - Nurses' schedules usually fixed 4-6 weeks out
  - Participants most available evenings and weekends

- Avoid burning out the team
  - Poor data
  - Mistakes will happen

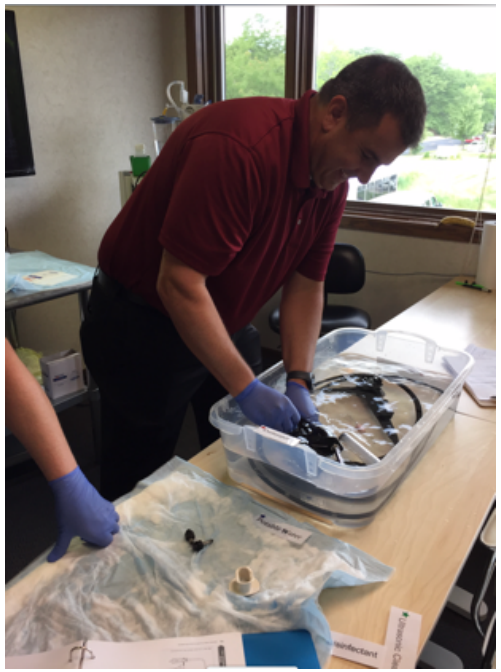
Recruiting Participants

- Leverage your experts
  - SGNA SME
- Conferences & professional associations
- Be mindful of complications with participants' employers
- Consider whether you need IRB approval



Test Environment

- Environmental factors (what matters?)
  - Lighting
  - Humidity
  - Sound
  - “messy”
- Simulated use
  - Avoid “solutions”
  - No running water

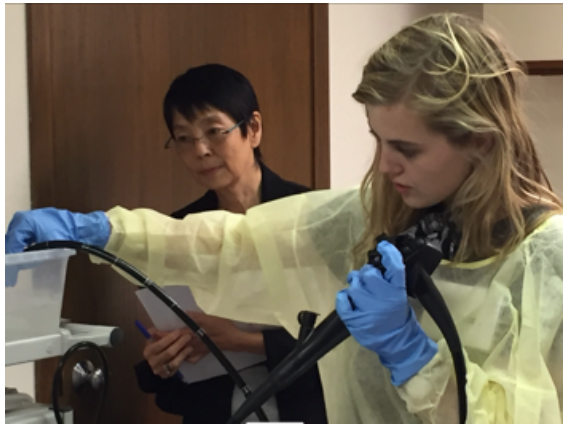


Video & Other Tech

- You may need a dedicated team member
- Monitor your cameras
  - Working?
  - Capturing data?
  - Battery ok?
- Plan enough time between sessions to download, recharge, reset, etc.

Conducting the Test

- Who's in the room?
- Where are your cameras?
- What do you need to see?
- When can you talk?
- When should you take breaks?
- It can take a while, be comfortable.



Data Analysis

- Audit your video
- Find the right tools – invest early, save later
- QC everything (mistakes matter)

Test Report

- The FDA is busy… very busy. Make it easy for them.
  - Don't make the FDA hunt for the results. Summarize clearly and put the rest in appendices.
- Fundamentally, they're looking for a *qualitative* report.
  - What happened?
  - How often?
  - Why?
  - What should be done about it?

Quality

- Nothing formally required, but you get what you paid for
- GLP (General Lab Practice) certification
- Cost of mistake…

DIRTY SCOPES, DEAD PATIENTS

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Submission

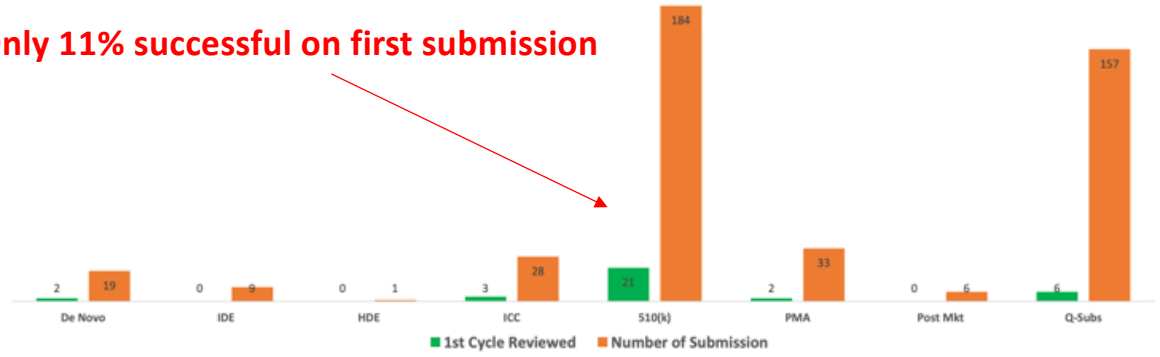
- 3 keys the FDA looks for:
  - Who signed the report (if no HF person, strike one)
  - Compare the TOC with FDA guidance (if not aligned, strike two)
  - Is risk analysis traceable through report – user task & analysis? (if not, strike three)

Submission (cont)

2018 Human Factors Premarket Review: Review Statistics

FDA

Only 11% successful on first submission



HF/UE reviews completed compared to 1st adequate reviewed premarket submission in 2018

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Questions?

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Thank you for attending!

Share your experiences at #HWGSEC