Developing a Framework for HIT Usability:

Lessons Learned from the Medical Device Industry*

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* and years of designing HIT too!

How is HIT Different from Medical Devices?

- ✧ Both are information technology (i.e., information generating or using) & involve complex human-system interactions.
  - Greater ability & desire to customize.
  - Safety implications more subtle & indirect.
- ✧ Similar contextual use & design issues.

The Road to Improved Medical Device Usability

- 30 years of evolutionary improvement
- Still a work in progress!
- Took a multimodal approach that includes federal regulation …
- … but also consensus international standards and industry self-regulation

Medical Device Industry *circa* 1985

- Recognition of the problem by academics, anesthesiologists and by the FDA
- Cottage industry with limited knowledge and application of HFE
- No meaningful regulation of the UI
- Few if any relevant consensus standards

Hurdles to be Overcome:
The HIT Industry

- Safety implications of bad design
- Role of human factors engineering
- Importance of life-cycle processes
- Importance of standardization

Hurdles to be Overcome:
The HIT "Regulators"

- Importance of life-cycle processes
- Importance of standardization
- One size does *not* fit all
- Consistent & predictable approach

Getting Beyond the "Fallacies"

Viewpoint paper

Health information technology: fallacies and sober realities

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ABSTRACT

Current research suggests that the rate of adoption of health information technology (HIT) is low, and that HIT may not have the touted beneficial effects on quality of care or costs. The twin issues of the failure of HIT adoption and of HIT efficacy stem primarily from a series of fallacies about HIT. We discuss 12 HIT fallacies and their implications for design and implementation. These fallacies must be understood and addressed for HIT to yield better results. Foundational cognitive and human factors engineering research and development are essential to better inform HIT development, deployment, and use.

INTRODUCTION

Current research demonstrates that health information technology (HIT) can improve patient safety and healthcare quality, in certain circumstances.[1–6] At the same time, other research shows

reliable complex physical systems (eg, bridges, buildings, cars), but it took more than a century to understand and mitigate the myriad of hazards of these systems. In contrast, we cannot yet design and deploy complex software systems that are on time, within budget, meet the specified requirements, satisfy their users, are reliable (bug free and available), maintainable, and safe.[23 24] Edsger Dijskstra, a recognized leader in software engineering, lamented that:

> … most of our systems are much more complicated than can be considered healthy, and are too messy and chaotic to be used in comfort and confidence. The average customer of the computing industry has been served so poorly that he expects his system to crash all the time, and we witness a massive worldwide distribution of bug-ridden software for which we should be deeply ashamed.[23]

There are two additional reasons why HIT failures are particularly problematic. First, they are often opaque to users and system managers alike; it

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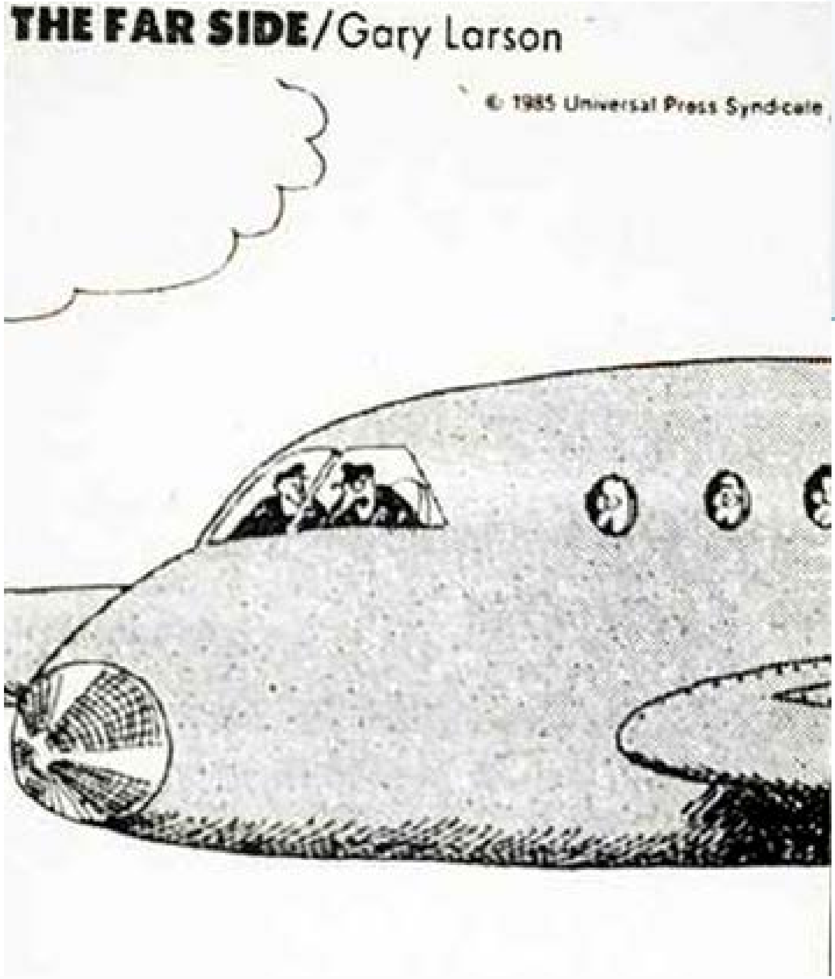
Ten HIT Fallacies and Sober Truths

- **HIT is "risk free"**
- **"It's not a device"**
- **Learned intermediary**
  [users know best]
- **[It's the] "bad apples"**
- **Messy Desk**
  [rationalizing clinical work]
- **Use = Success**
- **Father knows best**
  [designing for purchasers not end users]
- **Field of Dreams**
- **"Sit-Stay" [computers are no better than dogs]**
- **One size fits all**

Karsh, Weinger, Abbott, & Wears: J Am Med Inform Assoc (JAMIA) 17(6): 617-23, 2010



The fuel light's on, Frank! We're all going to die! … Wait, wait … Oh, my mistake – that's just the intercom light.

Lesson #1

The vast majority of adverse events associated with the use of medical technology are due to poor design!

Lesson #2

Use Error, not User Error!

When technology use is associated with patient harm, the technology's user interface design *must* be considered a contributory factor until investigation proves otherwise.

As stipulated by IEC/ISO 62366-2007

Lesson #3

It's <u>all</u> about the user(s)!

- The users are not the purchasers
- Design focus must be on users' actual needs in the real world
- There is *never* just one user
- User centric not technology centric

Substantial User Diversity

- Age
- Gender
- Height/Weight
- State of health
- Motivation
- Fatigue
- Attention
- Memory
- Mood
- Clinical experience
- Experience w/technology
- Training status
- Competence
- Personality attributes
- Goals
- Biases
- Cultural expectations
- etc.

Lesson #4 – “Expert” users are *not* expert all of the time

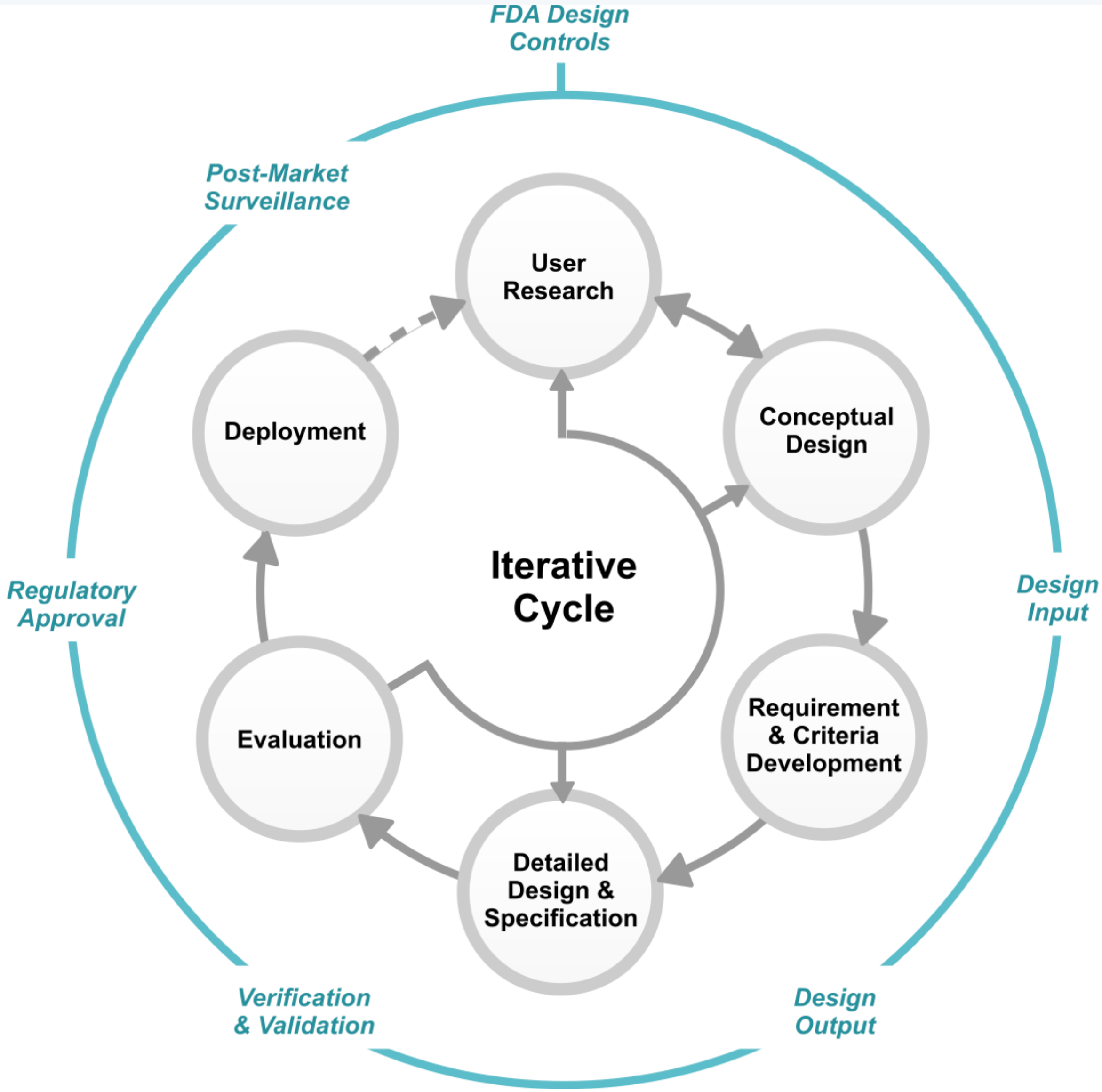
“Expertise is not a fixed property of a person but rather a dynamically varying relationship between the demands imposed by the environment and the resources of that particular person at that particular time.”

Dreyfus & Dreyfus as quoted in Olsen & Rasmussen, 1989

Lesson #5 – Need to design for the full product life-cycle

- HIT evolves over time – function & use migration are common
- Even with the best up-front design, one cannot anticipate all use scenarios or potential use errors
- Must have robust post-market surveillance and corrective action

Lesson #6



A Human Factors Design Life-Cycle Approach Does Work!

AAMI/ANSI HE74 →
IEC/ISO 62366

Lesson #7 – Traditional inputs to UI design are insufficient!

- Sales force feedback
- Marketing “studies”
- Focus groups
- Domain expert consultants
- Customer complaints

More Effective Ways to Learn about Users and the Use Environment

- **Field studies (i.e., observations of users in the actual use environment)***
- **Structured interviews of multiple individual *typical* users***
- **Task analysis (behavioral & cognitive)**
- **Formal testing (laboratory, simulation, or actual use environment)***

Medical Device Usability Scale™

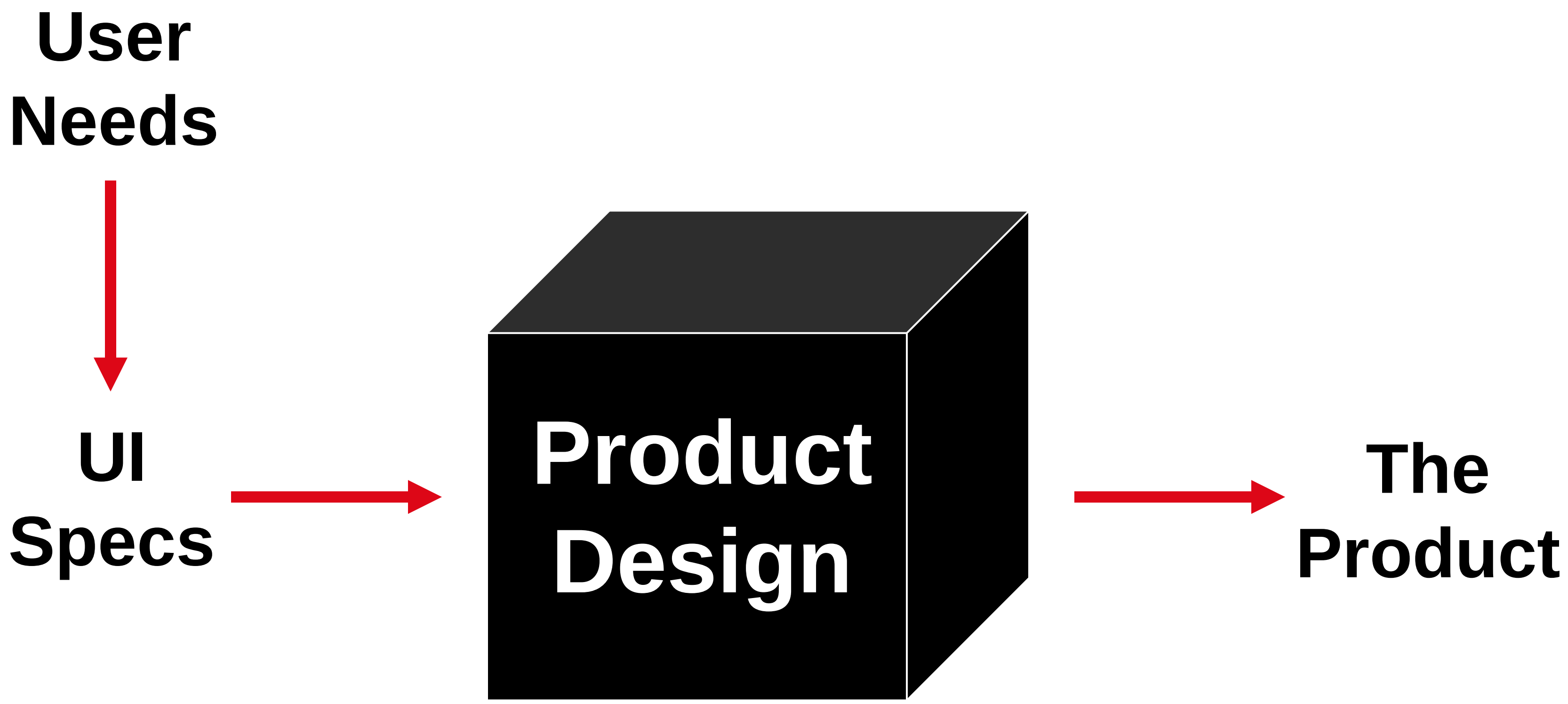
Developed by Michael Wiklund, American Institutes for Research

Circle a number.

		Strongly Disagree				Strongly Agree
1	I was able to perform routine tasks effectively.	1	2	3	4	5
2	I was able to perform non-routine tasks effectively.	1	2	3	4	5
3	I expect that I could master the device's major functions in a reasonable amount of time.	1	2	3	4	5
4	I was physically comfortable interacting with the device.	1	2	3	4	5
5	I was able to detect when I made an error.	1	2	3	4	5
6	I was able to correct or overcome errors.	1	2	3	4	5
7	The device provides the information and controls necessary to accomplish tasks.	1	2	3	4	5
8	Operating the device draws upon my previously established knowledge and skills.	1	2	3	4	5
9	The device is easy to learn to use.	1	2	3	4	5
10	The device operates in a manner that is compatible with related medical devices.	1	2	3	4	5
11	The device has an appropriate size, shape, and appearance.	1	2	3	4	5
12	The device enables me to respond effectively to emergencies.	1	2	3	4	5
13	The device enables me to focus on the important task at hand.	1	2	3	4	5
14	The device exhibits an appropriate degree of manual versus automatic control.	1	2	3	4	5
15	I was able to develop a clear and complete mental model of how the device works.	1	2	3	4	5
16	The device effectively alerts me to adverse conditions.	1	2	3	4	5
17	The device is easy to setup.	1	2	3	4	5
18	The device enables me to work quickly when I am under time pressure.	1	2	3	4	5
19	I can tell what the device is doing at all times.	1	2	3	4	5
20	I would be pleased to use the device for an extended period of time.	1	2	3	4	5

Score: ____________

Lesson #8 – Engineers, marketing experts, and clinicians are not User Interface designers!



User Interface design is a distinct skill that requires extensive training and experience

Conclusions

- HFE is essential to the design and implementation of safe & effective HIT
- Better processes lead to better outcomes
- Effective design begins with studies of intended users' needs & requirements
- Iterative UCD until meet your users' needs
- NIST has invested in work to inform creation of HIT UI best-practice guidelines

Questions?

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Lesson #9 – Agile methods must be modified to address usability

- Traditional HFE (& good design) rely on a clear front-end definition of “the product”
- Agile pre-disposes to feature creep
- Business pressures infrequently allow time to redesign the UI “at the end”
- HFEs are developing new methods to integrate usability into Agile processes

Lesson #10 – Investment in HFE will Reduce Overall Product Cost

- Development costs ↑
- Implementation costs ↓
- Training costs ↓
- Maintenance costs ↓
- Upgrades/Obsolescence ↓