ECRI | The Most Trusted Voice in Healthcare

Wearables – Consumer vs Medical Grade/Regulatory Perspective

Presentation for APSF

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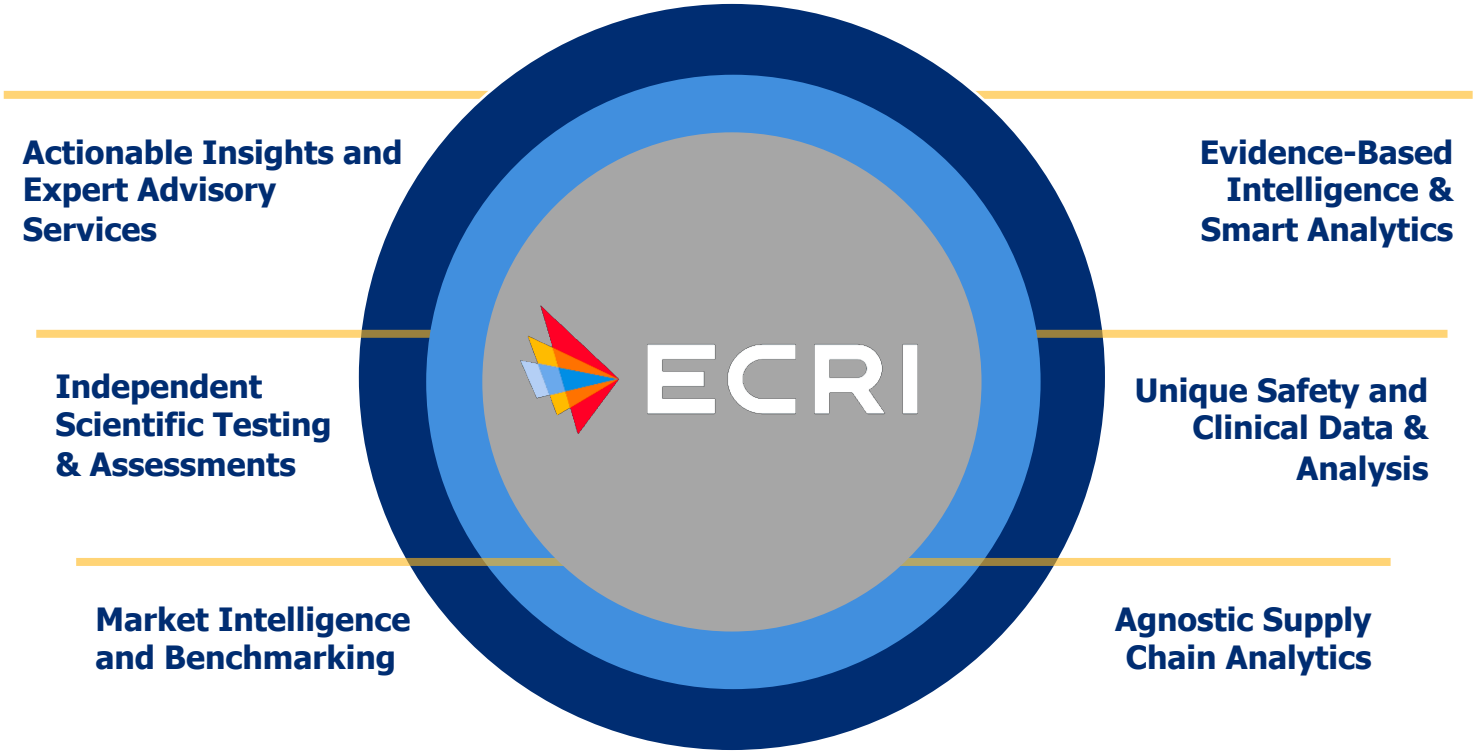
The ECRI Difference | Data Empowers. ECRI Delivers.

ECRI is a leading independent patient safety expert reducing preventable harm, and making healthcare more transparent and accessible

- 50+ years of experience as a global leader in patient safety and applied human factors engineering
- At the forefront of providing data, expertise, and advisory services related to healthcare technologies, patient safety and evidence-based medicine
- A leading provider of GPO-agnostic price benchmarking and market intelligence



Committed to Integrity, Transparency, and Excellence

The ECRI Difference | By The Numbers.

Clinical Evidence Reports & Solutions
representing 40% of all Procedure Types

2.5k

256 Devices
Evaluated Across 83 Categories Over 3 years

> 3,500 Alerts
Delivered to the Right Person In 2020 with 750 **Posted Before the FDA**

$128B

Supply and Capital Spend databases
with over 24,000 manufacturers

Delivered in Potential **Savings Per Year**

$7B

5M+

Adverse Events Reported
in our PSO Reporting System

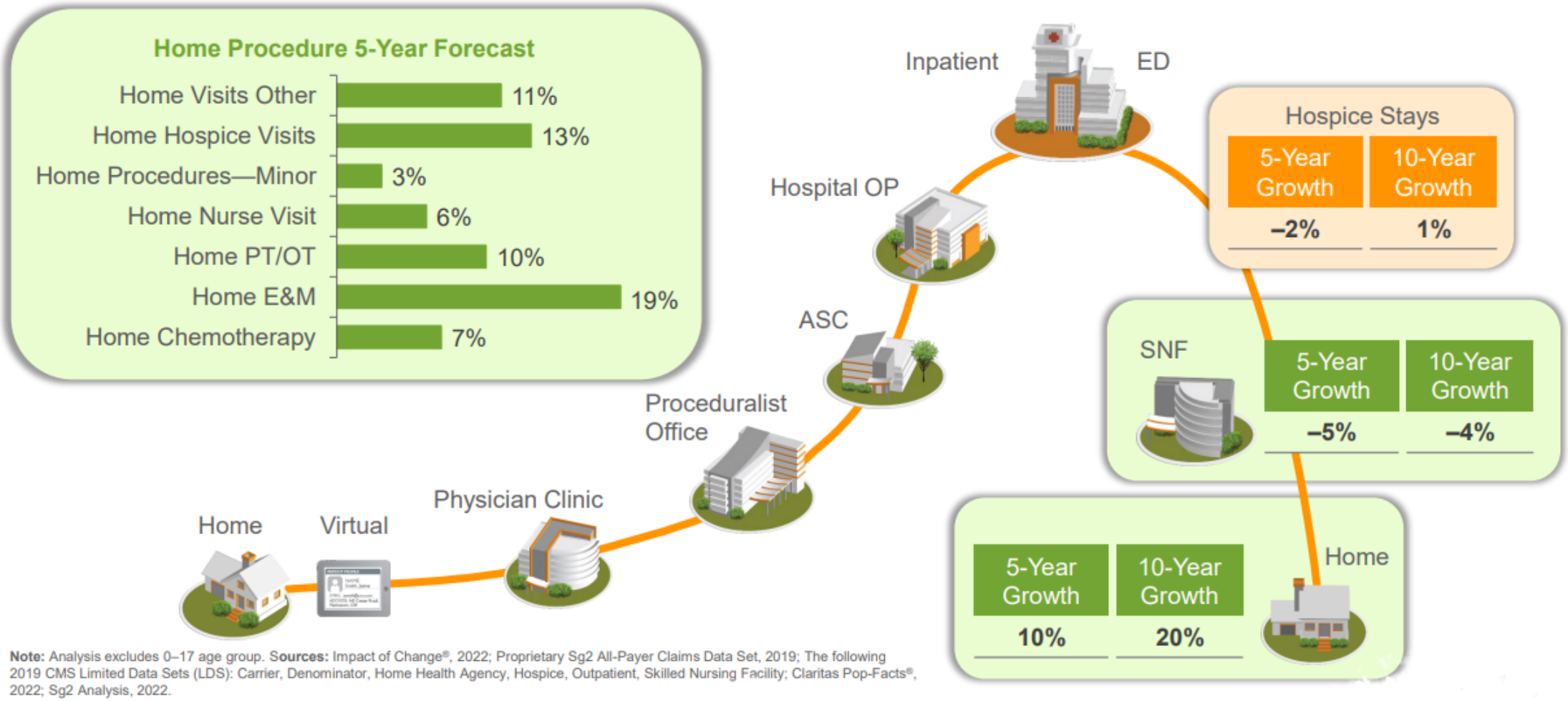
Emerging Technologies
currently monitored for potential healthcare disruption

350

850+
Risk, Safety, Quality guidance articles across the continuum of care

ECRI

Patient Care is Shifting to Home



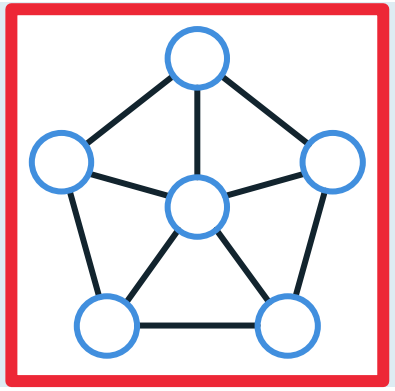
Source: "Sg2 2022 Impact of Change® Forecast Highlights", sg2, 2022.

Challenges as Healthcare Shifts

Sicker patients in non-acute care settings

Reduced LOS in acute care environment

Onus of care on patients themselves with little to no clinical supervision



Proliferation of new and complex devices need user centered design rethinking

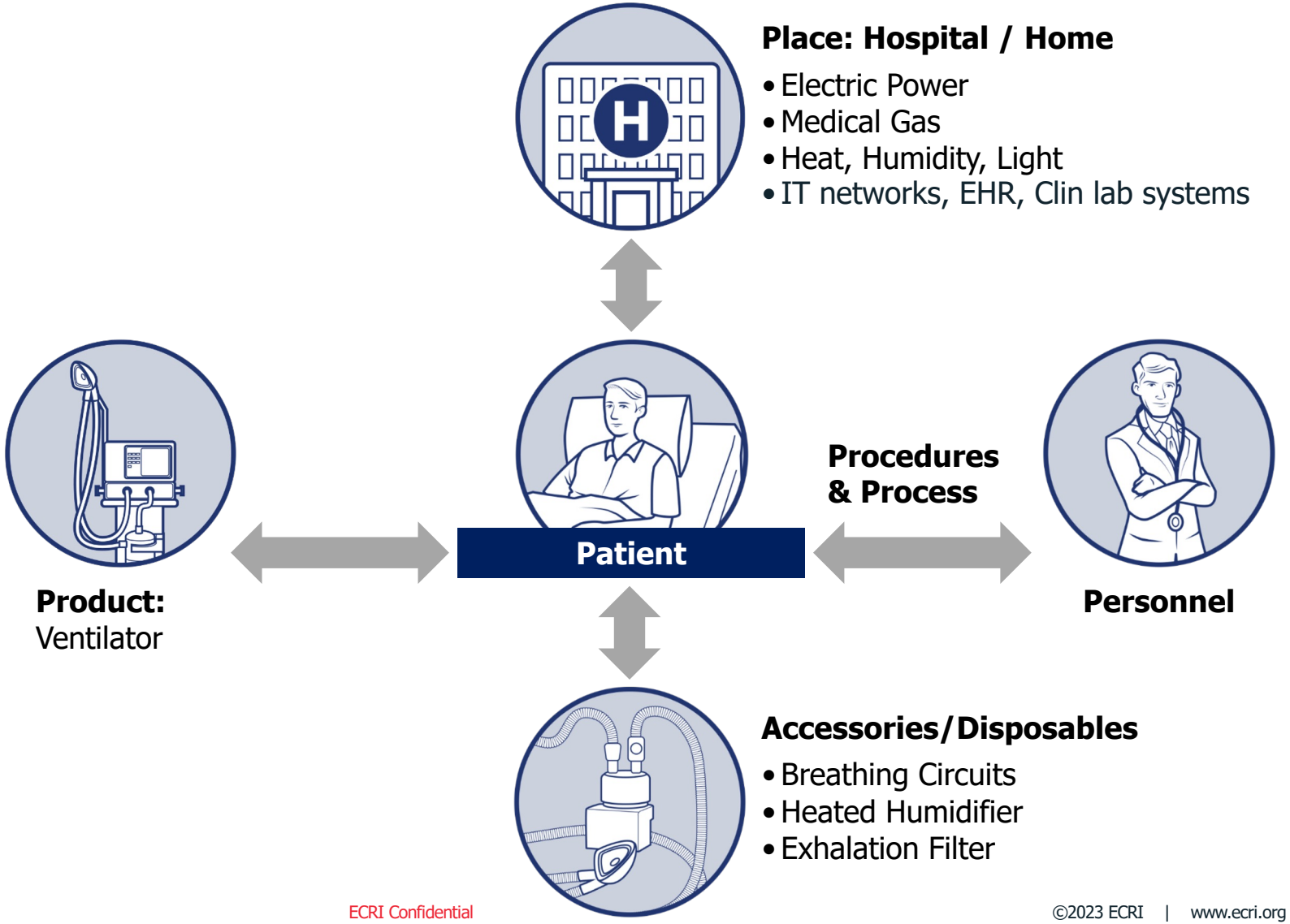
Health, technology and numerical literacy levels

Medical Grade vs Unregulated/Consumer Devices Regulatory Landscape

Information	Medical Grade	Consumer Grade
FDA registration requirement	Yes	No
FDA review and approval	FDA evaluates perceived risk associated with the device's use and categorizes into Class I, Class II or Class III devices.	Most manufacturers don't register with FDA or seek premarket review.
Accuracy of products	FDA reviews safety, efficacy, and claims for Class II and III devices.	• ECRI found poor accuracy in some unregulated devices. • Vendors add disclaimers to address medical use concerns.
Compliance with GMPs and QS	Manufacturers must adhere to GMPs to ensure safe and effective products and have QS in place.	No obligation to follow GMPs or have a QS in place.
Post-Market Surveillance	• Manufacturers must have a process to address reported problems. • FDA monitors post-market issues through this surveillance process.	• FDA generally unaware of specific products being marketed. • Many products sold online, some made by unrecognized overseas companies.

Why Apply HF to Healthcare?

Patient Safety Is Complicated



Human Factors Considerations

? **Who are the users** that interact with the system you are creating?

- Physical size, strength, and stamina
- Sensory & cognitive abilities
- Background & training
- Work objectives, critical tasks

? **Where do the users work?** In what environment?

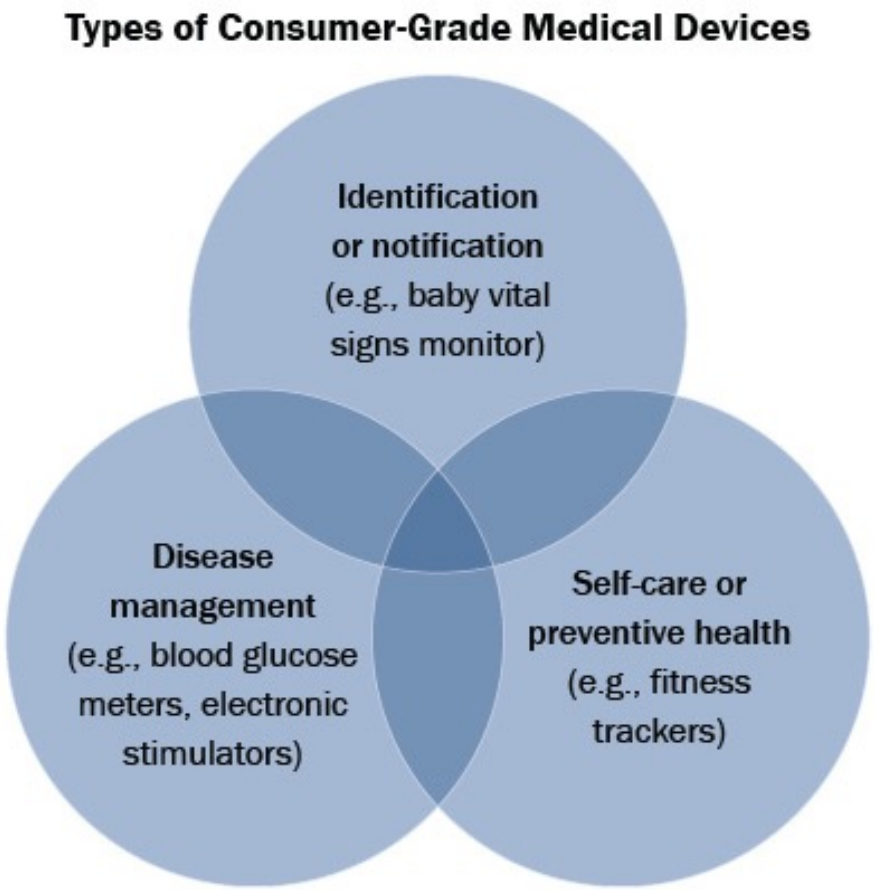
- Lighting level(s)
- Noise level(s)
- Nearby equipment also in use

? **What kind of user interface** does the system have?

- Size & shape of device, components
- Information indicators (lights, sounds)
- Packaging & labeling

ECRI's Evaluations

- ECRI's testing focuses on identifying and mitigating key performance, safety and usability issues.
- Examples of devices tested
  - Pulse oximeters,
  - Blood glucose meters,
  - ***Smartphone-enabled ECG monitors,***
  - ***Smartwatches***,
  - ***Home cholesterol kits***,
  - Remote patient monitoring solutions,
  - ***Wearable baby vital signs monitoring socks***



Medical Smartwatches

Device Details

- Wearable
- Available direct to consumer without a prescription
- Tested 6 devices from 3 vendors

Key Findings

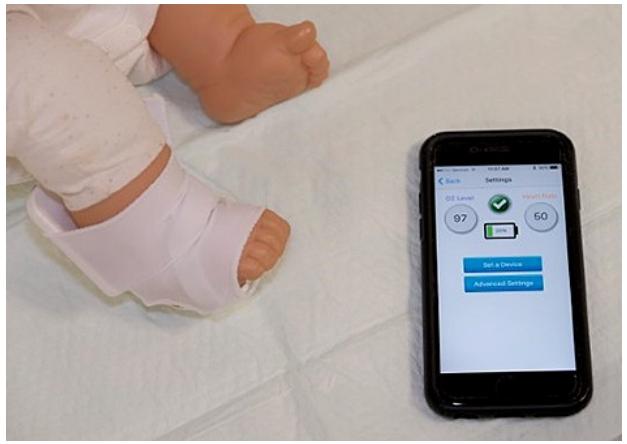
- Core functionality is sound
- Non-ECG medical features are less reliable
  - Fall detection is good in theory but didn't work reliably in our testing
  - Passive afib detection (based on pulse variability) can scare users

Identified Usability Issues

Most problems have been in the associated phone apps

- Access to the actual recorded ECG (as opposed to just the result of the algorithm) is not always easy
- Sharing ECG traces with physicians is important, but the method varies and can be confusing.

Consumer Marketed Baby Vital Signs Monitors/Smart Socks



Device Details

- Wearable- Available direct to consumer without a prescription
- Tested 2 devices from 2 vendors
- Not considered medical devices and do not currently require FDA premarket review to enter the market

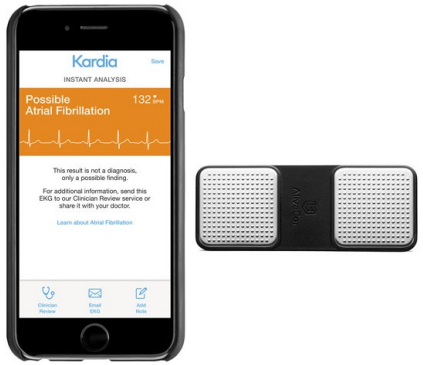
Key Findings

- Controversy about the need for or the utility of these technologies
- Poor blood oxygen saturation alarm sensitivity for the monitors tested
- Poor agreement of blood oxygen saturation readings with medical-grade pulse oximeter

Identified Usability Issues

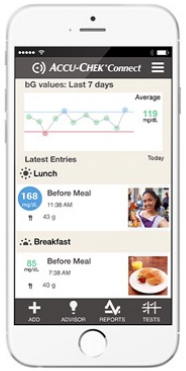
- Setting up Wi-Fi connectivity and use of the smart socks was complicated for first time users

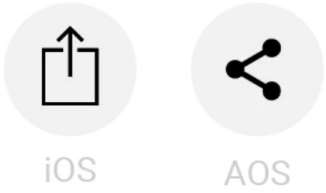
Smartphone-Enabled Devices



The KardiaMobile smartphone app (left) and ECG recorder (right). (Images courtesy of AliveCor.)

The ECG Check smartphone app (left) and handheld monitor (right).





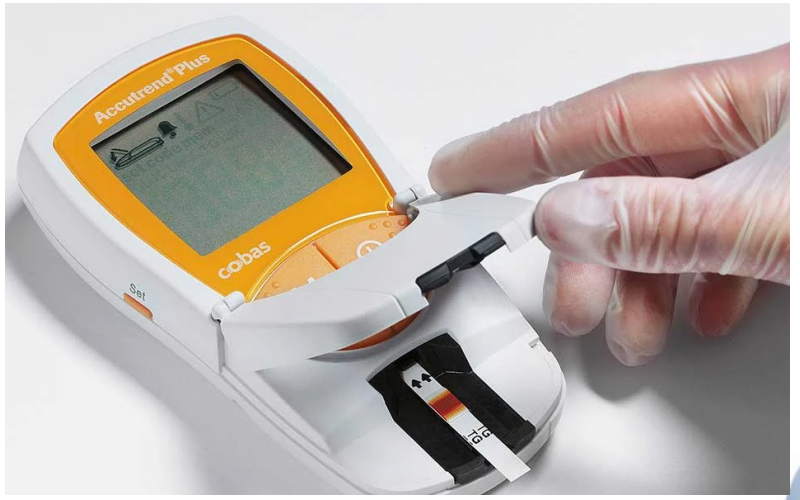
Device Details

- Available direct to consumer without a prescription
- ECRI has tested smart glucometers, RPM as well as handheld ECG devices (e.g., AliveCor)
- Combination of FDA cleared and unregulated consumer grade devices

Key Usability Findings

- Using a smartphone as the user interface for a medical device is challenging
  - Screen size and resolution can vary substantially
  - Patients may not be familiar with smartphone design shorthand (e.g., share icon)
- Design process needs to consider how critical medical information is communicated
  - Small fonts may be hard for patients with poor eyesight to read.
  - Essential information that is communicated in color only may be inaccessible to colorblind users (e.g., green and red used for normal vs high/low values)

Home Cholesterol Test Kits



Device Details

- Available direct to consumer without a prescription
- 4 FDA cleared test kits evaluated;
  - Majority of the 40+ marketed consumer home cholesterol test kits have not been FDA cleared

Key Usability Findings

- Assessed using nine usability heuristics, e.g., Consistency, Message, Error
- Found numerous minor, moderate, and major design problems with the four evaluated products
- Example of a major violation of the Error heuristic: When total cholesterol test strips are inserted backwards and without blood sample into the corresponding handheld meter, the meter performs testing and provides a result of Cholesterol < 100 mg/dL

Recommendations for Vendors and Regulators

Safety and Efficacy

- Additional clinical, performance, and usability data is required to ensure the safety of consumer products that lack FDA clearance.

- This is crucial to reduce the potential risks of both direct and indirect harm.

Access to Data

- All data is not good data.

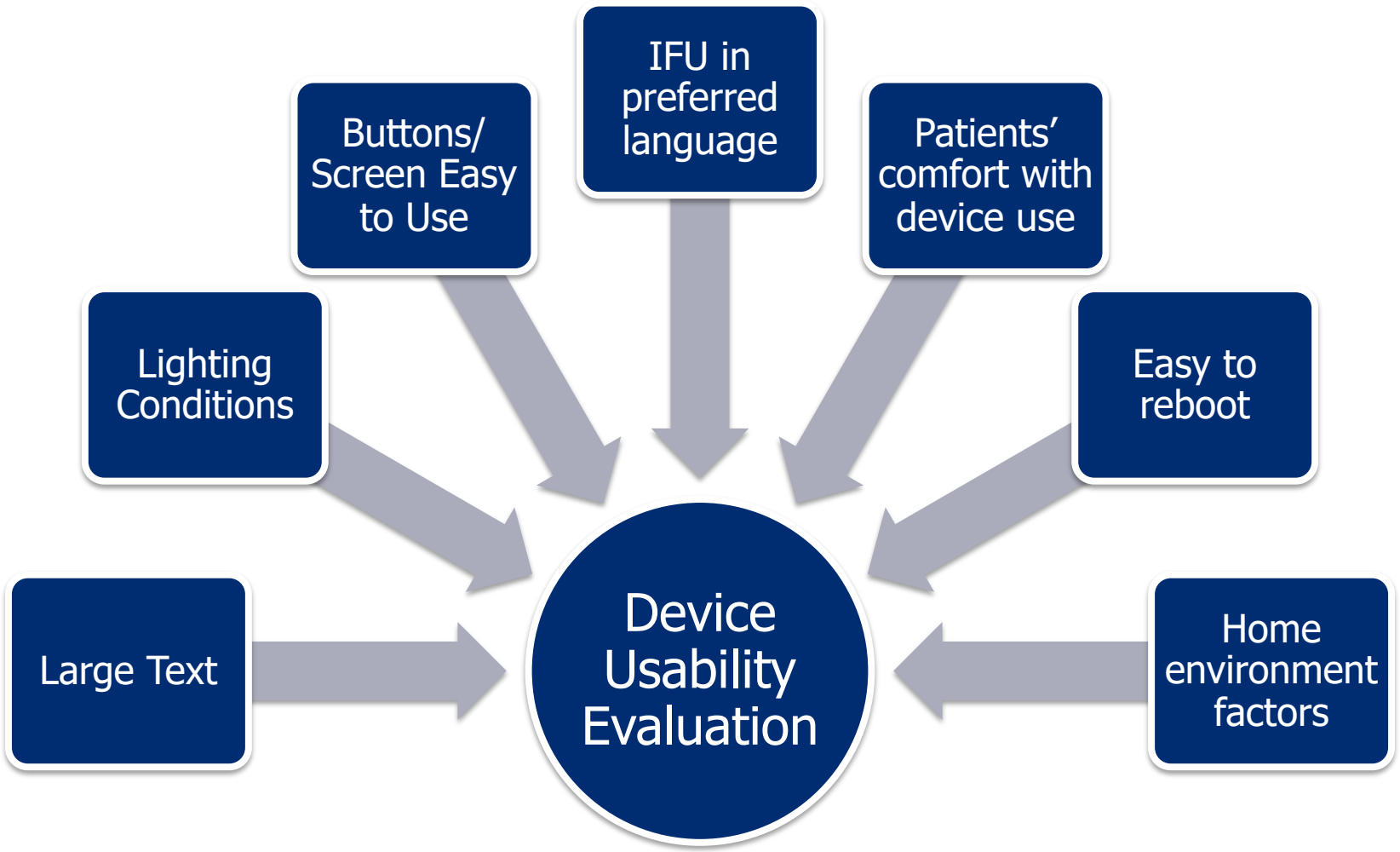
- The quantity, quality, and relevance of data received by care providers is crucial.

Technology Ease of Use

- Ease of use needs to be evaluated through appropriate HF testing for all end-users (care providers and patients).

-If the system is not easy to use for patients, it won't lead to optimal technology adoption.

Recommendations for Assessing Device Usability



Summary

- Human Factors Engineering improves process and workflow by understanding work on medical and consumer grade devices.
  - Product development must consider HFE principles right from pre-development stages.
- Usability testing is important to assess safety, efficacy, and effectiveness of devices.
  - Test products in all care settings they are intended to be used.
- Reporting needs for safety incidents involving consumer-grade devices must be explored.

Questions