

AHIC Virtual Summit Utility of Digital Tools for Remote Patient Monitoring: Insights from CTA/ACC Best Practices Report

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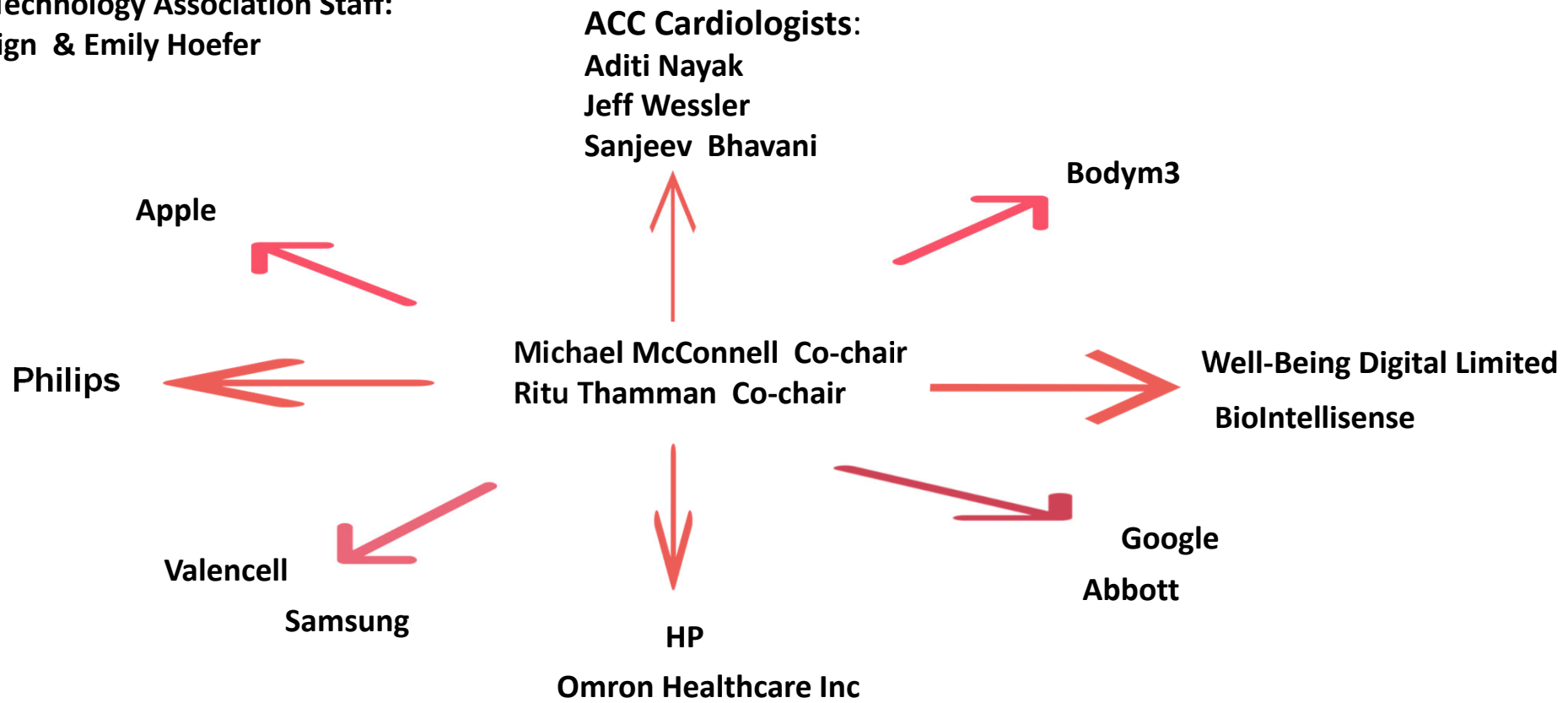
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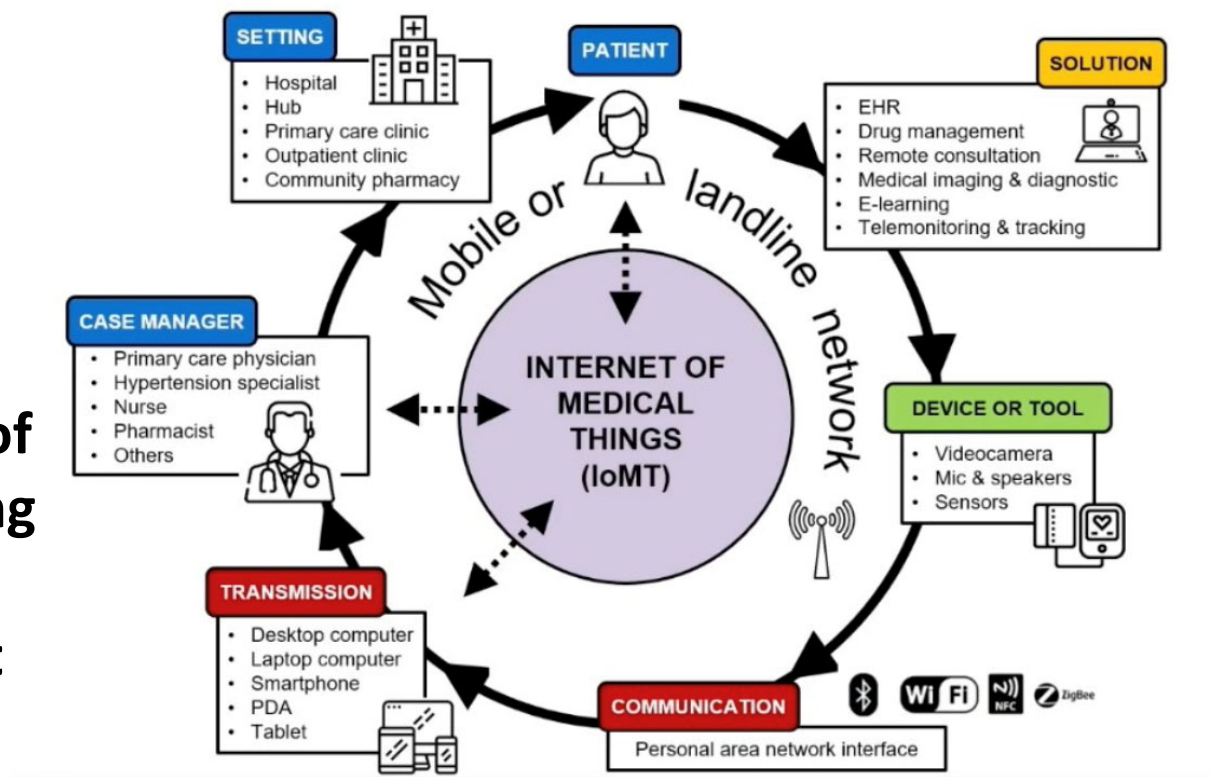


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best practices framework for device selection, standards-based metrics for accuracy, privacy, security, and clinical workflow integration

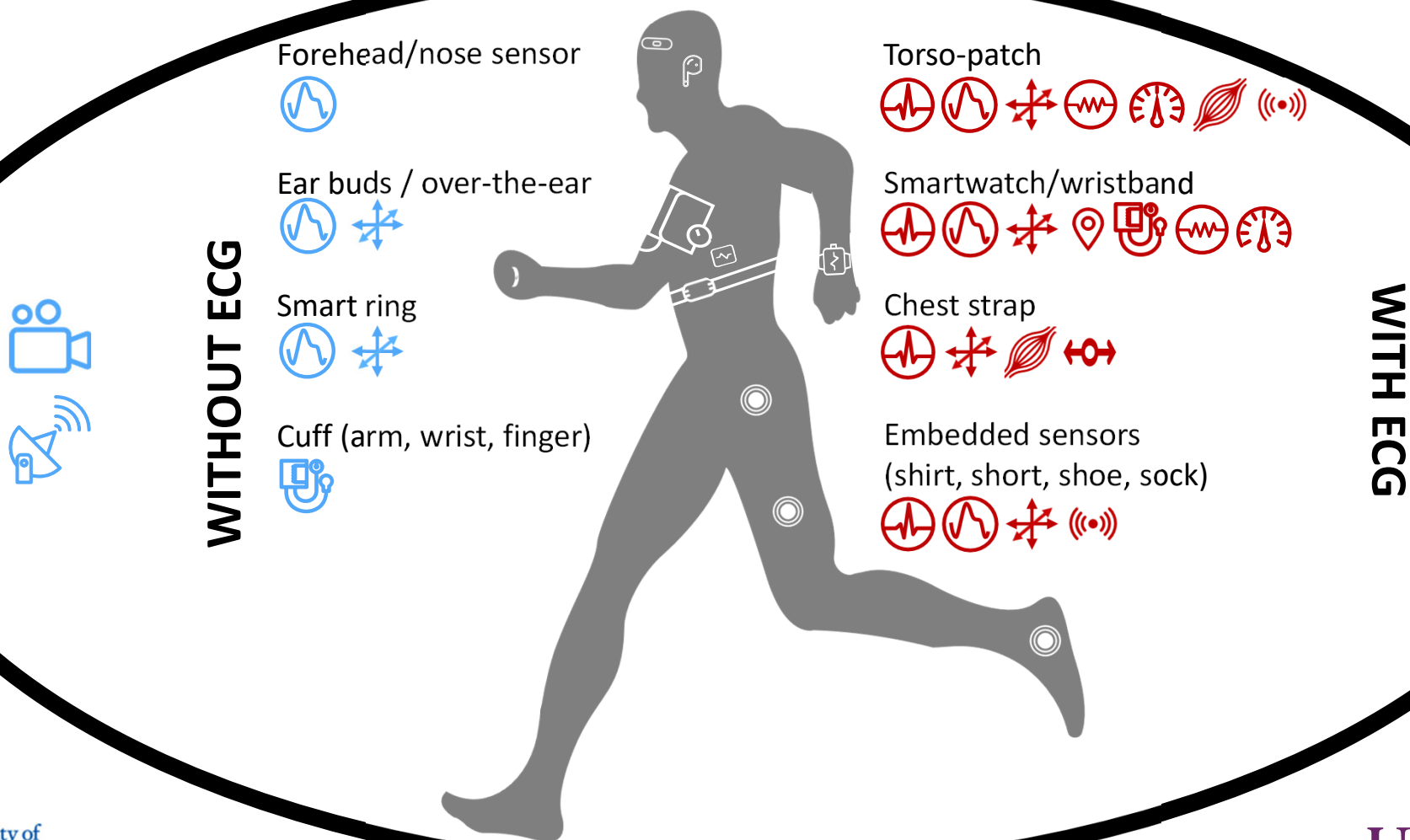
Mobile devices (also tablets) primary means of accessing the Internet



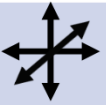





♥ >4.6 billion people access to the Internet at end of 2020.
♥ global online Internet penetration 60%
♥ > 92% access Internet via mobile devices
♥ 50% of global internet traffic is mobile 2020



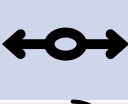



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Consumer-focused Cardiovascular Sensors and Device Locations



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	Accelerometry
	GPS
	ECG
	PPG
	Oscillometry
	Electromyography

	Barometry
	Skin conductance
	Strain
	Radar
	Inductive
	Video

Focused on 3 use cases

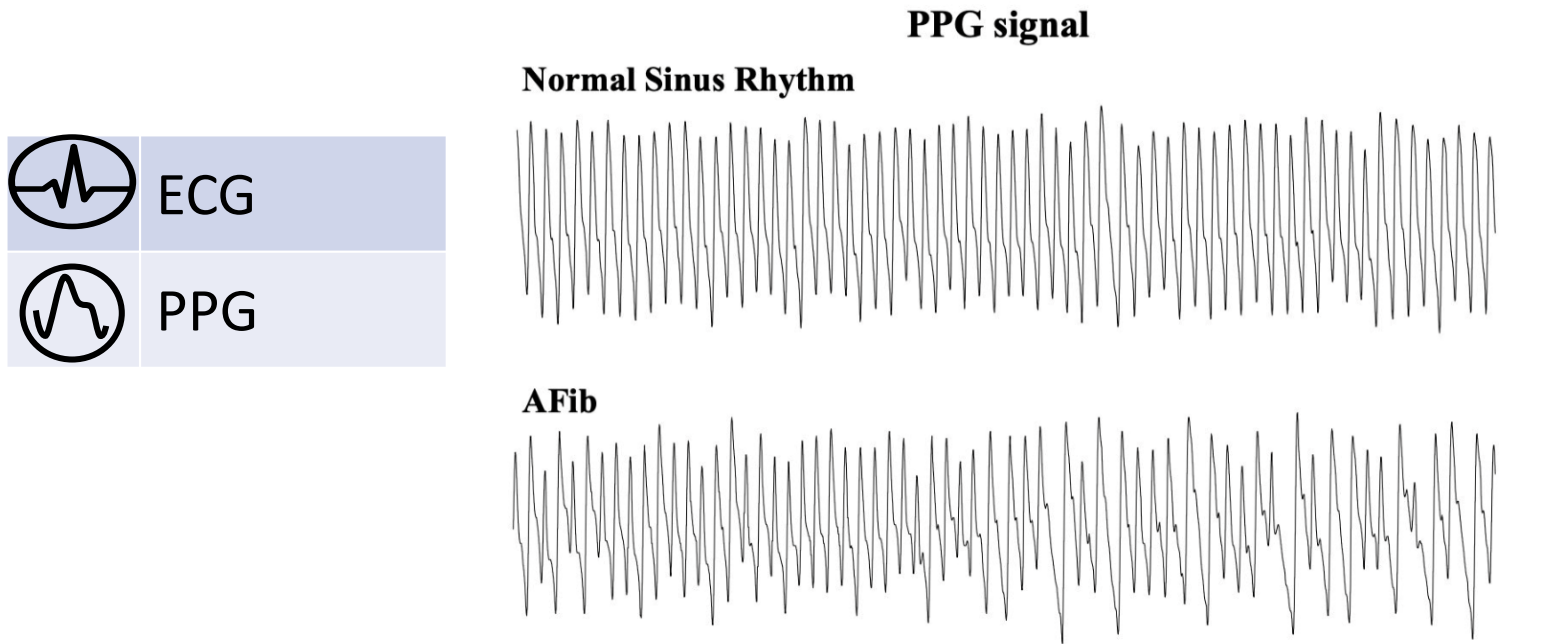
Use Case 1: Physical activity and markers of physical fitness (RHR, HRR, VO2max) are modifiable risk factors and strong predictors of cardiovascular outcomes.

Use Case 2: HTN and AFib screening can be initiated by the user or recommended by the HCP. confirmation of diagnosis relies on HCP review and often additional testing to guide further therapy

Use Case 3: HTN management typically needs medication adjustment while Cardiac Rehab typically requires prescription by HCP.

Use Case 2 Example

INTERPRET-AF: No accuracy difference between physician interpretation of PPG vs ECG to detect or exclude Afib. When does PPG become diagnostic?



Gruwez, Henri et al. "Accuracy of Physicians Interpreting Photoplethysmography and Electrocardiography Tracings to Detect Atrial Fibrillation: INTERPRET-AF." *Frontiers in cardiovascular medicine* vol. 8 734737. 20 Sep. 2021,

Metrics for RPM Clinical Workflow Integration

- For all of these use cases, current **gap between the continuous nature of RPM data provided by consumer devices and the infrequent assessments** made by health care providers during patient encounters. Bridging the gap between the scale of consumer device data and the need to have a tractable amount of interpretable, actionable data points for the provider is a **primary challenge** of integrating consumer devices into the clinical workflow.
- **Interoperability:** An additional challenge is **integrating the data from consumer devices into the electronic health records (EHR) systems** used by providers. These systems are complex and installations are usually customized for each health system. While organizations such as HL7 (hl7.org) have established widely used standards (e.g. FHIR) for the exchange of health information for clinical settings, **interfacing with these systems is still quite challenging.**
- **Data:** EHR companies (e.g. large ones like EPIC/Cerner) have their own strong stance (and thus wishes/needs/requirements etc.) and their own business model which needs to match the use of these devices before they can be integrated. Especially with consumer devices this will be challenging. **Who owns the data?**
- **User Onboarding and Consent** importance of accessibility and digital literacy
- **Facilitating the dialogue between users and their providers around their data** Educating the user on when it is appropriate to contact, convey capabilities and limitations of a consumer device health feature to healthcare staff.
- **Monitoring and Notifications** Clear labeling should describe how frequently a user's data is monitored or screened for the possible presence of a condition, and the latency around a notification or alert.
- **Communication Thresholds** Since RPM pays monthly, the review of data by a physician will likely be monthly unless there is an alert set off automatically. This will be an area where artificial intelligence will play a large role potentially. What the threshold is should be set by clinical guidelines.

Metrics for accuracy

Usage: are sensors/software accurate and clinically validated?

- 1) Verification** – Do the sensors function properly? Example evidence: optical PPG sensors generate an electrical signal that correlates with the fluctuation in light reflected by a target surface.
- 2) Analytical validation** – Are the raw sensor signals accurately transformed to a biometric signal? Example evidence: optical PPG sensors can accurately detect a pulse rate when compared to the heart rate as measured by ECG?
- 3) Clinical validation** – Do the biometrics have clinical value as determined by performance in a clinical study. Example evidence: The pulse rate as measured by PPG sensors can detect irregular pulse rates which correspond to atrial fibrillation.

Metrics for privacy and security

Data: Rights, Governance, Storage, and Privacy

Interoperability

Privacy define a set of baseline recommendations and best practices related to the responsible collection and use of mobile health solutions data, while being easily understandable, leaving developers flexibility in their implementation.

Security

Resources for Identifying Risk

Resources for Protection Internet Protocol (IP) traffic.

TCP Transmission Control Protocol and

UDP User Datagram Protocol

TCP is connection oriented – once a connection is established, data can be sent bidirectional.

UDP is a simpler, connectionless Internet protocol.

Multiple messages are sent as packets in chunks using UDP.

App suppliers do not help users distinguish b/w useless/dangerous apps & valid solutions. The latter are few ; others (useless) are characterized by rapid obsolescence, lack of interactivity & lack of authoritative information

Table 2: IMS Institute for Healthcare Informatics App Functionality Scoring System

Functionality Scoring Criteria	Description
1. Inform	Provides information in a variety of formats (text, photo, video)
2. Instruct	Provides instructions to the user
3. Record	Capture user-entered data
<i>a. Collect data</i>	Able to enter and store health data on individual phone
<i>b. Share data</i>	Able to transmit health data
<i>c. Evaluate data</i>	Able to evaluate the health data entered by patient and provider, provider and administrator, or patient and caregiver
<i>d. Intervene</i>	Able to send alerts based on the data collected or propose behavioural intervention or changes
4. Display	Graphically display user-entered data/output user-entered data
5. Guide	Provide guidance based on user-entered information, and may further offer a diagnosis, or recommend a consultation with a physician/a course of treatment
6. Remind or alert	Provide reminders to the user
7. Communicate	Provide communication between healthcare professionals and patients and/or provide links to social networks

Total score (0–11): one point is assigned to each functionality that is present.

IMS Institute for Healthcare Informatics App Functionality Scoring System

Mortara, Andrea et al. "Would You Prescribe Mobile Health Apps for Heart Failure Self-care? An Integrated Review of Commercially Available Mobile Technology for Heart Failure Patients." *Cardiac failure review* vol. 6 e13. 25 May. 2020.

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Thank you AHIC and ACC

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