A Medtech Leader's Perspective on the Digital Health Revolution

Rick Kuntz, MD, MSc
Former Chief Medical and Scientific Officer
Medtronic, Inc.
Outline

• Brief History of Med Tech, Mission and Industry Structure
• Why We Need a Digital Health Revolution
• The Promise and Challenges of Digital Health
• Med Tech Adaptation and Contributions to Digital Innovation
• Evidence Development in a Digital Health World
• Examples: Biometric Sensors and Challenges
• Conclusions
My Background and Influential Sources

- Interventional Cardiologist, fellow/faculty BIDMC/BWH/HMS 1987-2005
- Founder/CSO of the Harvard Clinical Research Institute/Academic CRO 1993-2005
- Chief, Division of Clinical Biometrics, BWH 1999-2005
- Academic Interests: clinical trial methodology, mathematical modeling of coronary thrombosis and restenosis
- Founding Governor PCORI (Patient Centered Outcomes Research Institute, as part of the Affordable Care Act) 2010-2018
- Co-chair EMAC (Evidence Mobilization Action Committee) of the NAM (National Academy of Medicine) 2013-2022
- NSF Engines Grant: “Advancing Digital Health” 2022-23
  UMN (GMM, JS, ML), and CCF/CWRU
- Multiple NAM publications on Digital Health
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• The Need for Biometric and Phenotype Sensor Devices
• Conclusions
IN THE BEGINNING, it started by FULLFILLING AN UNMET MEDICAL NEED
BY WORKING TOGETHER THE PACEMAKER WAS INVENTED
Mission

IT INSPIRES US... IT DEFINES US... IT GUIDES US...

Contributing to human welfare by the application of biomedical engineering to alleviate pain, restore health, and extend life.

A technology company dedicated to improving patient outcomes.
Technology Focus areas
Megatrends → Health Conditions → Strategic Imperatives

Global Megatrends
- “Silver Tsunami”
- Globalization
- Unconstrained Connectivity
- Consumers Take Charge
- Costs
- Value thru Data

Health Conditions
- Constrained Resources
- Predict, Prevent, Personalize
- Accelerated Convergence

Strategic Imperatives
- Therapy Innovation
- Economic Value: VBHC
- Globalization
**MEDTECH innovation**

**AN EXAMPLE: THE EVOLUTION OF THE PACEMAKER**

<table>
<thead>
<tr>
<th><strong>INVENT NEW MARKET</strong></th>
<th><strong>CONTINUALLY INNOVATE</strong></th>
<th><strong>DISRUPT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Creating and developing new therapies that result in new markets</td>
<td>Enhancing the clinical outcomes and economic value of existing products</td>
<td>Disruptive therapies in existing markets</td>
</tr>
</tbody>
</table>

This is a process we run in parallel, across multiple therapy areas.
1. CONTINUOUS INNOVATION

- **Evolut PRO+**
  - Transcatheter Aortic Valve Replacement
  - Removes clots and restores blood flow for Ischemic Stroke

- **Solitaire™ X**
  - Solitaire™: Stent System & Vessel Sealing
  - Enables consistent staple lines across variable tissue & faster sealing times

- **Coronary Stents**
  - Restores blood flow for coronary blockage

2. INNOVATION / DISRUPTION

- **InterStim™ Micro Neurostimulator**
  - Treats urinary & fecal incontinence

- **Personalized Closed-Loop System**
  - Personalized real-time automatic insulin delivery

- **Percept™ PC DBS Primary Cell + Sensing**
  - Deep brain stimulation and sensing

- **Micrany**
  - Improved accuracy & longevity

- **Next Generation R-chargeable device (NGRC) with ECAPS**
  - Closed loop stimulation system for pain management

  - **Athena**
    - Fully implantable Left Ventricular Assist Device system

3. DISRUPTION

- **Mazor X Stealth Edition**
  - Spinal surgery robot

- **Medtronic Robotic-assisted Surgery Platform**
  - General surgery robot

- **Micra**
  - Extravascular ICD
  - Transcatheter, leadless pacing system

- **Pulsed Field Ablation**
  - Treats fast heart rhythms with lead outside of heart & veins

- **Portable Hemodialysis System**
  - Transforms atrial fibrillation ablation with non-thermal electroporation

  - Portable system uses 75% less water

4. INVENTION

- **LINQ HF**
  - Creates risk score related to Heart Failure

- **SPYRAL**
  - Renal denervation for management of resistant hypertension

- **Intrepid™**
  - Transcatheter Mitral Valve Replacement

- **PillCam Genius**
  - Endoscopy in a pill with reduced reading time
Technology Focus areas
Supporting current and future products

Additive Manufacturing
Big Data and Analytics
Biomarkers
Data Collection and Management

Combination Products (Drug Delivery)
Medical Imaging and Visualization
Materials, Coatings, and Interfaces
Microelectronics

Power and Batteries
Predictive Modeling
Communication Platforms (Wireless / RFID)
Sensors

Tissue Regenerative Medicine
Energy Delivery

14 TECHNOLOGIES
81 CATEGORIES
170 SUB-CATEGORIES
MedTech well positioned to lead journey to operationalize vbhc

THE QUEST TO IMPROVE OUTCOMES THROUGH TECHNOLOGY IS ENDLESS

Leveraging the long history of collaboration between physicians and engineers to solve clinical problems.
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Why We Need a Digital Health Revolution (1)

In the US, Existing Healthcare Systems are not efficient, and Health Inequities Prevail

- WHO defines health as “a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.”

- In the US, health policies and health system investments remain misaligned with this concept.

- Per capita, US spending on healthcare is >200% more than any economically developed country, yet health inequities prevail, with stark differences in life span, quality of life, and severity of disease across the socio-economic spectrum, accounting for >$40B in lost productivity and >$90B in excess medical costs annually.

- In the US, health policies and health systems remain misaligned, ~90% of all health expenditures go to disease and injury treatment rather than to addressing the predisposing factors of these illnesses and injuries.
Why We Need a Digital Health Revolution (2)

In the US, Existing Systems are not efficient, and Health Inequities Prevail

• By 2020, US healthcare had grown to $4.1 trillion

• Spending in the health care sector is projected to increase to over $6 trillion annually, and encompass 20% of the nation’s GDP by 2028.

(Keehan SP, et al, Health Affairs, 2020; CMS 2019)

• Majority Black urban populations, such as Detroit (78.6% Black) and Cleveland (49.6% Black) have a 6-year deficit in median life expectancy (72.4 and 73.1 years, respectively) compared to the US average of 79 years.

In Cleveland, a 23-year life expectancy gap separates neighborhoods who live only 8 miles apart along Euclid Avenue, minutes from two-world class healthcare systems.
The current “episodic” focused health care system in the US is largely inefficient and overly expensive, and needs a more continuous and preventive health approach.

Thesis: Advancing “Digital Health,” with its more intensive real-time data collection, data access and accessories (e.g., home and wearable sensors, tele-medicine, etc.) and near real-time predictive analytics will address the gap in prevention and improve access to healthcare for the underserved.
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Why Digital Health?

1. Mountains of data, molehills of usable data

2. Episodic data, episodic care
   - Existing data is underutilized
   - Generated data is disorganized, unfocused, and incomplete
   - Future data is unstandardized

3. Health disparities
“The complexity of medicine now exceeds the capacity of the human mind”

David Eddy MD, PhD, NEJM editorial

1982
Digital Health in the 21st Century

“Digital Health has evolved as a broad term encompassing electronically captured data, along with technical and communications infrastructure and applications in the health ecosystem.

Developments such as cloud computing, artificial intelligence, machine learning, blockchain, digitally mediated diagnostics and treatment, tele-health, and consumer facing mobile health applications are now routinely used in self-management, health care, and biomedical science.

These developments promise to drive earlier diagnoses and interventions, improve outcomes, and support more engaged patients.”

NAM 2022
Digital Innovation and the Learning Health System

“The application of digital technologies at scale serves as the nervous system for the continuously learning health care system: one in which science, informatics, incentives, and culture are aligned for continuous improvement, innovation, and equity – with best practices and discovery seamlessly embedded in the delivery process, individuals and families’ active participants in all elements, and new knowledge generated as an integral by-product of the delivery experience.”

NAM, 2020
Digital Health Revolution Data Challenges (1)

• Healthcare ecosystems are largely fragmented
• Data systems (EHRs, labs, imaging, drug/device inventory, out-patient clinics, etc.) need seamless interoperability in order for the data to be aggregated and analyzed for proper inference and decision making.
• The 21st Century Cures Act addresses foundational standards to drive interoperability.
  • Curation methods and APIs that interface with EPIC/CERNER
  • ONC: Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR)
  • SNOMED, OMOP and others
• Data provenance (privacy and data rights)
Digital Health Revolution Data Challenges (2)

• Longitudinal data continuity between in-hospital records and local/regional outpatient clinics is often difficult.

• Recognition of data “missingness” and methods to correct it are needed.

• Data interoperability collaboration policies are needed among stakeholders: patients, providers, healthcare systems, industry drug and device providers.

• Data provenance (patient privacy, consent and data rights):
  • HIPAA likely needs to be expanded beyond the traditional care data sources

• Identification of data quality standards are needed that allows proper analysis.
Themes

1 Federated Data Systems
   Integrating disparate data sets for clinical insights and research

2 Learning Health Systems
   Making data inform patient care in real time

3 Devices, Sensors, and Algorithms
   Ensuring secure, high-quality data production and integration with relevant databases
"Despite important gains in the last two decades...the promise of digital health remains illusory."

Advances in Digital Health can drive huge improvements in

- Diagnosis
- Treatment
- Care continuity
- Reducing health disparities

- Remote patient management
- Patient self-care
- Reduction of error and waste

The Promise of Digital Health: Then, Now, and the Future. doi.org/10.31478/202206e, 06/27/2022
FIGURE 1 | Evolving Applications of Digital Technology in Health and Health Care

FIGURE 2 | Infrastructure Requirements for Progress in Digital Health
**BOX 1 | Core Principles for Stewards of the Digital Health Infrastructure and Data**

**Personal:** Discretion on control and use of personal data resides with the individual or their designee.

**Safe:** Data stewardship protocols safeguard against use resulting in personal harm.

**Effective:** Data are collected and maintained according to validated stewardship protocols.

**Equitable:** Data systems are designed to identify and counter bias or disparities.

**Efficient:** Every digital equipment acquisition or service license enhances health system interoperability.

**Accessible:** Data are available when and where needed for decision-making.

**Measurable:** Digital health performance is continuously monitored for accuracy and interoperability.

**Transparent:** Personal data sources and uses are clearly indicated, including timing and context.

**Adaptive:** Data strategies are regularly calibrated to ensure continuity, currency, and utility.

**Secure:** Data sharing protocols are considered secure by users.

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Med Tech Must Focus on Data and Sensors

• Interoperable data systems must be developed for implantable and wearable medical devices, in collaboration with patients, providers and healthcare systems, to share information and analyses (including AI/ML) to optimize the promise of disease prevention and good health promised by the Digital Health Revolution.

• Med Tech must focus on advancing device embedded biometric sensor technology, as well as advanced wearable biometric technology, data communications and storage systems, and data sharing platforms to realize the promise of continuous optimum healthcare and disease prevention, moving away from the business model based on episodic care.
Ensure Medtronic patients and products can be identified within the HCO data ecosystem starting with performing a crosswalk using Medtronic’s cardiovascular devices.

Steps

1. Obtain approvals (privacy/IRB/legal)
2. Align on sampling method
3. Pull device registration extraction and GTIN crosswalk
4. HCO Queries EDW by GTIN
5. Perform validation of completeness
6. Assess the reliability of results (Match %)
7. HCO creates a cross tabulation report (PHI removed)
**Cobalt XT (TriageHF) – implantable cardioverter defibrillator**

**Disease state:** Heart Failure with reduced EF

**Data collected:**

Structured *(combine w/ patient demographics, hospitalization & outcomes data):* Current metrics collected by Triage HF algorithm *(HR variability, VT rate during AT/AF, shocks, % ventricular pacing, tissue impedance etc.)*

Combine raw device data w/ patient outcomes data to seek novel risk identification measures

**Value to customer:**

Short term – Develop virtual HF clinics to improve quality of care and reduce cost of care per patient – identify patients with highest and lowest needs for near term follow up *(shown to have a 64% reduction in time spent in care setting & 50% decrease in costs to treat HF patients)* – Starting with retrospective, then moving toward prospective

Long term – More hospital beds open up for the increasing number of patients needing VADs *(ventricular assistant devices)* & transplants

**Value to MDT:**

Short term – Leverage combined data for RWE

Long term – Differentiate MDT ICDs
Evolution to deliver better patient outcomes & patient experience

From standalone products to manage patient condition

To integrated product suite to manage patient care continuum

- Patient Id & Selection
- Optimal Care Pathway
- Disease Management
- Therapy Planning
- Recovery Optimization

LHS
Health Information Exchange (HIE) Framework
USING DATA AND ANALYTICS TO IMPROVE PATIENT OUTCOMES AND EXPERIENCE

Data Sources
- Data From Other Sources (Claims, etc.)
  - OPTUM
  - UnitedHealthcare
  - WellPoint
- Health System Data
  - Epic
  - Cerner
- Patient Generated Data
  - Medtronic Device Data
- Medtronic Device Data
- Sense
- Collect
- Assess
- Insight
- Share

Advanced Analytics
- Patient Cohort Analysis
- Algorithms
- Pathway Analysis

Longitudinal Patient Record Database

Enrich
Analyze

Insights
Digital twins exist at the nexus of physical engineering, data science, and machine learning, and their value translates directly to measurable business outcomes.*
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INVENTION: CREATING NEW THERAPIES THAT RESULT IN NEW MARKETS

Restores blood flow and retrieves clots in the brain for patients experiencing acute ischemic stroke

2009
SOLITAIRE™ FR

2015
5 NEW ENGLAND JOURNAL OF MEDICINE PUBLICATIONS

2013-2018
AHA / ASA GUIDELINES

$2.5B Market Worldwide in FY18 Growing ~20%

Developing EMS Routing Protocols and Patient Care Pathways

Comprehensive Platform Anchored by Market-Leading Technology

2013: Guidelines Established
2015: Stent retriever / 6 hours
2018: “Extended Window” 16-24 hours

SWIFT PRIME | EXTEND IA | ESCAPE | REVASCAT | MR CLEAN

INNOVATE, INVENT, DISRUPT: THE IMPORTANCE OF MEDICAL TECHNOLOGY IN TRANSFORMING HEALTHCARE FOR THE FUTURE | SEPTEMBER 2018
In a Digital Health World...

- The main aim of Digital Health, and its reliable, real-time data and analysis is to improve the health of people:
  - Permit better access, for the underserved, to needed prevention and treatment providers
  - Make earlier diagnoses of treatable disorders
  - Manage chronic conditions to prevent “episodes” of hospitalizations

*There will be a strong desire to use seemingly reliable, real-time data, and aggregate it and perform traditional clinical research (epidemiological, prospective studies and trials).*
The Challenges of Performing Clinical Research on Data from Unstructured Databases.

- **Making clinical research inference on databases requires basic rules**
  - The derived clinical research databases should be viewed as retrospective observational databases
    - POC randomization may be possible in some scenarios
  - The data fields must be standardized
    - Techniques like NLP and AI/ML may be used but are not always reliable for this application
  - Missing data cannot be tolerated
    - > 10% missing data for any field introduces incomplete ascertainment bias
    - There are very few, if any fixes for missing data
Special Features of Device Trials

Rationale for RCT in Med Tech/Device Trials

• Observational studies are often confounded.
  • The actual cause of an outcome may not be due to the intervention under study, but rather to an unmeasured factor (confounder). Randomization cures this problem.
  • Device trials are especially vulnerable to procedure/operative invasion, enhancing placebo and Hawthorne effects.

• The basis of Clinical Evidence-Based Medicine is the RCT.
  • Medical Devices are generally developed by for-profit industry sponsors, and objectivity is a requisite.

• For any subjective, or semi-objective endpoint, a blinded, sham RCT is generally required to determine the true effect of an intervention.
Special Features of Device Trials

Trial Effects

• Clinical trials are experiments that aim to test interventions (therapies, preventive strategies, diagnostics) for real world conditions.

• The experimental conditions aim to assure validity, but these conditions can add unwanted effects:
  • Selection bias that limits generalizability
  • Hawthorne Effect
  • Placebo Effect
Laser Angiogenesis Trials

• Laser Angiogenesis Trials for Intractable, Advanced Coronary Disease:
  – Therapeutic proposition: Application of partial small laser holes in “hibernating” myocardium would cause growth of new blood vessels.
  – Time on treadmill and thallium perfusion will likely improve during the trial with medical therapy
  – Difficult to partition treatment effect from “healthy patient” and placebo effects
Biosense Pilot Single Arm Study

ETT: Time to Termination

Mean Score

Baseline (n=76)  1 month (n=69)  6 months (n=35)

P = <.001
PACIFIC Laser Angiogenesis
Open Label RCT
Exercise Tolerance Change

Data Matched Against Baseline

p <0.0002
3&6 mos

3 Months 6 Months
Treated Control
n=92 n=74
n=94 n=85
Summary of Symptom Evaluation

• Marked improvement in CCS and all QOL dimensions
• Similar magnitude to coronary revascularization trials
• Sustained improvement at 6 months
Biosense Laser Angiogenesis RCT

- Three arm RCT
  - High dose Laser
  - Low dose laser
  - Sham, no laser
Direct (PMR) Exercise Duration

\[ p = NS \]

\[ p = NS \]

\[ p = NS \]

\[ n = 240 \text{ patients} \]

![Bar chart showing exercise duration in seconds for baseline, 6-month follow-up, and change, with no significant difference (p = NS) for low dose, high dose, and placebo groups.](chart.png)
Biosense Laser Angiogenesis RCT

• Conclusion
  – Laser Angiogenesis is not effective in improving exercise tolerance.
  – Prior single arm Biosense studies and the open label Pacific trial of laser angiogenesis for refractory coronary disease, were plagued by placebo and Hawthorne effect.
Placebo Effect is a Consequence of Cognitive Dissonance

- Perceived therapeutic response can be a rationalization of the dissonance between subjective invasiveness and subjective lack of improvement

Device Trials are more invasive, and often unblinded or poorly blinded
• Activation of the Opioidergic Descending Pain Control System Underlies Placebo Analgesia
• Eippert F, et al; Neuron 63, 533–543, August 27, 2009
• Activation of the Opioidergic Descending Pain Control System Underlies Placebo Analgesia

• Eippert F, et al; Neuron 63, 533–543, August 27, 2009

• Cortical Effects:
  • Dorsolateral prefrontal cortex, Rostral anterior cingulate cortex

• Brainstem Effects:
  • Hypothalamus, Periaqueductal gray, Rostral ventromedial medulla
Placebo analgesia involves the endogenous opioid system, as administration of the opioid antagonist naloxone decreases placebo analgesia.

“Placebo analgesia involves the endogenous opioid system, as administration of the opioid antagonist naloxone decreases placebo analgesia.”
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Miniaturizing a Clinic into a Wearable Device

Conventional Approach

Biomarkers

Blood Oxygen Saturation • Respiratory Rate
Heart Rate • Hydration
HRV • Body Temp.
Blood Pressure
Alcohol • Lactate • Glucose

In-Clinic • Clinician-Led • Non-Continuous

SWIR

Continuous • Non-Invasive • Non-Supervised
Rockley's proprietary clinic-on-the-wrist™ module condenses traditional tabletop technology onto a wearable chip.
Rockley’s Unique Technology Solution

Rockley’s novel SWIR sensor consists of multiple laser wavelengths that target biomarker spectral features, and detectors that allow for varying depths of penetration into the dermis.

Light from numerous, distinct laser lines propagates through tissue layers with biomarkers, reflects back to detectors.

Rockley’s lasers operate at a range higher than typical LEDs, allowing for extraction of specific and novel biomarkers, useful in a variety of health-related use cases.
Why the Short Wave Infrared (SWIR) Region?

Absorption of Key Blood Constituents

Transmission Spectrum of Water

*Rockley Data on File
## Rockley Band Biomarker Sensor Offerings

<table>
<thead>
<tr>
<th>Biomarker</th>
<th>Baseline Band</th>
<th>Pro Band</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO₂</td>
<td></td>
<td>![SpO₂]</td>
</tr>
<tr>
<td>HR</td>
<td>![Heart]</td>
<td>![Heart Pro]</td>
</tr>
<tr>
<td>HRV</td>
<td>![Heartbeat]</td>
<td>![Heartbeat Pro]</td>
</tr>
<tr>
<td>Respiratory Rate</td>
<td>![Lungs]</td>
<td>![Lungs Pro]</td>
</tr>
<tr>
<td>Hydration</td>
<td>![Water]</td>
<td>![Water Pro]</td>
</tr>
<tr>
<td>Body Temperature</td>
<td>![Thermometer]</td>
<td>![Thermometer Pro]</td>
</tr>
<tr>
<td>Glucose</td>
<td></td>
<td>![Glucide]</td>
</tr>
<tr>
<td>Ethanol</td>
<td></td>
<td>![Ethanol]</td>
</tr>
<tr>
<td>Lactate</td>
<td></td>
<td>![Lactate]</td>
</tr>
</tbody>
</table>

**Traditional PPG**

**SWIR Spectrometry**
Hydration Index: Monitoring and Preventing Dehydration

Hydrated State

Dehydrated State

Moderate Dehydration

Mild Dehydration

Euvolemia (Hydrated)
Bioptx Band Use Case Examples

**Hydration** and **Temperature** Remote Monitoring for the Prevention of Dehydration and Accidental Hyperthermia

Monitoring during times of risk... and monitoring recovery at home.

<table>
<thead>
<tr>
<th>Baseline Measurement (Individualized)</th>
<th>Example Scenario: Poor Recovery (Acute)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SpO₂</strong></td>
<td>95-100% Decrease if poorly acclimated; chronic nonfunctional overreaching</td>
</tr>
<tr>
<td><strong>RR</strong></td>
<td>12-20 bpm Increased</td>
</tr>
<tr>
<td><strong>HR</strong></td>
<td>Resting HR (60-100 bpm) Slow recovery / Increased resting HR (≥5%)</td>
</tr>
<tr>
<td><strong>HRV</strong></td>
<td>50-100 ms (healthy adults) Decreased HRV</td>
</tr>
<tr>
<td><strong>BP</strong></td>
<td>&lt;120/&lt;80 mmHg Poor recovery to baseline</td>
</tr>
<tr>
<td><strong>Temperature</strong></td>
<td>~37° C Increased; slow or poor recovery</td>
</tr>
<tr>
<td><strong>Hydration</strong></td>
<td>Euhydration Dehydration (Mild or greater)</td>
</tr>
<tr>
<td><strong>Other:</strong></td>
<td>As required by use case application Sleep quality “poor” or physiological strain “high” using an associated index derived from composite biomarkers</td>
</tr>
</tbody>
</table>

- **Real-Time Heart Rate:** Elevated
  - 125 bpm
- **Temperature:** Slightly Elevated
  - 38.0° C
- **SpO₂:** 97%
- **Hydration Index:** Dehydrated
  - -3

“Drink fluids”

Mildly Dehydrated
Sensor Biometrics
- SpO₂
- Heart Rate
- Heart Rate Variability
- Respiratory Rate
- Blood Pressure
- Core body temperature
- Hydration
- Glucose
- Alcohol

Physiologic Indicators
- Tissue perfusion / Ischemia
- Infection
- Decompensation
- Pain
- Performance
- Overtraining
- Strain
- Movement / Activity
- Core Body Temperature
- Resting HR
- Real-time HR
- HR max
- HR thresholds
- VO₂ / VO₂peak
- Intensity
- Sleep quality, disturbance
- AHI
- ODI
- METs
- Metabolic Health
- Caloric cost
- Hemodynamics
- Sleep quality
- Stress
- General health status (e.g. vitals status)

Applications
- Chronic Disease Risk Reduction
- Lifestyle Management
  - Diet, Physical Activity
- Heat Illness
- Fluid Intake:
  - Dehydration
  - Overhydration
- Cognitive Performance
- Physical Performance and Training
- Stress
- Fatigue & Recovery
- Trauma & Shock
- Human Application / Clinical Research
- Disease and Illness Monitoring
- Sleep disorders; SRBDs
- Fertility

Users
- In-Patient Practitioners / Surgeons
- Specialists (e.g. nephrologists)
- Field Medics / EMT
- Corporate Wellness / Insurance
- Research Institutions
- Military, DoD
- Public Safety
- Transport
- Coaches, Trainers
- Athletes (Extreme/Endurance)
- Agriculture
- Building/Construction
- Mining / Oil / Mills / Welding
- Technical Professions
- Teachers
- Women's Health
High Global Incidence of Hypertension

Hypertension Prevalence is ~30% Worldwide

*Data shown is for women only, similar data for men
Relative Risk Reduction Proportional to Decrease in OSBP
Irrespective of Baseline BP or CVD History in 2 Meta-Analyses

<table>
<thead>
<tr>
<th>Event</th>
<th>Relative Risk Reduction (%)</th>
<th>-5 mmHg (N=344,716)</th>
<th>-10 mmHg (N=613,815)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major CVD</td>
<td>-10%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>-13%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart Failure</td>
<td>-13%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ischemic Heart Disease</td>
<td>-8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular Death</td>
<td>-5%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Challenging Hypertension

• Arguably the most destructive disorder

• Undiagnosed and untreated hypertension is a global epidemic
  • In underserved communities, the first indication of untreated hypertension can be kidney failure.

• There are at least 4 med tech companies working on, or are marketing, wearable intermittent and/or continuous BP monitoring watches:
  • Tula Health
  • AKtiia
  • Biobeat Technologies
  • Rockley Photonics
Wearable BP Monitor Challenges

• How would a continuous BP wearable (watch) measure and notify patients, caregivers and providers?
  • BP goes up and down (above levels that might be concerning) in activities of daily life, especially when exercising. Could be false positives.
  • Are there qualified levels of exercise BP that are diagnostic of a problem?
  • Should BP be measured primarily in a traditional seated position?
    • If so, what advantage does it have over an automated BP cuff device.
  • Are there enough known patterns of BP at night while sleeping to develop an alert or diagnosis?
  • Should initial wearable BP devices just provide a log for a provider to review, maybe with input from an accelerometer device (phone) and a diary?
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- Brief History of Med Tech, Mission and Industry Structure
- Why We Need a Digital Health Revolution
- The Promise and Challenges of Digital Health
- Med Tech Adaptation and Contributions to Digital Innovation
- Evidence Development in a Digital Health World
- Examples: Biometric Sensors and Digital Devices and Challenges
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A Medtech Leader's Perspective on the Digital Health Revolution

Conclusions

• The principals of digital health and its applications, including advanced analytics, are critical to move to a more effective disease management system in near realtime, and to a preventive strategy that realizes health as “a state of complete physical, mental and social well-being -- and not merely the absence of disease or infirmity.”

• The alignment and collaboration of MedTech is critical to its own future and to the success of the Digital Health Revolution.
  • MedTech must focus on interoperable and sharable device data systems that combine with patients, providers and health/health care systems (e.g., EHRs) to allow aggregable and analyzable data for greater health insights.
  • A focused pipeline on medical device-embedded and wearable biometric sensor technology will improve both the goals of continuous preventive strategies and access to care for the presently underserved.