Managing Metabolic Disorders:

The Role of the Pharmacist within the Technological Ecosystem

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Objectives

- Define how the technological ecosystem interacts with individuals and organizations
- Describe current applications for managing metabolic disorders
- Discuss barriers and implications of technology integration

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Disclosures

We, or our immediate family members, including spouse or partner, have no financial relationship(s) relevant to the content of this educational activity

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Technological Ecosystem

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Polling Question

What pharmacy setting do you primarily practice in?

A. Chain Community
B. Independent Community
C. Managed Care
D. Ambulatory Care
E. Inpatient
F. Other

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Polling Question

Free response

What type of digital health technologies do you encounter in your practice setting?

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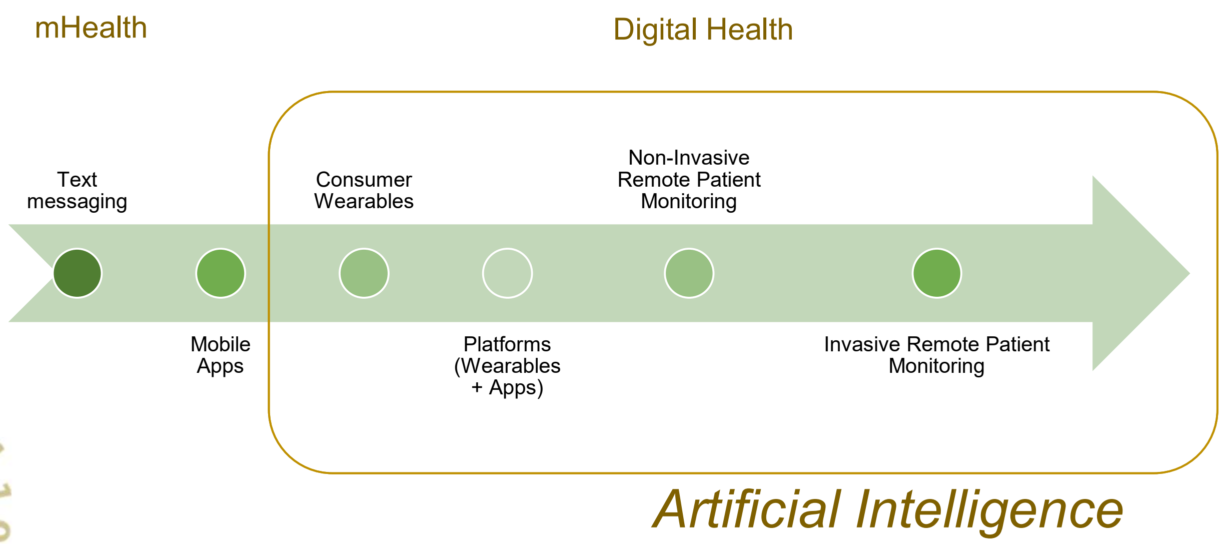
Timeline of Technology



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Ecosystem

- Definition: a set of capabilities and services that integrate value chain participants through a common commercial model and virtual data backbone
  - Enables seamless data capture, management, and exchange
- Purpose:
  - Create improved and efficient consumer and stakeholder experiences
  - Solve significant pain points
  - Improve inefficiencies

Singhal S., Kayyali B., Levin R., Greenberg Z. The next wave of healthcare innovation: The evolution of ecosystems. Healthcare Systems & Services, McKinsey & Company. June 2020.

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Ecosystem

- 5 key industry forces driving technology innovation:
  1. Industry inefficiencies
  2. High rates of healthcare technology investments
     - Patient engagement
     - Data and analytics
     - New care models
  3. Battle for market share (partnerships & acquisitions)
  4. Regulatory
  5. Healthcare industry investment

Singhal S., Kayyali B., Levin R., Greenberg Z. The next wave of healthcare innovation: The evolution of ecosystems. Healthcare Systems & Services, McKinsey & Company. June 2020.

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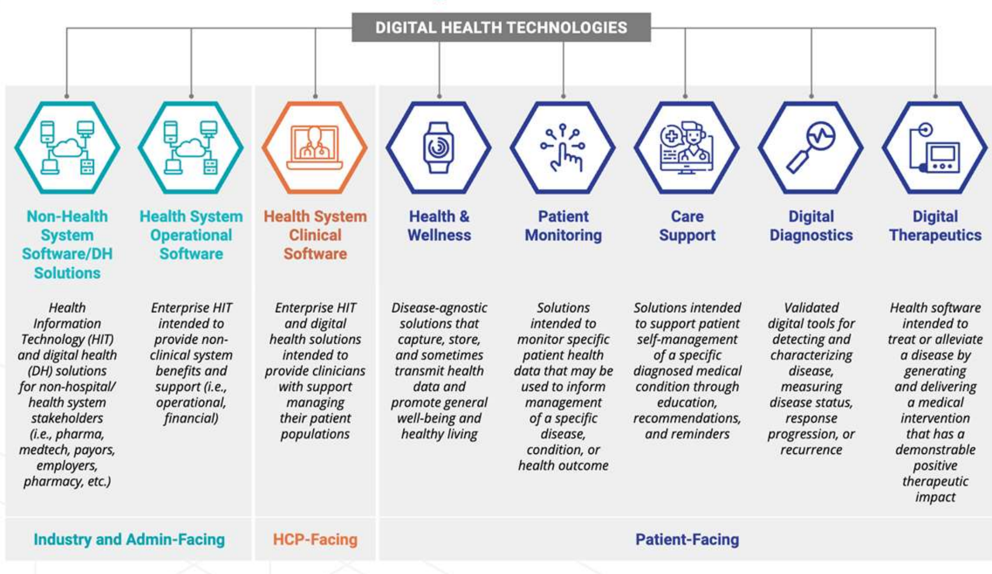
Digital Health Ecosystems



https://digital.health

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Digital Health Technologies (DHTs)

- DHTs are computing platforms, connectivity, software, and sensors used for health care and related issues
- DHT categorization based on:
  - End users/beneficiaries
  - Intended benefits/claims
  - Level of regulatory scrutiny
  - Strength of evidence
  - Intervention type

U.S. Food and Drug Administration, "What is Digital Health?," September 22, 2020

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Digital Health Technologies

Non-Patient Stakeholders	Patient-Facing
Industry & Admin-Facing • Non-Health System Software/DH Solutions • Health System Operational Software **Healthcare Provider-Facing** • Health System Clinical Software	• Digital Therapeutics • Digital Diagnostics • Care Support • Patient Monitoring • Health & Wellness

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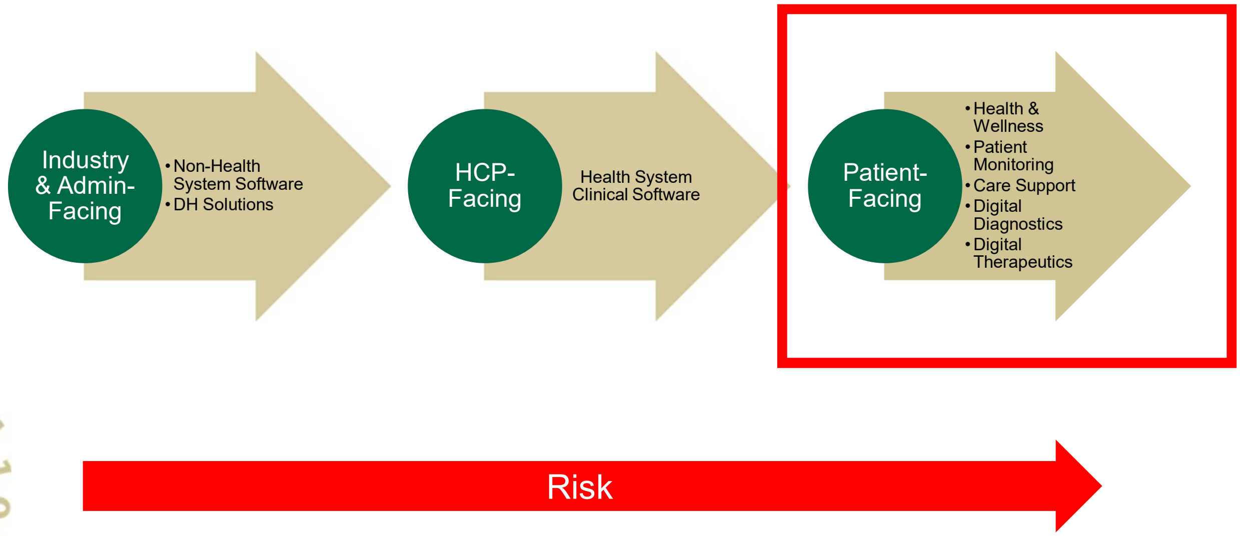
Digital Health Technologies



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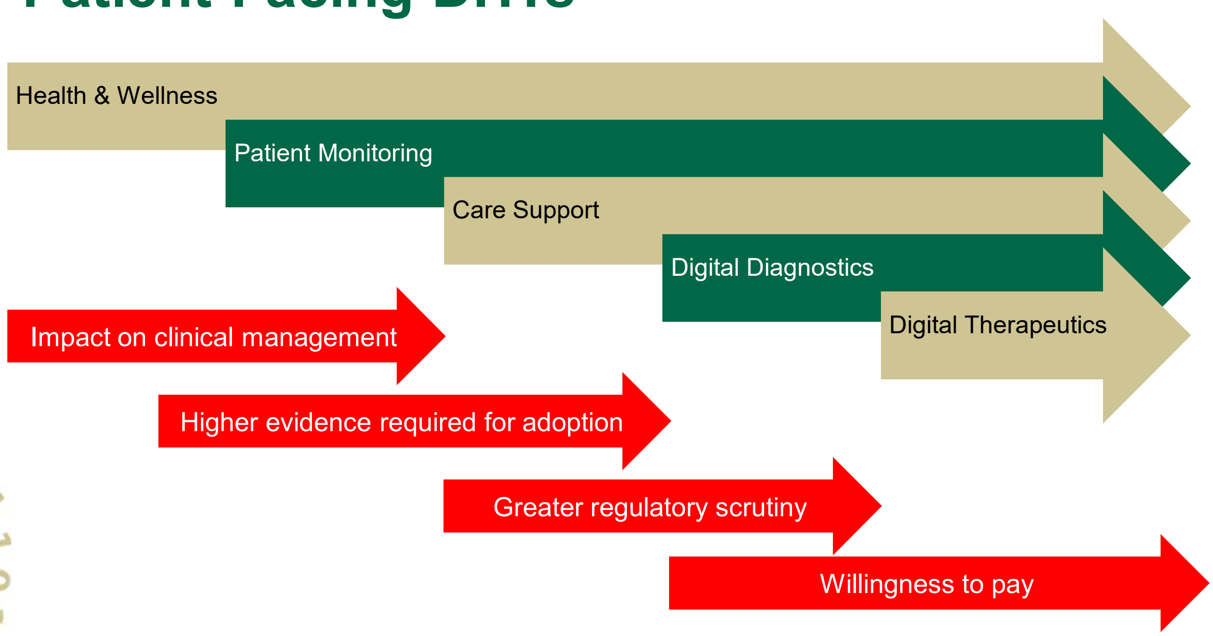
Patient-Facing DHTs



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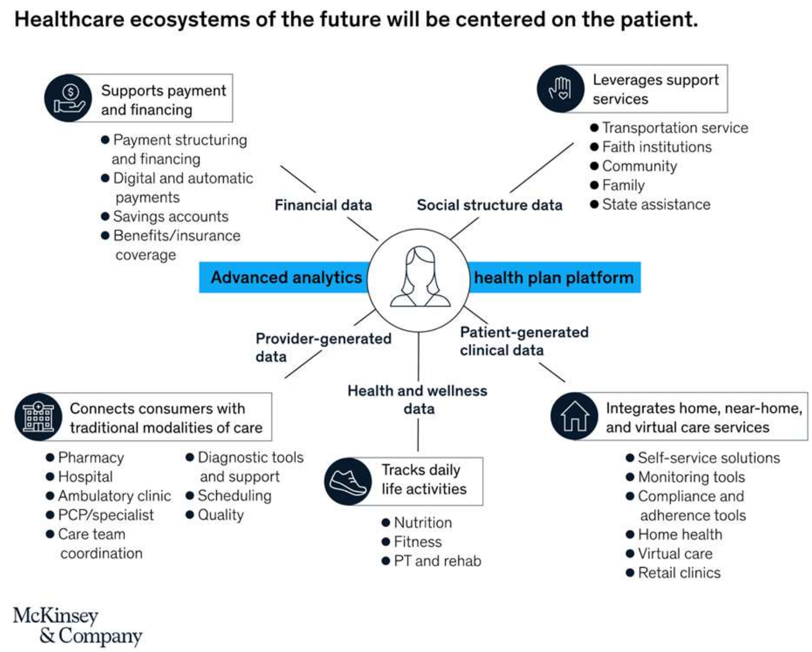

Singhal S., Kayyali B., Levin R., Greenberg Z. The next wave of healthcare innovation: The evolution of ecosystems. Healthcare Systems & Services, McKinsey & Company. June 2020.

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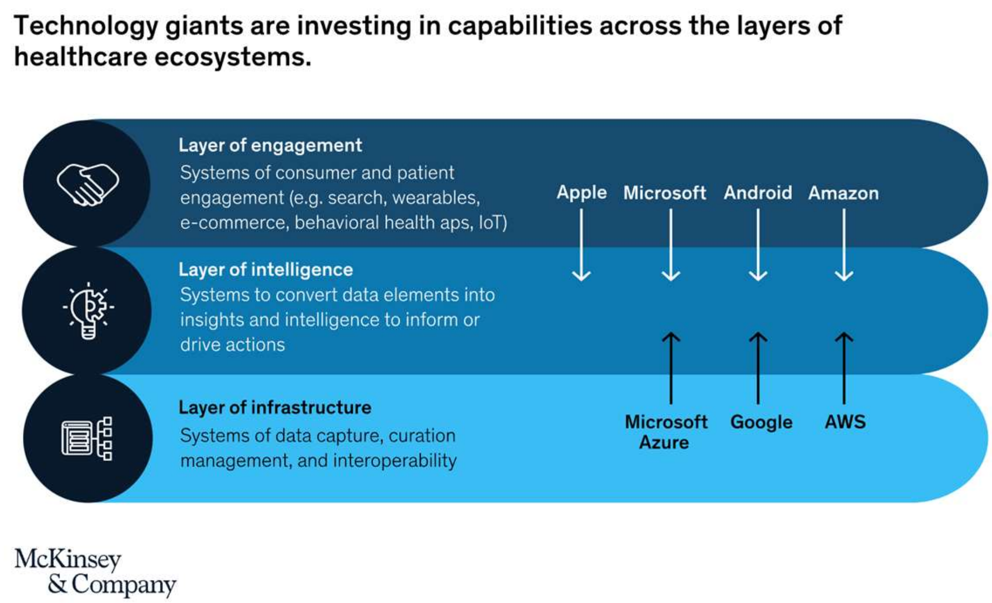

Singhal S., Kayyali B., Levin R., Greenberg Z. The next wave of healthcare innovation: The evolution of ecosystems. Healthcare Systems & Services, McKinsey & Company. June 2020.

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Assessment Question

Digital health ecosystems serve the purpose of

a. Creating improved and efficient consumer and stakeholder experiences
b. Solving significant pain points
c. Improving inefficiencies
d. All the above

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Assessment Question

The patient-facing digital health technology that has the greatest potential for impact on clinical management, requires higher evidence for adoption, is more scrutinized by regulations, however, presents the greatest opportunity for pay is

a. Health and wellness
b. Patient monitoring
c. Care support
d. Digital diagnostics
e. Digital therapeutics

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Current Applications and Evidence

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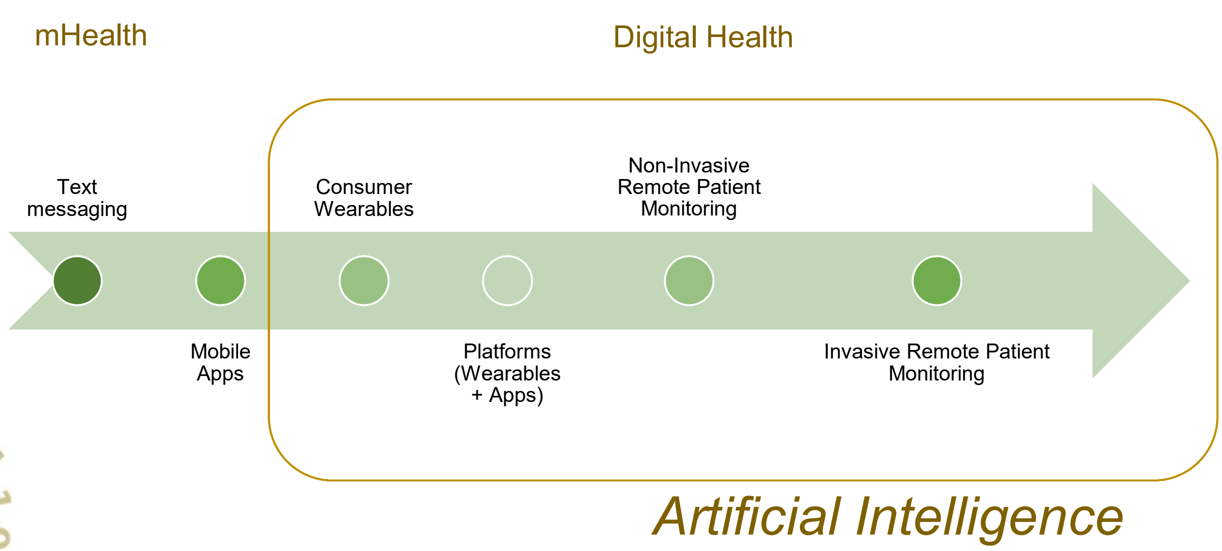
Timeline of Technology



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Changes Due to COVID-19

- Significant disruption - Major push for telehealth and remote monitoring opportunities
- Other areas that require addressing:
  - Reimbursement for new digital services
  - Expanded regulatory relief
  - Evaluation of clinical care provided by these technologies

Keesara S, et al. NEJM 2020; 382 (23):e82(1 – 3)

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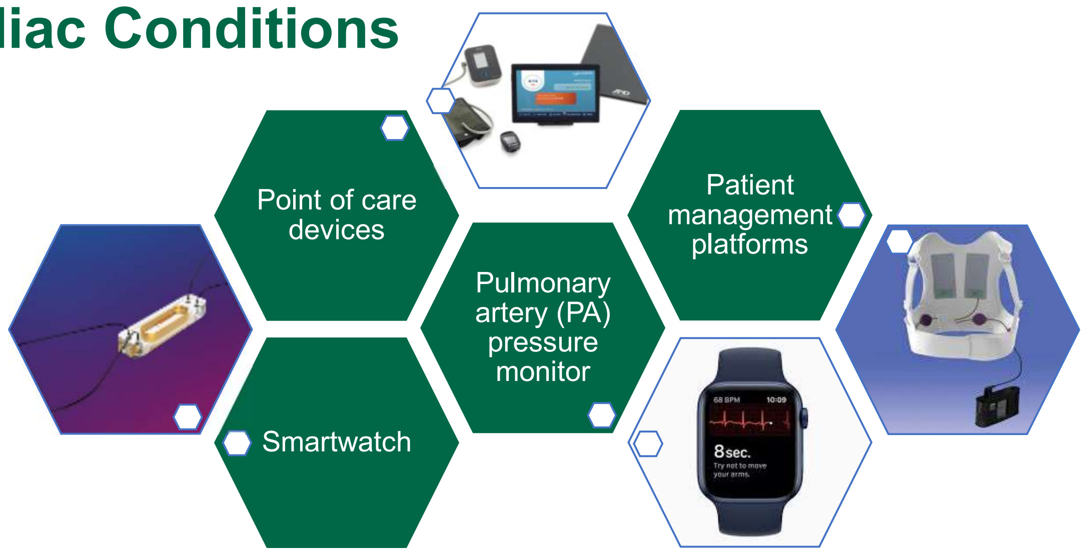
Cardiac Conditions



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Digital Health in Medication Adherence

- Gandapur Y, et al., Systematic review (n = 10)
  - Included text messages, Bluetooth-enables pillboxes, online messaging platforms, interactive voice calls
  - Current evidence suggest it can improve medication adherence in patients with cardiovascular disease
- Conway CM, et al., Integrative review (n=13)
  - Included interactive voice response, SMS, text messaging, telemonitoring, and interactive software technology
  - No conclusive evidence for improve medication adherence in patients with diabetes or hypertension

Gandapur Y et al. EHJ – Quality Care and Clin Outcomes 2016; 2: 237-244; Conway CM et al. JMIR Diabetes 2017 Jul-Dec; 2(2): e20

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Pros of Wearables

- Patient engagement and behavior modification
- Medication adherence
- Personalized health care
- Disease detection/diagnosis
- Decision support for disease management
- Novel biosensors
- Patient-generated health data
- Clinical research

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Varma N, et al. J Am Coll Cardiol 2024; 83(5): 611-631

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Types of Technology

Direct-to-Consumer (D2C) Wearables

- Ex: Pulse oximeters, smartwatch
- Easy to use
- Some are FDA cleared
- Accuracy not validated
- Not usually integrated into EMR
- Poorly defined billing pathways

Prescribed Monitoring Technologies

- Ex: external cardiac monitors, cardiac telemetry
- Prescribed/initiated in healthcare setting
- FDA cleared, higher quality control
- Sometimes integrated into EMR
- Billing pathways

Varma et al. JACC 2024; 83(5): 611-631

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Screening for Atrial Fibrillation

- REHEARSE-AF: Use of single-lead smartphone-based ECG in patients > 65 y/o with CHADS-VASc score $\geq$ 2 – associated with 4-fold increase in rate of AF detection
- VITAL-AF: Screened patient either through PE or device and showed similar rates of detection
- Largest Mass Population-Based Studies:
  - (1) Apple Heart
  - (2) Huawei Heart
  - (3) Fitbit Heart

How much does this matter?

Varma et al. JACC 2024; 83(5): 611-631

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Detecting AFib

Image: Apple Website

Image: AliveCor Website

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Hypertension

ORIGINAL ARTICLE

A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops

Authors: Ronald G. Victor, M.D., Kathleen Lynch, Pharm.D., Ning Li, Ph.D., Ciantel Blyler, Pharm.D., Eric Muhammad, B.A., Joel Handler, M.D., Jeffrey Brettler, M.D., +5, and Robert M. Elashoff, Ph.D. Author Info & Affiliations

Published March 12, 2018 | N Engl J Med 2018;378:1291-1301 | DOI: 10.1056/NEJMoa1717250 | VOL. 378 NO. 14

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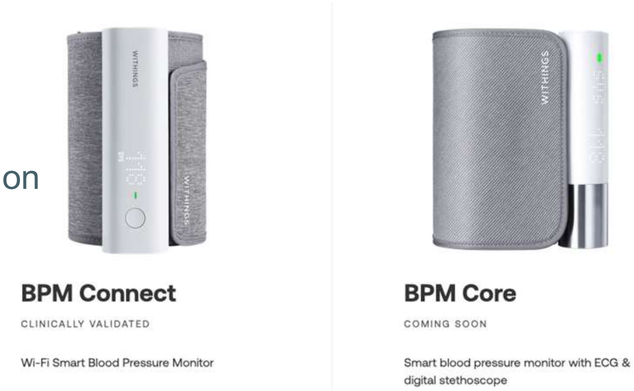
Hypertension

- Other modalities in the literature:
  - Text message reminders for medication adherence
  - Mobile apps
  - Remote BP monitoring
  - Virtual behavioral coaching



- Meta-analysis – Hypertension management in US Population Experiencing Health Disparities (n = 28)
  - Multicomponent interventions (primarily remote BP monitoring) vs. standard care had greater reductions in SBP at 6 and 12 months

Katz MR, et al. JAMA Network Open 2024; 72(2):e2356070

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Original Investigation

FREE

November 9, 2022

Results of a Remotely Delivered Hypertension and Lipid Program in More Than 10 000 Patients Across a Diverse Health Care Network

Alexander J. Blood, MD, MSc[1,2]; Christopher P. Cannon, MD[1,2]; William J. Gordon, MD[2,3,4]; et al

» Author Affiliations | Article Information

JAMA Cardiol. 2023;8(1):12-21. doi:10.1001/jamacardio.2022.4018

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Remote Patient Monitoring (RPM)

- Defined as recording, saving, transmitting, and interpretation of certain health parameters, continuously or intermittently, outside of a clinical encounter setting
- RPM ≠ telehealth or telemetry
- Provider and/or patient interpretation to guide therapeutic, preventative, and wellness measures

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Das T. et al. Remote Patient Management Workbook. American College of Cardiology

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Not to be confused with telemedicine...

- **TeleMEDICINE**: The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities (WHO, 1997)
  - Key components: Delivered via communication technology, connects clinicians to patients or other clinicians, used to deliver health care services
- **TeleHEALTH**: The use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration
  - Includes: videoconferencing, the Internet, store-and-forward imagining, streaming media, and terrestrial and wireless communications

Health Resources and Services Administration, 2019

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Remote Patient Monitoring (RPM)

Non-Invasive

- Wearables
  - Smart watches, step trackers, chest straps
- POC Devices
  - Pulse oximeters, smartphones, glucose monitors
- Ambulatory Cardiac Monitors:
  - Continuous ECG monitor straps, event monitors, patch & button monitors, external loop recorder

Invasive

- Subcutaneous
  - Implantable loop recorders, CGMs
- Intravascular sensors
  - Pulmonary artery pressure monitors, future structural & vascular devices
- Electrophysiology devices
  - Pacemakers, defibrillators

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Advantages of RPM

- Increase access to medical care
- Longer periods of monitoring increasing sensitivity and diagnostic power
- Detection outside of clinic visit
- Detection of deterioration or decompensation
- Improve patient lifestyle facilitate treatment adjustments/minimize complications
- Improve perioperative/periprocedural outcomes, discharge time, safety
- Screen for under-detected health conditions in high-risk populations

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Das T. et al. Remote Patient Management Workbook. American College of Cardiology

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Evidence for PA Pressure Sensors

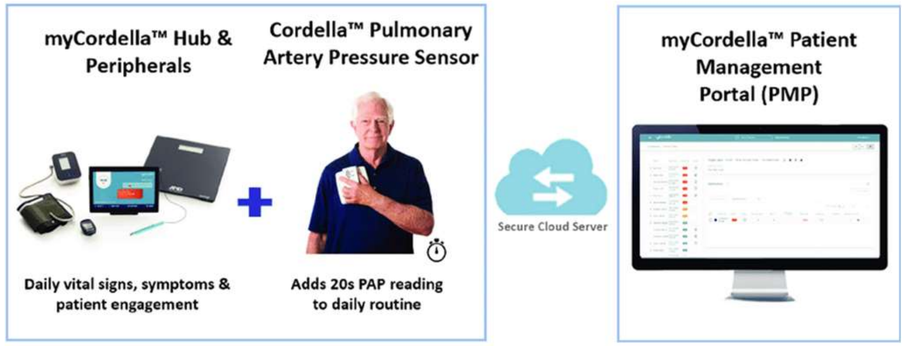
CardioMEMS
- CHAMPION
- GUIDE-HF
- MONITOR-HF

Cordella System
- PROACTIVE-HF
- PROACTIVE-HF 2

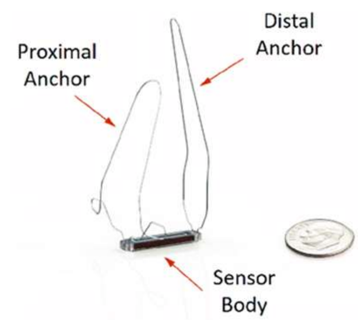
V-LAP
- VECTOR-HF

CardioMEMS

Carmona-Rubio A, et al. Curr Treat Options in Cardiovascular Medicine 2020; 22(25)



myCordella System



Mullens W, et al. ESC 2020. doi: 10.1002/ejhf.1870

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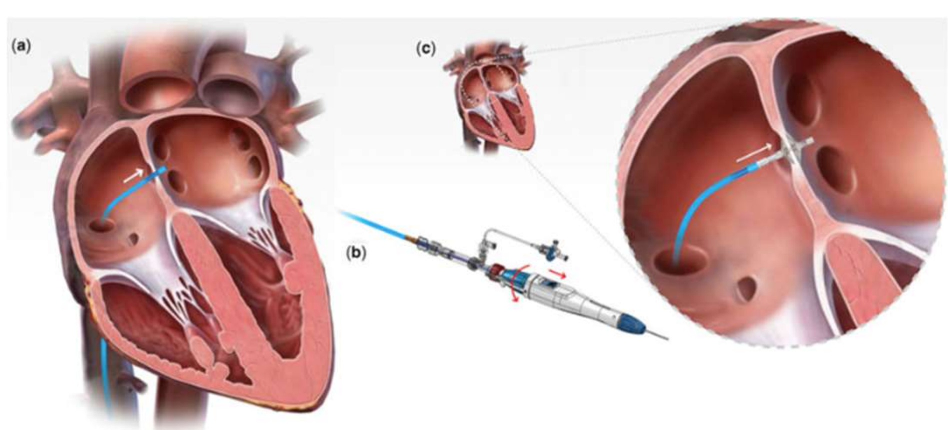
V-LAP



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Physicians' Perception of RPM

- **Concerns for:**
  - Payment model/billing (40%)
  - Clinician buy-in (38%)
  - Patient cost/lack of reimbursement (36%)
  - Evidence of improved outcomes (35%)
  - EHR integration (20%)
- **More likely to use** if:
  - Devices were medical grade (86%)
  - EHR interoperability (86%)
  - More accurate data (82%)

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Das T. et al. Remote Patient Management Workbook. American College of Cardiology

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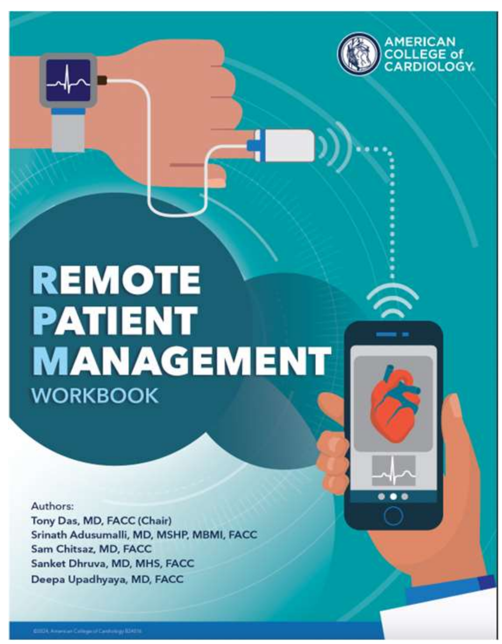
Guidance from Professional Organizations

- Considerations for adoption
- Data elements to monitor
- CPT codes to support RPM, CCM, and transition to value-based care
- How to document for billing



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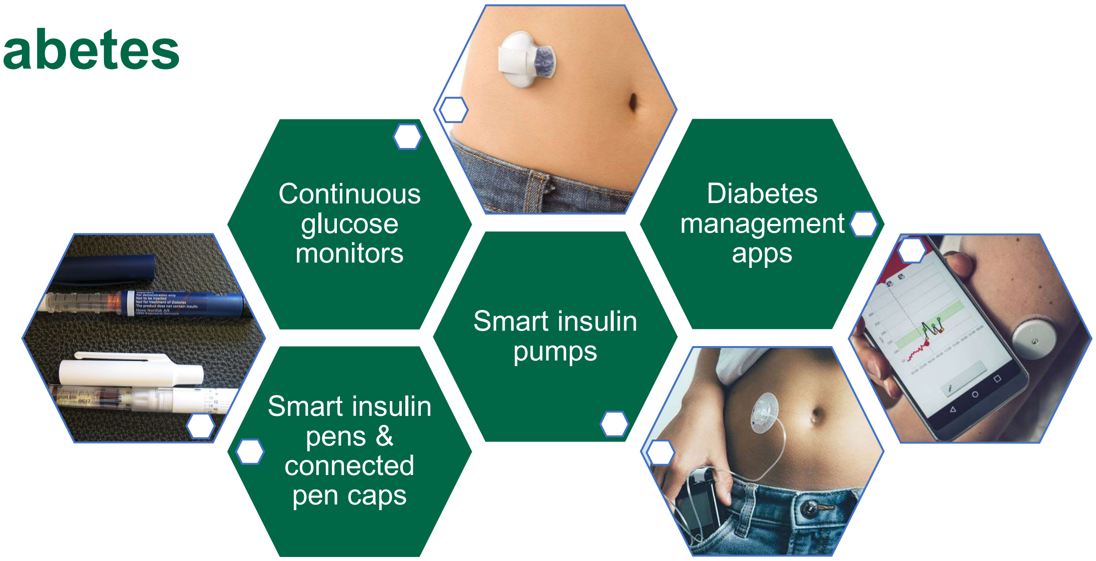
Diabetes



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Diabetes Management Apps

- Stand-alone vs. Integrated
- Facilitate tracking of lifestyle factors
- Shareable with care team

Source: SingleCare

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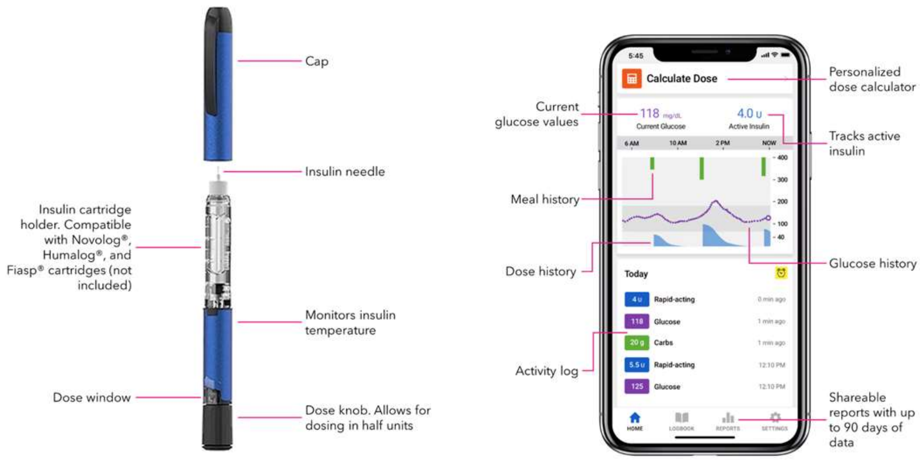
Smart Insulin Pens & Connected Pen Caps



- Helps multiple daily injection users take the right amount of insulin at the right time
- Real-time tracking and decision support.

Source: Medtronic

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Insulin Smart Pens/Pen Caps

- Insulin pens introduced in 1985 provided advantage over syringes in dose accuracy and consistency
- Insulin pens with memory function introduced in 2007 and first re-usable smart insulin pen in 2017 followed by smart pen caps some with built-in interfacing technology with smart phone apps
- Literature review (2019) to assess clinical benefits of smart insulin pens with connectivity
  - Peer-reviewed journals (n=9) T1/T2DM
  - Found that majority of focus was on:
    - Memory function and not connectivity capabilities
    - Patient preference, adherence, and usability and not clinical endpoints
- Pen cap paring with CGM introduced in 2023
- Opportunity for further technology advancement and clinical outcome assessment

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Heinemann L, Schnell O, Gehr B, Schloot NC, Görgens SW, Görgen C. Digital Diabetes Management: A Literature Review of Smart Insulin Pens. J Diabetes Sci Technol. 2022 May;16(3):587-595. doi: 10.1177/1932296820983863. Epub 2021 Jan 11. PMID: 33430644; PMCID: PMC9158248.

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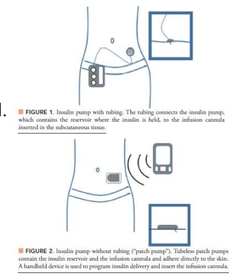
Insulin Pumps

- Insulin pumps introduced in 1970s with surge in use early 2000 after Diabetes Control & Complications Trial (DCCT) demonstrated importance of intensive insulin regimen to maintain tight glycemic control and prevent diabetic complications
- > 350K using today (90% T1DM, 10% T2DM)
- Multicenter observational cohort study 2017-2021 of children & adults with T1DM (n=22,000)
  - Insulin pump use association with:
    - More optimal A1C
    - Increased use of CGM
    - Lower rates of DKA
    - Lower rates of hypoglycemia
  - Insulin pump use + CGM association with:
    - Lower rates of acute events

Source: Berget et al.



Kajal Gandhi, et al. T1D Exchange Quality Improvement Collaborative; Insulin Pump Utilization in 2017–2021 for More Than 22,000 Children and Adults With Type 1 Diabetes: A Multicenter Observational Study. *Clin Diabetes* 15 January 2024; 42 (1): 56–64. https://doi.org/10.2337/cd23-0055

Berget C, et al. A Clinical Overview of Insulin Pump Therapy for the Management of Diabetes: Past, Present, and Future of Intensive Therapy. Diabetes Spectr. 2019 Aug;32(3):194-204. doi: 10.2337/ds18-0091. PMID: 31462873; PMCID: PMC6695255.

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Smart Insulin Pumps

- Integration of CGM (Sensor Augmented Pump or SAP)
  - Synchronizes data allowing visualization on insulin pump screen and easier access to data
  - Studies demonstrated after 12 months greater reduction in A1C and more likely to achieve glycemic control than multiple daily injection (MDI)
- Integration with CGM and "Smart" technology providing:
  - Hypoglycemia suspension and predictive ("suspend before low") technology
    - Studies demonstrated 50—80% reduction in nocturnal hypoglycemia and 30-50% reduction in hypoglycemia compared to SAP with no increase in mean glucose value or hyperglycemia
  - Automation of insulin delivery (artificial pancreas or closed-loop systems) aim to reduce hypo/hyperglycemia to improve overall glycemic control and increasing TIR; insulin pump + CGM + control algorithm (calculates & adjusts insulin delivery in real time)
    - Hybrid closed-loop system – modulates basal insulin delivery but requires users to deliver bolus doses for meals or hyperglycemia using bolus calculator
  - Studies demonstrated using "auto mode" A1C decrease 0.5% and TIR increase of 8% after 3 months of use; no occurrence of sever hypoglycemia or DKA

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Berget C, et al. A Clinical Overview of Insulin Pump Therapy for the Management of Diabetes: Past, Present, and Future of Intensive Therapy. Diabetes Spectr. 2019 Aug;32(3):194-204. doi: 10.2337/ds18-0091. PMID: 31462873; PMCID: PMC6695255

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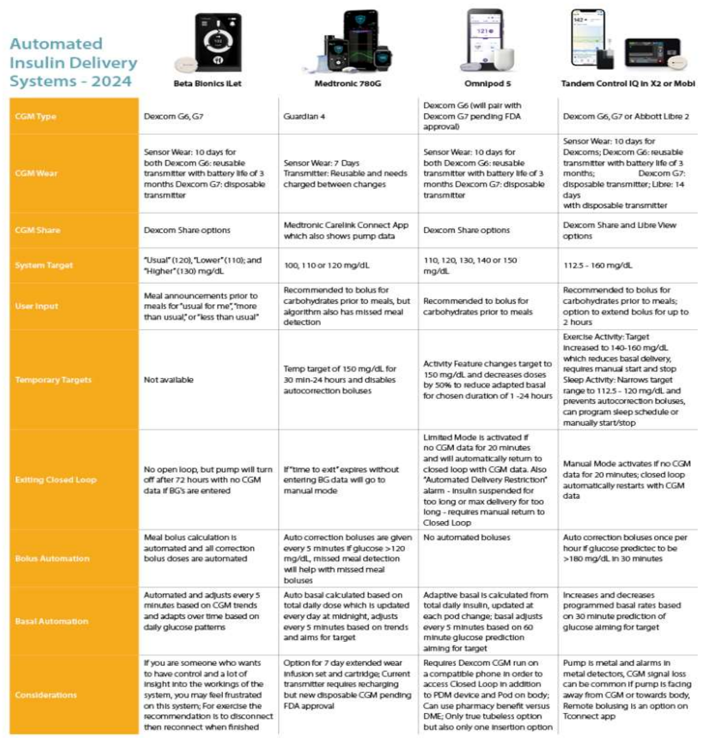

Automated Insulin Delivery Systems - 2024	Beta Bionics iLet	Medtronic 780G	Omnipod 5	Tandem Control IQ in X2 or Mobi
CGM Type	Dexcom G6, G7	Guardian 4	Dexcom G6 (will pair with Dexcom G7 pending FDA approval)	Dexcom G6, G7 or Abbott Libre 2
CGM Wear	Sensor Wear: 10 days for both Dexcom G6: reusable transmitter with battery life of 3 months Dexcom G7: disposable transmitter	Sensor Wear: 7 Days Transmitter: Reusable and needs charged between changes	Sensor Wear: 10 days for both Dexcom G6: reusable transmitter with battery life of 3 months Dexcom G7: disposable transmitter	Sensor Wear: 10 days for Dexcoms; Dexcom G6: reusable transmitter with battery life of 3 months; Dexcom G7: disposable transmitter; Libre: 14 days with disposable transmitter
CGM Share	Dexcom Share options	Medtronic Carelink Connect App which also shows pump data	Dexcom Share options	Dexcom Share and Libre View options
System Target	"Usual" (120), "Lower" (110); and "Higher" (130) mg/dL	100, 110 or 120 mg/dL	110, 120, 130, 140 or 150 mg/dL	112.5 - 160 mg/dL
User Input	Meal announcements prior to meals for "usual for me", "more than usual," or "less than usual"	Recommended to bolus for carbohydrates prior to meals, but algorithm also has missed meal detection	Recommended to bolus for carbohydrates prior to meals	Recommended to bolus for carbohydrates prior to meals; option to extend bolus for up to 2 hours
Temporary Targets	Not available	Temp target of 150 mg/dL for 30 min-24 hours and disables autocorrection boluses	Activity Feature changes target to 150 mg/dL and decreases doses by 50% to reduce adapted basal for chosen duration of 1 -24 hours	Exercise Activity: Target increased to 140-160 mg/dL which reduces basal delivery, requires manual start and stop Sleep Activity: Narrows target range to 112.5 - 120 mg/dL and prevents autocorrection boluses, can program sleep schedule or manually start/stop
Exiting Closed Loop	No open loop, but pump will turn off after 72 hours with no CGM data if BG's are entered	If "time to exit" expires without entering BG data will go to manual mode	Limited Mode is activated if no CGM data for 20 minutes and will automatically return to closed loop with CGM data. Also "Automated Delivery Restriction" alarm - insulin suspended for too long or max delivery for too long - requires manual return to Closed Loop	Manual Mode activates if no CGM data for 20 minutes; closed loop automatically restarts with CGM data
Bolus Automation	Meal bolus calculation is automated and all correction bolus doses are automated	Auto correction boluses are given every 5 minutes if glucose >120 mg/dL, missed meal detection will help with missed meal boluses	No automated boluses	Auto correction boluses once per hour if glucose predictec to be >180 mg/dL in 30 minutes
Basal Automation	Automated and adjusts every 5 minutes based on CGM trends and adapts over time based on daily glucose patterns	Auto basal calculated based on total daily dose which is updated every day at midnight, adjusts every 5 minutes based on trends and aims for target	Adaptive basal is calculated from total daily insulin, updated at each pod change; basal adjusts every 5 minutes based on 60 minute glucose prediction aiming for target	Increases and decreases programmed basal rates based on 30 minute prediction of glucose aiming for target
Considerations	If you are someone who wants to have control and a lot of insight into the workings of the system, you may feel frustrated on this system; For exercise the recommendation is to disconnect then reconnect when finished	Option for 7 day extended wear infusion set and cartridge; Current transmitter requires recharging but new disposable CGM pending FDA approval	Requires Dexcom CGM run on a compatible phone in order to access Closed Loop in addition to PDM device and Pod on body; Can use pharmacy benefit versus DME; Only true tubeless option but also only one insertion option	Pump is metal and alarms in metal detectors, CGM signal loss can be common if pump is facing away from CGM or towards body, Remote bolusing is an option on Tconnect app

Source: Children with Diabetes

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Smart Infusion Pumps

1. MiniMed™ 780G insulin pump
with advanced
SmartGuard™ technology

2. Guardian™ 4 sensor and transmitter
with no fingersticks with SmartGuard™ automation§

3. Medtronic Extended™ infusion set
for up to 7 days of wear||

4. MiniMed™ Mobile app
Allows patients to view glucose levels, pump information, and insulin data on their phone or Apple Watch. View this reference chart for a list of compatible smartphones.

Source: Medtronic

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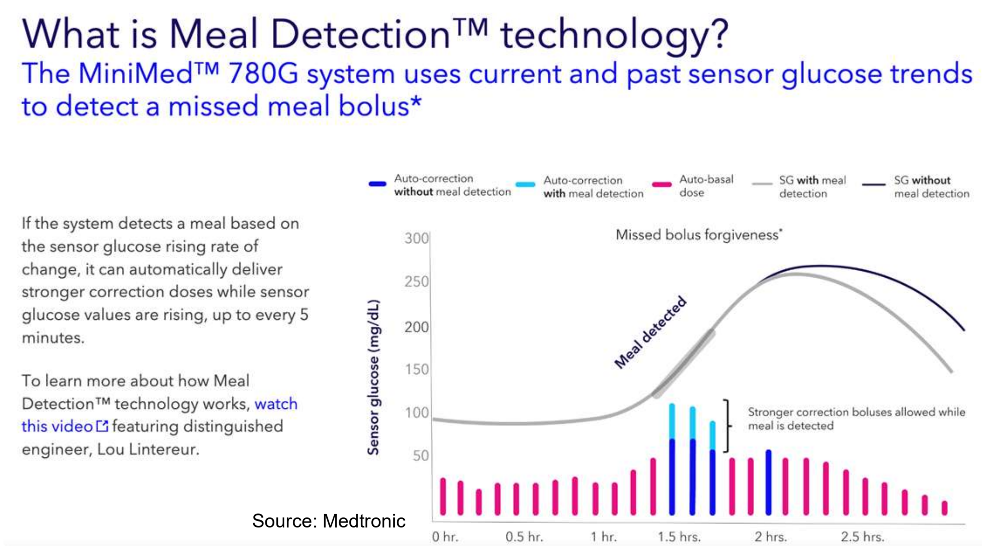
Smart Infusion Pumps



Source: Medtronic

Smartguard™ technology suspend before low, predictive low glucose suspend, and adaptive insulin delivery* via Auto Mode

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Continuous Glucose Monitoring (CGM)

Diabetes

- Used since 2000; initially T1DM, now used in both T1/T2DM
- Increased utilization driven by:
  - Improvements in sensor technology
  - Patient acceptance
  - Improved clinical outcomes - improved glycemic control, reduced hypoglycemia, increased patient activation and engagement from data, expanded managed care coverage

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Continuous Glucose Monitoring (CGM)

Diabetes

- Literature search 1999-2021
  - Strong evidence for CGM use in T1DM with reduced A1C and hypoglycemia, increased TIR
  - Similar benefits in T2DM (less strength of evidence)
  - Improved patient satisfaction in patients and parents of children using CGM
  - Improved clinical experience
  - Limitations include cost, accuracy, perceived inconvenience, integration into EHR

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Lin, R., Brown, F., James, S., Jones, J. and Ekinci, E. (2021), Continuous glucose monitoring: A review of the evidence in type 1 and 2 diabetes mellitus. Diabet Med, 38: e14528. https://doi.org/10.1111/dme.14528

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CGM Options in the U.S. 2024

	Abbott Libre 2	Abbott Libre 3	Dexcom G6	Dexcom G7	Dexcom Stelo	Eversense E3	Medtronic Guardian 3	Medtronic Guardian 4
Sensor Wear Time	14 days	14 days	10 days	10 days	10 days	3-6 months*	7 days	7 days
Age Indication	4+ years		2 years +	2 years +	18 years+	18 years+	2+ years	7+ years
Sensor Readings	Every minute		Every 5 minutes			Every 5 minutes	Every 5 minutes	Every 5 minutes
Transmitter Style	Integrated	Integrated	Separate	Integrated	Integrated	Separate	Separate	Separate
Transmitter Duration	14 days	14 days	90 days	10 days	10 days	1 year	1 year	1 year
Approved Wear Locations	Back of upper arm	Back of upper arm	2-17 years: abdomen & upper buttocks 18 years+ abdomen and arm	2-6 years: arm, abdomen & upper buttocks 7 years+ arm and abdomen	2-6 years: arm, abdomen & upper buttocks 7 years+ arm and abdomen	Upper Arm	Abdomen, arm, upper buttocks	Abdomen, arm, upper buttocks
Sensor Warm Up Time	1 hour	1 hour	2 hours	20-30 minutes	20-30 minutes	24 hours	2 hours	2 hours
Alarm Customization	Optional alarms. Can turn off ALL alerts, even urgent low, for up to 6 hours	Optional alarms. Can turn off ALL alerts, even urgent low, for up to 6 hours	Urgent Low required, customizable features for sounds and repeat alerts	Quiet Mode optional	Quiet Mode optional	Vibrate on body transmitter, customizable on phone app	Customizable on Pump	Customizable on Pump & Phone App
Data Sharing	Libre Link App	Libre 3 App	Dexcom Share	Dexcom Share		Eversense Now App	Medtronic Connect App	Medtronic Connect App
Data Access	Intermittent or Continuous options	Continuous	Continuous	Continuous	Continuous	Continuous	Continuous	Continuous
Compatible Insulin Pumps	Tandem t:slim X2	None yet	Omnipod, Beta Bionics iLet, Tandem t:slim X2, and Tandem Mobi system	Beta Bionics iLet and Tandem t:slim X2	None	None	Medtronic 630G, 670G and 770G	Medtronic 780G
Inserter Style	Integrated	Integrated	Integrated	Integrated	Integrated	Procedure - no inserter	Separate	Separate
Interactions	Vitamin C (Ascorbic acid)	Vitamin C (Ascorbic acid) & Salicylic Acid	Hydroxyurea	Hydroxyurea & Acetaminophen >1 gram every 6 h	Hydroxyurea & Acetaminophen >1 gram every 6 h	Tetracycline Antibiotics	Acetaminophen	Acetaminophen

Source: Children with Diabetes

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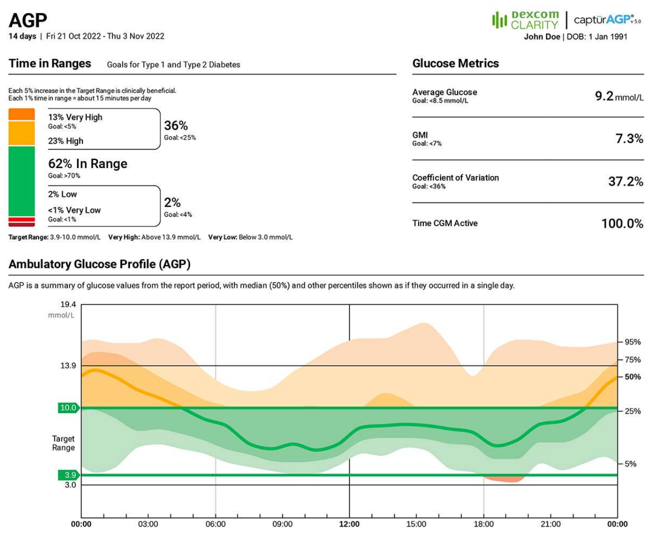
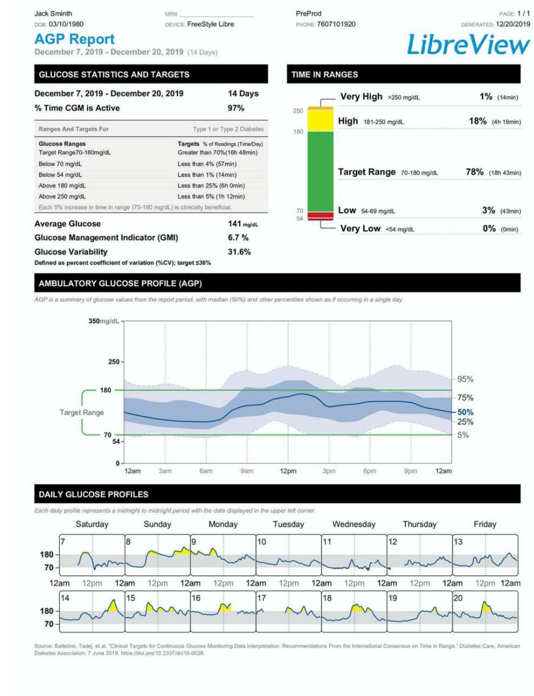
CGM Data Sharing





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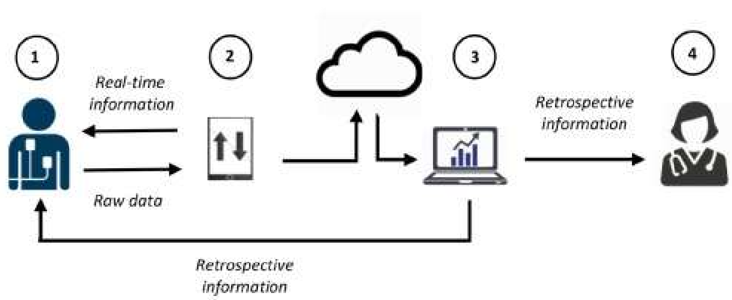
Continuous Glucose Monitoring (CGM)

RPM in Diabetes



1. Sensor: automatic data recording
2. Receiver/mobile app: data storage, manual data collection, data analysis, real-time information presentation
3. Wearable manufacturer's remote platform: information storage, analysis, and presentation on the patient portal
4. CPs in the clinical setting: retrospective information review and use for clinical decision-making. CPs mentioned three manners to access patient's information:
   - Patients access the report via a patient portal as part of the remote platform and email it to CP
   - CP receives the patient's username and password to access the portal
   - CPs access a professional portal designed explicitly to them by some CGM manufacturers

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Abdolkhani R, Gray K, Borda A, DeSouza R. Patient-generated health data management and quality challenges in remote patient monitoring. JAMIA Open. 2019 Sep 20;2(4):471-478. doi: 10.1093/jamiaopen/ooz036. PMID: 32025644; PMCID: PMC6993998.

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Continuous Glucose Monitoring (CGM) Alternative Use Cases

Prediabetes

Symposium/Special Issue

Objective Determination of Eating Occasion Timing: Combining Self-Report, Wrist Motion, and Continuous Glucose Monitoring to Detect Eating Occasions in Adults With Prediabetes and Obesity

Journal of Diabetes Science and Technology 2024, Vol. 18(2) 266–272
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DOI: 10.1177/19322968231197205
journals.sagepub.com/home/dst
Sage

Collin J. Popp, PhD, MS, RD[1], Chan Wang, PhD[2], Adam Hoover, PhD[3], Louis A. Gomez, MS[4], Margaret Curran, MS[1], David E. St-Jules, PhD, RD[5], Souptik Barua, PhD[7], Mary Ann Sevick, ScD[6,7], and Samantha Kleinberg, PhD[4]

Open access Protocol

BMJ Open **Continuous glucose monitoring metrics for earlier identification of pre-diabetes: protocol for a systematic review and meta-analysis**

Sara Gottfried,[1] Laura Pontiggia,[2] Andrew Newberg,[1] Gregory Laynor,[3] Daniel Monti[1]

Commentary

Behavior Modification in Prediabetes and Diabetes: Potential Use of Real-Time Continuous Glucose Monitoring

Journal of Diabetes Science and Technology 2019, Vol. 13(2) 271–275
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DOI: 10.1177/1932296818790994
journals.sagepub.com/home/dst
SAGE

Nicole Ehrhardt, MD[1] and Enas Al Zaghal, MD Endocrine Fellow[1]

Review Article

Continuous glucose monitoring system and new era of early diagnosis of diabetes in high risk groups

Ashraf Soliman, Vincenzo DeSanctis[1], Mohamed Yassin[2], Rania Elalaily[3], Nagwa E Eldarsy
Department of Pediatric, Alexandria University Children's Hospital, Alexandria, Egypt, [1]Pediatric and Adolescent Outpatient Clinic, Quisisana Hospital, 44121 Ferrara, Italy, [2]Department of Hematology and Oncology, Alamal Hospital, Hamad Medical Center, [3]Department of Primary Health Care, Doha, Qatar

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Continuous Glucose Monitoring (CGM) Alternative Use Cases

Obesity

Article

Utilising a Real-Time Continuous Glucose Monitor as Part of a Low Glycaemic Index and Load Diet and Determining Its Effect on Improving Dietary Intake, Body Composition and Metabolic Parameters of Overweight and Obese Young Adults: A Randomised Controlled Trial

Khadidja Chekima[1], Mohd Ismail Noor[2], Yasmin Beng Houi Ooi[3], See Wan Yan[1], Mohammad Jaweed[1] and Brahim Chekima[4,*]

Continuous Glucose Monitoring in Adolescents With Obesity: Monitoring of Glucose Profiles, Glycemic Excursions, and Adherence to Time Restricted Eating Programs

Monica N. Naguib[1], Elizabeth Hegedus[1], Jennifer K. Raymond[1], Michael I. Goran[2], Sarah-Jeanne Salvy[3], Choo Phei Wee[4], Ramon Durazo-Arvizu[5], Lilith Moss[5] and Alaina P. Vidmar[1*]

Continuous glucose monitoring for automatic real-time assessment of eating events and nutrition: a scoping review

Julian Brummer, Christina Glasbrenner, Sieglinde Hechenbichler Figueroa, Karsten Koehler and Christoph Höchsmann*
Department of Health and Sport Sciences, TUM School of Medicine and Health, Technical University of Munich, Munich, Germany

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Continuous Glucose Monitoring (CGM) Alternative Use Cases

Athletics/Wellness

sensors — https://www.mdpi.com/journal/sensors — MDPI

Perspective

Continuous Glucose Monitoring in Healthy Adults—Possible Applications in Health Care, Wellness, and Sports

Roman Holzer [1], Wilhelm Bloch [1] and Christian Brinkmann [1,2,*]

The role of continuous glucose monitoring in physical activity and nutrition management: perspectives on present and possible uses

Young-Im Kim[1] / Youngju Choi[2] / Jonghoon Park[1*]

1. Department of Physical Education, Korea University, Republic of Korea
2. Institute of Specialized Teaching and Research, Inha University, Republic of Korea

Continuous Glucose Monitoring Profiles in Healthy Nondiabetic Participants: A Multicenter Prospective Study

Viral N. Shah,[1] Stephanie N. DuBose,[2] Zoey Li,[2] Roy W. Beck,[2] Anne L. Peters,[3] Ruth S. Weinstock,[4] Davida Kruger,[5] Michael Tansey,[6] David Sparling,[7] Stephanie Woerner,[8] Francesco Vendrame,[9] Richard Bergenstal,[10] William V. Tamborlane,[11] Sara E. Watson,[12] and Jennifer Sherr[11]

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Continuous Glucose Monitoring (CGM) Alternative Use Cases

Polycystic Ovary Syndrome (PCOS)

AOGS ACTA Obstetricia et Gynecologica Scandinavica

AOGS MAIN RESEARCH ARTICLE

Increased mean glucose levels in patients with polycystic ovary syndrome and hyperandrogenemia as determined by continuous glucose monitoring

JIE-PING ZHU[1], YIN-CHENG TENG[1], JIAN ZHOU[2], WEI LU[2], MIN-FANG TAO[1] & WEI-PING JIA[2]

[1]*Department of Obstetrics and Gynecology, the Affiliated Sixth People's Hospital, Shanghai Jiao Tong University, Shanghai, and* [2]*Department of Endocrinology and Metabolism, Shanghai Clinical Center for Diabetes, the Affiliated Sixth People's Hospital, Shanghai Jiao Tong University, Shanghai, China*

Glucose Evaluation Through Continuous Glucose Monitors in Polycystic Ovary Syndrome (GEMS-PCOS)

ClinicalTrials.gov ID NCT06050265

Sponsor University of California, San Francisco

Information provided by University of California, San Francisco (Responsible Party)

Last Update Posted 2023-11-18

Glucose Evaluation Through Continuous Glucose Monitors in Polycystic Ovary Syndrome

a study on Polycystic Ovary Syndrome and Insulin Resistance

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Assessment Question

Which of the following is an example of invasive RPM?

A. Smart watches
B. Pulse oximeters
C. Step tracker
D. PA pressure monitors

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Assessment Question

Which of the following have integrated smart technology that allows communication with continuous glucose monitors (CGM)? SELECT ALL THAT APPLY

a. Insulin pens
b. Insulin pen caps
c. Insulin pumps
d. Insulin vials

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Assessment Question

Benefits of continuous glucose monitoring (CGM) in both Type 1 and Type 2 diabetics include all of the following EXCEPT for?

a. Reduced A1C
b. Integration into EHR
c. Reduced hypoglycemia
d. Increased time in range (TIR)

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Barriers and Implications

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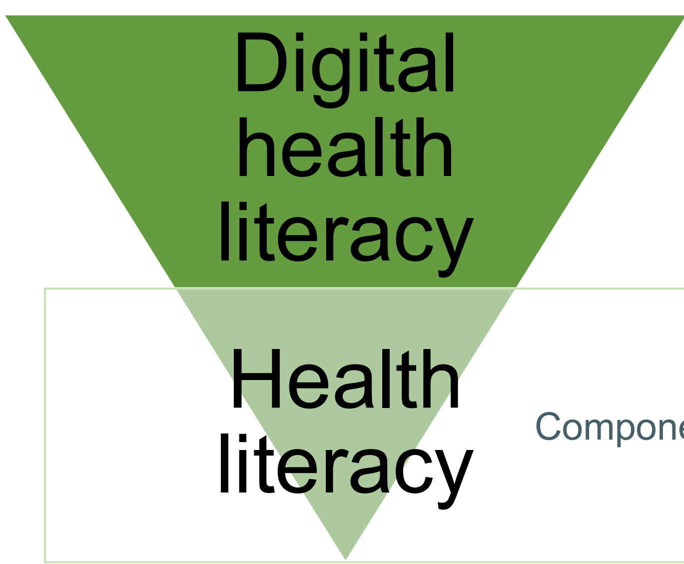
Digital and/or Health Patient Literacy



Access to technology
Infrastructure (broadband, Wi-Fi)
Readiness for adoption
Cost
Skin color and wearables
Setup

Component of digital health literacy

Digital Health Literacy. www.ahrq.gov. Accessed 8.8.24; Stevenson LW, et al. JACC 2023; 81(23)

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RPM Products

- Regulations
- Direct-to-consumer products granted FDA ‘clearance’ based on low risk however they have not undergone formal FDA approval and extensive testing
  - Not one-size-fits-all solution
- Devices may differ in diagnostic accuracy, sensitivity, and specificity
  - Manufacturer’s claim vs. clinician’s assessment
- No recognized approach for data interpretation and quality assurance

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Abdolkhani R, et al. Patient-generated health data management and quality challenges in remote patient monitoring. JAMIA Open. 2019 Sep 20;2(4):471-478. doi:10.1093/jamiaopen/ooz036. PMID: 32025644; PMCID: PMC6993998.

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RPM Products

- Single source solution for comorbidity management
- Integration issues
  - Most RPM data platforms are not incorporated into EHRs
  - Concerns with billing compliance
  - Third party RPM solution companies
- Costs provider and consumer
- Reimbursement

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Interoperability & Data Silos

- Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged
  - **Technical** interoperability ensures basic data exchange capabilities between systems
  - **Syntactic** interoperability specifies the format and structure of the data
  - **Semantic** interoperability ensures that the meaning of medical concepts can be shared across systems
  - **Organizational** interoperability involves organizations, legislations, and policies

- Despite significant advances in RPM, lack of interoperability prohibits breaking down of the data silos

Lehne, M., Sass, J., Essenwanger, A. *et al.* Why digital medicine depends on interoperability. *npj Digit. Med.* **2**, 79 (2019). https://doi.org/10.1038/s41746-019-0158-1

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Volume Overload

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Terminology

Artificial intelligence (AI)

- Computer actions that mimic human decision making based on learned experiences and data

Machine learning (ML)

- Processes that allow computers to derive conclusions from data
- A subset of AI that enables the ability for computers to learn outside of their programming

Deep learning (DL)

- Processes that power computers to solve very complex problems.
- A subset of ML that makes computations in multilayer neural networks feasible

https://www.oracle.com/artificial-intelligence/what-is-ai/ai-vs-machine-learning/

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Assessment Question

Which of the following is a barrier to acceptance and/or success of RPM?

a. Digital/Health literacy
b. Volume overload
c. Data silos
d. All the above

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Assessment Question

Processes that allow computers to drive conclusions from data and learn outside of their programming are

a. Artificial intelligence (AI)
b. Machine learning (ML)
c. Deep learning (DL)
d. All the above

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Considerations

- Limiting the number of devices/technologies with separate platforms
- Monitor specific disease states or cases to streamline the process
- User friendly

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Outcomes – Value Based Care

- Digital health ecosystem awareness, understanding, and acceptance
- There are several wearables and sensor devices available on the market
- Systems that represent disease specific solutions or multimodality components have shown promise
- Patient-facing digital health technologys have the greatest impact on clinical management of patients

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Managed Care

Private insurance - refer to specific plan

Medicare (https://www.cms.gov/medicare/payment/fee-schedules/physician)

- Established patient-physician relationship
- Patient consent
- Physicians and non-physician practitioners who are eligible to furnish evaluation and management services (E/M)
- Physiologic data must be electronically collected and automatically uploaded
- RPM device must meet FDA definition
- RPM data collected for at least 16 of 30 days
- RPM services monitor acute care/chronic condition
- Services may be provided by auxiliary personnel under supervision of billing practitioner

Medicaid – refer to state policies (https://www.cchpca.org/topic/remote-patient-monitoring/)

UNIVERSITY of SOUTH FLORIDA https://telehealth.hhs.gov/providers/preparing-patients-for-telehealth/telehealth-and-remote-patient-monitoring

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RPM CPT Codes

CPT Code	Description
99453	Initial setup and education on use of equipment, can be done remotely by practice staff
99454	Delivery of results/reports by practice staff to the physician caring for the patient
99457	First 20 minutes of physician's interpretation and interactive communication with the patient/ caregiver every month
99458	Subsequent 20 minutes of physician's interpretation and interactive communication with the patient/caregiver

Note: Multiple codes can be billed in a 1-month cycle per device per practice, but each coed can only be billed once every month per patient, except 99458. This is an add-on code of 99457 and can be billed an unlimited number of times each calendar month

Source: CMS.gov; ACP: https://www.acponline.org/practice-resources/business-resources/telehealth-guidance-and-resources/remote-patient-monitoring-billing-coding-and-regulations-information (Accessed 8.8.24)

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RPM Example DM - CGM

CPT Code	Description	Medicare physician office fee schedule	Medicare outpatient diabetes center	Private payer	Relative value unit (RVU) non-facility
95249 Personal CGM - Startup/Training *Bill only once during the time period that the patient owns the device*	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording	$65.24	$58.28 APC 5733	$130	1.96
95250 Professional CGM Do not bill more than 1x/month	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording.	$147.46	$125.95 APC 5012	$319	4.43
95251 CGM Interpretation Do not bill more than 1x/month	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report.	$34.29	Paid under physician fee schedule	$98	1.03

Source: CMS.gov

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Assessment Question

The same billing practices for RPM are applied for private insurance, Medicare, and/or Medicaid.

a. True
b. False

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Polling Question

Using a 5-point Likert Scale, rate your level of knowledge and experience in RPM billing.

1 - No knowledge, no experience

2 - Limited knowledge, no experience

3 - Limited knowledge, limited experience

4 - Good knowledge, some experience

5 - Good knowledge, a lot of experience

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Summary

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Key Take Aways

- Understanding digital health ecosystems is integral to successful implementation of pharmacy practices and delivering value to customers
- There are several wearables and sensor devices available on the market
- Systems that represent disease specific solutions or multimodality components have shown promise
- Patient facing digital health technologies have the greatest impact on clinical management, are the most vulnerable to regulations however provide the greatest opportunity for contribution to value-based care and willingness to pay

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Managing Metabolic Disorders:

The Role of the Pharmacist within the Technological Ecosystem

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