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Beyond Covid: From Virtual Care to Connected Health



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**Beyond Covid:
From Virtual Care
to Connected Health**

The Sentry is On Duty: The Ins and Outs of Remote Patient Monitoring

Joe McMenamin, MD, JD; Bonnie Britton, MSN, RN

Tue, March 2 @ 11:30 AM EST

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**Beyond Covid:
From Virtual Care
to Connected Health**

RPM: Legal Considerations

Ingenium Healthcare Advisors
2 March 2021

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Device Malfunctions

- Stay up to date on latest device information
 - Manufacturer's warnings
 - Device's safety record
 - Device's approved uses
- Monitor FDA alerts or recalls
- Read contracts with medical device vendors
 - Who is responsible in case of device malfunction or failure?
 - Indemnification
 - Insurance

Data Tsunami

- Alert fatigue
 - Staffers may ignore, override, or disable alerts
 - Document why an alert is ignored
- More staffing: respond either
 - Directly to the patient or
 - Alert the appropriate professional for intervention
- But: >4X improvement in staffing ratio during PHE
 - Made possible by having patients input their indicators remotely

Data Tsunami

- Decide:
 - Times when the device will be monitored
 - Which team members will monitor the data at each point in time
 - Circumstances when appropriate clinician will be alerted
- Prepare appropriate disclaimers

Delays

- Must collect data; upload from patient's device
- Device on mobile network:
 - Data must travel through network provider's infrastructure, then out on to the internet
 - Probably gets to service providers network via multiple data centers and RPM platform network
- Delays:
 - Any of these hops is interrupted, or
 - Outage occurs at any of the stops
- Mobile networks not always available.

Security

- Devices, apps, communication technologies
- Monitoring devices are not below hackers' notice
- Tech is deployed within patient's home
 - Videoconferencing through third-party platforms
 - The cloud
- Encrypt
- BUT: in emergencies, authorized user must be able to access data quickly

Security

- Viruses, malware
 - Don't rely solely on manufacturers to protect security
 - See that antivirus software and firewalls are up to date
 - Monitor the network for unauthorized use
 - Report any device cybersecurity problems to mfr
- Set ownership boundaries and security protocols
 - Determine whether PCPs or family members get access

Privacy

- RPM device company: HIPAA-compliant processes
 - Encryption both when the device is at rest and when the information is in transit
 - Business Associate Agreement (BAA)
- State law

Systems Integration

- Introducing a remote monitoring platform: avoid corrupting existing patient records
- See that any future systems migrations will not interfere with the RPM platform

Consent

- Check state law
 - Some states expressly require
 - Other states silent
 - Err on the side of obtaining and documenting
- Do not understate risks or overstate benefits
- Include language: Patient
 - Understands what she's reading
 - Had opportunity to ask questions
 - All questions answered to her satisfaction in OK language
 - Not under influence of impairing meds or EtOH
 - All blanks filled in

Consent: Items to Consider: I

- Am the only one who should be using the equipment
- Won't use device except for my own health monitoring
- Will not tamper with the equipment
- Am responsible for costs 2 ° equipment misuse
- Understand devices designed for RPM program only
- Acknowledge that I received BP Monitor Serial # _____
- Device is meant to collect BP Readings and transfer them to _____ website or X MD office

Consent: Items to Consider:

- Device is NOT AN EMERGENCY RESPONSE UNIT AND IS NOT MONITORED 24/7
 - Call 911 for immediate medical emergencies.
- Am aware my BP daily readings will be transmitted from the monitor to a website located at _____
- Can withdraw my consent to participate and revoke service at any time by returning the device
- Will do my best to take my BP every day
- Am aware that an RPM QHCP views my readings only once every X days (and not on weekends, e.g.)

Other Issues

- F&A statutes
 - Do your providers own equity in equipment companies?
- Pts lacking WiFi, cell phones, even electricity
- Physician skepticism of PGHD

The Future: Positives

- Earlier interventions, better adherence and clinical outcomes, lower costs
- Mobile-enabled
- Miniaturization
- Prevention

The Future: Negatives

- Precarious reimbursement: reputational damage; abandonment claims
- Hacking becomes more attractive
- Liability risk for failing to offer RPM

Questions?

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