Telemedicine and the eHealth Revolution: Being Cutting Edge While Remaining Compliant
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Overview

- Telemedicine is a rapidly expanding form of medicine.
- Hospitals are searching for ways to be "cutting edge."
- The greatest challenge is maintaining the delicate balance between implementation of new technology and remaining compliant.
eHealth: the use of electronic information and communication technologies (ICT) for health-related services

- Treating patients
- Conducting research
- Educating the health care workforce
- Tracking diseases
- Monitoring public health
- Electronic health records / Electronic medical records (EHR/EMR)
- General wellness
- Population health
What is This Thing Called “Telemedicine?”

- Centers for Medicare and Medicaid Service: “Real time interaction between the patient and a provider at a distant site.”
- American Telemedicine Association: “Remote delivery of healthcare services and clinical information using telecommunication technology.”
- Regardless of how you define it – The same standard of care apply to telemedicine as traditional in-office visits.
Definitions

- **mHealth:** the practice of medicine supported by mobile devices
- **eHealth:** the use of electronic information and communication technologies (ICT) for health-related services
- **Telemedicine:** the use of technology for the delivery of health care services when the health care practitioner and patient are not in the same physical location
- **Telehealth:** any type of remote health care related services that do not always involve clinical services
Evolution of Telemedicine

- Today telemedicine concepts are commonplace.
- 1950s Canadian radiologists created a tele-radiology system.
- In 1959 clinicians at the University of Nebraska used a 2-way interactive television to transmit information which included neurologic examinations.
- In 1964 clinicians at the University of Nebraska established a telemedicine link with Norfolk Hospital.
- In 1967 physicians at the University of Miami used existing voice radio channels to transmit electrocardiographic rhythms from fire-rescue units. This is a common place practice today.
Goals of Telemedicine

- Improve access to healthcare in underserved communities
- Improve patient compliance with treatment plans
- Maintain continuity of care when patient is out of town
- Provide for timely detection of disease and treatment options
- Reduce cost
- Access to new markets
What Specialties Utilize Telemedicine?

- ICU
- Psychiatry
- Neurology
- Emergency Medicine
- Radiology
- Pediatrics
- Obstetrics
- And MANY more ….
Telemedicine Modalities

- Live Video (Synchronous)
- Real-Time
- Store-and-Forward (Asynchronous)
- Remote Patient Monitoring (RPM)
- Mobile Health
- Robotic Modalities
Why?

Helping
- Patients
- Health Professionals
- Hospitals and Health Care Systems
- Communities

Overcome
- Time & Distance
- Health Care Workforce Shortages
- Cost of Care
- Limited Choice of Providers
Live Video

- Also known as “hub and spoke” video conferencing
- Patient who is in a remote location is treated by a physician in a hub location
- Video conferencing does not need to be recorded or stored
Live Video Examples
Live “Tweeting” Procedures

#UCLAORLive

@Sunnybrook heart surgery live-tweet
#SBheart
February 20, 8am EST
Informed Consent

Disclosure of PHI

Mobile Devices in the OR

What if something goes wrong during the procedure?

Can tweets be used in litigation?

Is live tweeting a distraction to providers?
Store-and-Forward

- Asynchronous computer based communication
- Can be between patient and provider (direct to the consumer) or between a provider and another medical specialist at a distant site
- Commonly used in radiology, pathology and dermatology
- Not usually reimbursable under Medicaid on its own, but can be reimbursed as interpretive service in conjunction with an office visit
Store-and-Forward Examples
Remote Patient Monitoring

- Collection of patient’s health data through digital devices outside of a conventional clinical setting
- Noninvasive monitoring of blood pressure, blood sugar, weigh, blood oxygen levels, heart rate and EKGs
- Helps improve patient compliance
- Improves health outcomes and lowers readmission rates
Remote Patient Monitoring Examples
Regulatory Landscape

- Centers for Medicare & Medicaid Services ("CMS")
- Food & Drug Administration ("FDA")
- Federal Communications Commission ("FCC")
- HIPAA/HITECH
- State Breach Notification Laws
- State Health Codes & Medical Boards
- Payment Card Industry ("PCI") Compliance
eHealth Risks & Challenges

- Licensure
- Credentialing & Privileging
- Prescribing
- Physical Exam/Physician-Patient Relationship Requirements
- Medical Malpractice
- Patient Privacy & Data Security
- Reimbursement
- Mobile Devices
Ask Yourself

- In what states or countries will the involved health care practitioners, patients, and any related technologies be located?

  - The laws of each of the involved jurisdictions will likely apply. Initially designing a telemedicine program that complies with the laws of the most rigorously regulated jurisdiction should make compliance with the other jurisdictions more manageable or will minimize multi-jurisdiction compliance burdens.
Issues to Consider

- Informed Consent
- Clinical Model Used
- Staffing
- Physician-Patient Relationship
- Patient Abandonment
- Continuity of Care
- Medical Record Integration
- Contractual Agreements
- Peer Review
Risks Associated with Telemedicine

- Data breach
- Abandonment of patient if technology fails
- Credentialing and licensing issues
- Informed consent
- Continuity of care
- Documentation
- Failure to Diagnose
- Prescribing
- Billing
Case currently pending before the Fifth Circuit Court of Appeals (No. Dist. Texas)

Drug Enforcement Administration (DEA) seeks to compel production of medical records of Dr. Zadeh’s patients as part of a DEA inquiry into whether or not he violated the Controlled Substances Act.

Dr. Zadeh argues the forced disclosure of private medical information will effect patients’ willingness to openly share such information with their provider.

Case will decide whether or not the DEA can use administrative subpoenas to obtain and review medical records without a warrant to determine if the provider has violated controlled substances prescribing laws.
Lessons Learned

- Understand state-specific and federal prescribing rules related to:
  - Licensure
  - Establishment of a physician-patient relationship
  - In-person physical exam requirements
    - How is it defined?
    - Standard of Care
    - Prohibitions on certain drugs, i.e., controlled substances
      - How is it defined?
    - Ryan Haight Act
    - Prohibitions on questionnaires alone
**Griffin v. Moon**

- Plaintiff contracted a parasitic mite resulting in break down of skin integrity and painful and debilitating skin infections
- Plaintiff alleges that Defendant should have
  - Seen Plaintiff in person instead of by telemedicine
  - Recommended testing and analysis of skin scrapings or biopsy samples before making a diagnosis
  - Referred Plaintiff to a specialist

**MacDonald v. Schriro**

- Telemedicine conference with prisoner re: left knee injury
- Telemed provider did not:
  - Perform a physical examination
  - Listen to Plaintiff’s symptoms
  - Obtain/review Plaintiff’s most recent MRI results
- Resulted in delay of treatment (knee surgery) for 3 years
Lessons Learned

- Standard of care when practicing via telemedicine is the same as if practicing in-person.
- Telemedicine providers need to account for continuity of care and patient abandonment issues.
- If telemedicine consult is not sufficient for diagnosis, provider should refer the patient to alternate providers for in-person care.
“Skyping” Patients

- Oklahoma doctor disciplined for using Skype to treat patients with mental health issues
- **Medical board documents that Skype is not an approved telemedicine communication**
- Dr. Thomas Trow was “practicing telemedicine via Skype on SoonerCare members and prescribing controlled drugs without ever seeing the patients in person for an initial evaluation”
- Placed on probation for two years and ordered to complete a course on prescribing practices
Lessons Learned

- Consumer video chat apps, such as Skype, were not designed for mHealth purposes
  - Not HIPAA-compliant
    - Encryption
    - BAAs
    - Documented Security Breaches
      - Viruses
      - Surveillance recording
      - IP address tracking
      - Storing messages and voicemails
FDA
- Regulates mobile medical apps:
  - Used as an accessory to an FDA-regulated medical device
  - Transform a mobile platform into a regulated medical device

HIPAA
- Frequently an app developer is not a Covered Entity or Business Associate subject to HIPAA rules
- App developers need to consider state law privacy and security statutes which apply to a much broader scope of companies than HIPAA

FTC
- Has reached settlements with two firms marketing melanoma detection apps, alleging they deceptively claimed the apps accurately analyzed melanoma risks
mHealth: Issues to Consider

- Watch out for “phony” apps
- Changing how caregivers communicate
- Digital distractions affect patient care
- Display limitations
- Smartphone cameras
- Cross-contamination
- Support considerations
Risk Management Solutions

- **Assess & Define**
  - Assess Service Needs and Environment
  - Define Program Model
  - Develop Business Case

- **Develop & Plan**
  - Develop and Plan Program and Technology
  - Develop Performance Monitoring Plan

- **Implement & Monitor**
  - Implement Telemedicine Program
  - Monitor and Improve Program (Ongoing)
- Develop comprehensive policies and procedures regarding the use of mHealth technologies.
- Conduct education and training at implementation and on a regular basis thereafter on policies, procedures, regulatory environment, and use of equipment.
  - Staff and patients
- Vet software and equipment vendors prior to purchasing mHealth technologies.
  - Privacy and security controls; contract language; cyber liability insurance
- Conduct periodic risk assessments.
Insurance Considerations

- Insufficient coverage when practicing across state lines
- Inability to cover reads that come from outside states
- Lack of premium pricing flexibility to base premium on exposures (# of reads or revenue)
- Lack of portability of coverage and “tail” issues for departing physicians
- Inflexibility in the underwriting requirements for preapproval of new or last minute physicians
Questions to Ask

1. Does your current policy allow for additions of employed or contracted physicians automatically or with a minimum amount of information about them up front?

2. Does your policy cover contracted services provided in any state?

3. Does your current policy have continuous coverage for terminated/departed physicians after they leave the group?

4. Does your current policy provide individual limits for each employed or contracted physician?

5. Can your insurance carrier provide you with limits up to $5M or more if statutes or contract clauses require it?
Key Takeaways

- Address key challenges before delivering care via the various mHealth modalities.

- Know the regulations and legislation applicable in any and all jurisdictions in which providers and patients are located.

- Connected Care = the Future of Healthcare – recognize the benefits of utilizing technology and eHealth modalities to improve patient care.

- Assess and plan before implementing; monitor and improve after implementing!
Key Takeaways

- Address key challenges *before* delivering care via the various “eHealth” modalities.
- Know the regulations and legislation applicable in any and all jurisdictions in which providers and patients are located.
- Connected Care = the [Future of Healthcare](#) – recognize the benefits of utilizing technology and eHealth modalities to improve patient care.
- Assess and plan *before* implementing!
Questions

Thank You
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Insurance Managers Association of Cayman