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Brave New World: Medicine in the Digital Age

What Telemedicine Looks Like Today

The Health Care industry is on the precipice of a brave new world. The Affordable Care Act has challenged the medical industry to find effective and cost efficient ways of providing medical treatment. The advent of innovations in medical technology has already changed the face of medicine with telemedicine leading the charge.

Telemedicine has the potential to create efficiencies in healthcare and extend the reach of existing providers but can create issues of safety and privacy. This program reviews the basics of telemedicine and discusses the potential benefits and risks of using the new technology

Telemedicine and Methods of Delivery

Telemedicine is the use of electronic communication to exchange medical information from one site to another with the goal of improving a patient's clinical health status. Telemedicine includes a growing variety of applications and services including two-way video, email, smart phones, wireless tools and other forms of telecommunications technology.

Standard methods of transmission include:

1. *Store and Forward:* Allows transmission of commonly used medical data to a doctor or specialist for assessment offline. It is routinely used in radiology, dermatology and pathology and allows practitioners to provide a quick review.
2. *Interactive:* This provides real time interactions between patient and provider or between providers. It allows a face to face exchange and can provide real time clinical data and aid in diagnosis. Benefits include patient satisfaction and cost effectiveness.
3. *Remote Monitoring:* Allows medical professionals to monitor patients remotely using technology including mobile medical devices or "apps". It is primarily used to managing chronic diseases or specific conditions such as diabetes or hypertension.

Potential Benefits of Telemedicine

Telemedicine can make it easier for patients to obtain medical care and for physicians to "see" patients quickly. It has been promoted as a way to improve efficiency and reduce health care costs. Indeed, there are many advantages to this type of medical care including:

1. **Big Data:** Monitoring and tracking patients with simple devices will provide access to a tremendous amount of data which can be analyzed and used to identify "at risk" patients. However, issues of access and privacy are still being sorted out
2. **Real time clinical information:** Patients provide medical history and describe symptoms directly to the medical practitioner which decreases the chance that information gets lost as it is passed between physicians or nurses. Medical providers can also access clinical information such as a patient's blood pressure or blood sugar and watch for changes throughout the day
3. **Less invasive procedures** Telemedicine can be used to monitor patient vital signs or lab values and decrease the need for intrusive medical tests
4. **Heightened ability to diagnose:** Clinicians can get up close and personal with patients as they examine them via video link and may see things they would otherwise miss.
5. **Increased access to care through remote access.** For patients who can not easily access medical care either because of distance or physical disabilities, telemedicine allows physicians to monitor, examine or even diagnose a patient via video access
6. **Preventative care:** Patients can be visited remotely by a nutritionist, therapist or primary care physicians. Information collected by health monitoring devices can be reviewed with patients and changes made in their life style or medication schedule.
7. **Monitoring the patient in their environment :** By observing patients in their home environment, health care providers can see if there are other factors which could be causing or exacerbating their symptoms
8. **Home Care Intervention:** Medical providers can examine a patient's environment and easily determine what services they may require. Telemedicine allows a virtual tour of a patient's home and improves the speed and efficiency of arranging post discharge services

Potential Risks of Telemedicine

Despite the perceived benefits of telemedicine, there are risks which must be considered. Medical practitioners and institutions must remain cognizant of the following pitfalls as they enter the world of telemedicine:

1. **Loss of PHI (personal health information)** Medical monitoring devices and records of video encounters should be equipped with a secure storage system to avoid unauthorized access through a data breach.

2. **User knowledge deficits:** Medical monitoring devices are flooding the market and there may be a learning curve for take medical personnel and users before they feel comfortable with the technology. During this time, data may be inaccurate or lost.
3. **Misinformation:** Users (patients and medical personnel) who are not familiar with the devices may not be able to obtain and maintain data
4. **Unexpected injury:** Devices which malfunction due to inexperience or a manufacturing defect may cause injury to the user or loss of data.
5. **Informed consent:** When telemedicine is used, patients should be informed of the risks and benefits so they can make a knowledgeable decision about treatment.
6. **Information overload...more is not always better:** The data obtained via telemedicine should be put in perspective and evaluated for relevance and accuracy.
7. **Over dependence on devices:** Practitioners who rely on the "machines" to collect data may miss valuable clinical information or be unable to locate data when it is needed.
8. **Reliance on 3rd party vendors:** Initially, medical practitioners may rely on outside vendors to manage and maintain the devices. However if the device malfunctions, the vendors may not be readily available for troubleshooting
9. **Loss of the "art" of medicine:** Use of medical devices may encourage medical practitioners to treat the patient's numbers (lab data, vital signs etc.) and ignore the clinical data.

Constraints and Limitations of Telemedicine in Practice

Once telemedicine is put into practice there are additional issues which need to be addressed in order to be successful.

1. **Design and implementation shock :** Clinicians will have to rethink how they deliver medicine as they incorporate telemedicine into their practice
2. **Work Flow and Staffing Changes:** Hospitals will have to reconfigure work flow patterns and staffing to accommodate the monitoring requirements of telemedicine systems.
3. **High costs –** Start up costs can be high as telemedicine systems are implemented. Medical practitioners will need to invest in the equipment, training and heightened security systems to maintain records.
4. **Challenges with integration of multiple systems:** Medical practices and Hospitals often have different systems to maintain and store data which may not be compatible. When medical devices are added to the mix, the difficulty in capturing and maintaining accurate data is increased.

5. **Regulatory inconsistencies:** State and Federal governments are beginning to address the use of telemedicine but the regulations may not be consistent. Practitioners must be prepared to navigate through these discrepancies and conform the systems to be successful.
6. **Reimbursement constraints:** Telemedicine services are not consistently accepted for reimbursement by government and/or private health plans. Hospitals and medical practitioners need to be aware of these specific guidelines as well.
7. **Resource needs:** Medical devices have the capability of providing 24/7 monitoring, but practitioners must decide on the level of staff and training needed to perform engage in telemedicine.

Putting telemedicine into Practice

The use of telemedicine in a clinical setting requires planning beyond purchasing the technology and ramping up the speed of the institutional servers. Hospitals and medical practices must consider the following when incorporating telemedicine in their practice:

Policies on telemedicine - specific guidelines should be implemented which address:

1. **Monitoring:** When and where patients can be monitored with specific programs for inpatient and out patient or at home monitoring.
2. **Providing remote consultations:** Plans for how remote consultations can be provided should be formulated. Physicians should know the institutional parameters for providing consults for hospital based patients or for colleagues outside of the institution.
3. **BYOD: bring your own device:** Many practitioners use their personal phones or tablets to record data including consults and photos. Since these devices are not connected to a secure network, the data may be accessed inappropriately. Also if the data is not transmitted to the medical records, it could be lost.
4. **Billing Compliance;** Hospitals and medical practice need to initiate billing standards and practices to comply with the myriad of reimbursement requirements
5. **Documentation:** Standards should be set for documentation of all telemedicine encounters – both written and video.

Cyber considerations

1. **HIPAA compliance:** Guidelines for keeping records secure are needed to comply with HIPPA
2. **Security standards:** A strong security system to protect of records against a cyber attack should be instituted and maintained by medical practices and hospitals.

Training & Education

1. **Credentialing:** Additional credentialing guidelines for telemedicine should be instituted to ensure the staff is prepared to engage in the practice of telehealth. Practitioners need to have the appropriate training and experience to engage in telemedicine.
2. **Resources:** Medical practices and Hospitals must institute a training program for staff to ensure the staff is comfortable with the equipment and how to convert the encounters into a medical record
3. **Monitoring for updates:** Procedures should be enacted to ensure updates and new techniques are captured and shared with the staff.

Regulatory Oversight:

State and Federal governments have embraced telemedicine as a way of increasing access to medical care and containing costs. There are several bills moving through Congress which address not only the use of telemedicine under Medicare but also reimbursement for services.

2015 Medicare Telehealth Parity Act:

The goal of this bill is to remove geographic barriers and expand telehealth services to underserved areas. Currently, telehealth is limited to specific locations and by a select group of practitioners. Remote monitoring and store & forward technology is not covered. The new law would expand the use of store & forward and video technology and increase the number and type of practitioners (physical therapist, speech therapist etc.) who can use it. It would also allow remote monitoring and cover some home care applications.

2015 Telemedicine for Medicare Act

This bill allows a Medicare participating physician who is licensed in 1 state to provide telemedicine service to a Medicare beneficiary in another state, without obtaining a comparable license

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Expands the use of telehealth and remote patient monitoring services for Medicare patients. Allows telestroke evaluation and management sites, dialysis facilities for home dialysis and use at Native American health service facilities. It includes telehealth and RPM (remote patient monitoring) as basic benefits within Medicare Advantage. Proponents of this bill predict it will lead to savings of \$1.8 billion over the next 10 years.

So What Happens if Something Goes Wrong? Areas of Potential Exposure for Clinicians and Hospitals

Medical technology is new and shiny and promises to revolutionize the way medical treatment is provided. However there are legal issues which have not caught up with the technology and should be considered by users of telemedicine. This section will look at concerns facing hospitals and medical practitioners as they enter this brave new world.

Where are Telemedicine encounters captured?

1. Maintaining records of consults and digital visits. Clinicians should ensure the results of their encounter are documented for future access. The issue of how Records must be stored i.e. electronic entries, data streaming, video recordings has not been determined
2. HIPAA compliance. Patients are entitled to access to their protected health records but the question of what a medical record includes is subject to varying State and Federal laws.

Practicing medicine across jurisdictions

1. **Physician Licensure:** 1 state vs. several. If a physician maintains a license in several states, not all allow the practice of telemedicine
2. **Interstate Physician Licensure Compact:** this offers voluntary expedited pathway for physicians who want to practice in multiple states. It has been enacted in 12 states and introduced in 14 states.
3. **Standards of Practice:** Standard of Care varies from state to state and can be implicated with telemedicine treatment or consults across state lines

Scope of practice

Use of physician extenders (Physician assistants, Nurse Practitioners) has become a popular method of supplementing staffing Hospitals and medical practices. Whether they also practice telemedicine has not been affirmatively addressed by the state and federal governments

One issue is the availability of physician oversight for monitoring done by physician extenders. The Hospital should ensure any telehealth encounters done by non physicians have sufficient medical back up.

There is also a risk that physician extenders may be used to fill the new roles created by telemedicine because they are "cheaper" than physicians. Hospitals should institute standards and review to ensure non physicians provide the same quality of telemedicine as physicians

Potential Claims:

1. **Breach of Warranty/Product Liability** claims can arise if the medical device malfunctions and either causes loss of data or injury to the patients
2. **Negligence** claims can involve allegations of the failure to properly monitor or interpret the data retrieved from medical devices; or provide "bad" advice to a patient or other medical practitioner when interacting remotely
3. **Cyber, Security and Privacy:** Recent data breaches in the health care arena show how easy it is to access confidential patient records. Failure to have adequate security to protect PHI may give rise to a separate cause of action.
4. **Practitioner Licensure:** Physicians will have to ensure they are properly licensed to practice telehealth
5. **Credentialing Issues:** Hospitals may be tagged if they do not have sufficient credentialing guidelines to cover telehealth
6. **Consent:** Patients may look to include a claim for informed consent if the risks and benefits of using telehealth is not shared with them
7. **Regulatory:** State and Federal regulatory bodies have maintained strict scrutiny over potential billing fraud. Now that telemedicine can be reimbursed, they will undoubtedly start looking at these issues as well.
8. **Software design exposure:** If the software used with medical devices is defective or "hacked" by an outside party, data can be lost or improperly recorded.

What Lawyers will look for – Will Telemedicine increase Liability and Damages

As plaintiff lawyers become familiar with telemedicine and how it is used, they will look for new ways to enhance their claims and increase damages. Issues which should be considered are:

Jurisdiction

Where does the action arise – what if a telehealth physician in one state gives advice to a patient in another state – which jurisdiction prevails?

The answer varies among jurisdictions – some states allow jurisdiction over a defendant who commits a tortious act which injures a patient in their state. Many attorneys look at standards used by state medical boards for guidance. They generally find jurisdiction where the patient is located. However these standards are not issued for determining jurisdiction and may not be accepted by the Courts as controlling.

Standard of Care

Will vary among jurisdictions. Practitioners may be held to varying standards of care, depending on where the patient or colleague is located.

Under the locality rule, the standard of care where the physician practices is the yardstick used to measure accepted medical care.

However when care crosses state lines, will the standard of care where the physician practices be used or the standard where the patient resides? This will have to be considered when evaluating telemedicine claims.

Conflict of Law

This will involve similar issues as those with jurisdiction in terms of where the malpractice take place. Varying standards will allow the plaintiff to forum shop to benefit from the most generous laws in terms of statute of limitations and the presence of tort reform.

Physician – patient relationship

Does telehealth or advice over the phone - establish a physician - patient relationship. This is an issue which will undoubtedly be raised as a defense but may not provide complete protection.