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WHO and the Surgical Care Outcomes Assessment Program Surgical Checklist

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Checklists as tools for safety have demonstrated value in complex systems and thus have been mandatory in the aviation industry. Until recently, they were missing from medicine, save the anesthesia pre-induction checklist. Now, checklists are being adopted in hospitals, yet without standardization beyond the pre-procedure time out. The inherent complexities of surgical procedures, critical and emergency care strategies, and technology are magnified exponential when combined as a system for care. Such complexity allows the possibility for alignment of component failures that can result in catastrophic outcomes. Synchronizing all system components before "go" helps to reduce the opportunities for serious error.

As the number of surgical procedures worldwide approaches the quarter-billion mark, initiatives to improve outcome by reducing errors have multiplied. One such initiative is the World Health Organization (WHO) surgery checklist. Comprised of 19 items, the checklist improves communication among members of the surgical team and prevents errors of omission and commission.

As reported by Haynes and colleagues[1], use of the WHO surgery checklist was associated with a substantial reduction in the rate of complications within 30 days of operation in a diverse group of nearly 4,000 patients undergoing surgical procedures. The mortality rate was cut in half from 1.5% to 0.8%, and the complication rate was reduced by over one third, from 11% to 7%. The spectrum of measured complications was broad and consistent with definitions from the American College of Surgeons National Surgical Quality Improvement Program and captured a broad spectrum: acute renal failure, transfusion of $\geq$ 4 units of red blood cells within 3 days of surgery, cardiac arrest requiring cardiopulmonary resuscitation, coma lasting more than 24 hours, venous thromboembolism, myocardial infarction, unplanned intubation, post-operative ventilator use $\geq$ 48 hours, stroke, acute wound failure, surgical site infection, the sepsis continuum, vascular graft failure, and unplanned reoperation. Six standard safety processes were measured as well and included

- Accurate preoperative airway evaluation
- Use of pulse oximetry at anesthesia initiation
- Sufficient vascular access, given anticipated blood loss
- Prophylactic antibiotic administration within one hour of incision
- Performance of a time out before incision to confirm patient name, operative site, and pending operation
- Completion of a sponge count at the end of the operation

The Surgical Care and Outcomes Assessment Program (SCOAP) in Washington State is disseminating a modified checklist (Figure) as best practice. The elements of the checklist are not "rocket science." They constitute essentials for intra-team relationships. In executing the checklist, all members of the operative team (surgeons, nurses, and anesthesia providers) affirm a common understanding about what they are going to do and voice anticipation of potential problems.

The checklist process begins with Step 1, the pre-

operative briefing. Collectively, the team confirms patient identity, operative site, and intended operation. Then, anesthesia, nursing, and surgeon review sequentially issues in their respective domains.

Step 2 reviews important quality and safety processes that have been previously defined as best practice. This step was not an original part of the WHO checklist, yet is readily incorporated in the checklist approach. Included are confirmation of the display of essential imaging, active warming, glucose control, beta-blockade, DVT prophylaxis, antibiotic prophylaxis, presence of vital equipment (e.g., cell-saver, specific instruments), and sharps injury prevention plan.

Step 3, the debriefing, begins as the operation nears completion before incision closure and opens with the question, "Are the instrument, sponge, and needle counts correct?" The response is verbalized to the entire team and allow for immediate corrective action if incorrect. The members of the team then review the operation, reiterating the important activities that should have occurred, and verifying that the specimen has been appropriately handled with confirmation of patient identity on the specimen and special instructions for the pathologist. Opportunities for improvement are addressed with equipment and processes, and the key post-operative concerns are verbalized.

The reasons that checklists improve outcome are likely multiple, but the common pathway is a reduction in variability. Changes in systems and surgical team behavior occur. Behavior in studies may be positively influenced by team members knowing that they are being observed, rather than by completion of the checklist in and of itself. Yet the question is, from where does the checklist drive accountability? Intra-team, rather than external observation, may play a larger role. It is important to remember that the checklist is a means to an end, not the end itself. Given its extremely low cost in time and resources, associated with clear improvement in outcomes, the checklist is a simple tool that has come of age in health care delivery.

Citations:

1. Haynes, et. Al, A Surgical checklist to reduce Morbidity and Mortality in a Global Population. NEJM, January 29, 2009 p491-499.
2. http://www.scoap.org/checklist/index.html (includes a video interview of the process with Dr. E. Patchen Dellinger)

SCOAP
Surgical Checklist Initiative
"A System for Safer Surgery"

Step 1: Briefing—Prior to Skin Incision

- ❑ Team members introduce themselves by name and role
- ❑ Surgeon, Anesthesia Team and Nurse confirm patient (at least 2 identifiers): Site, Procedure, Position

Anesthesia Team Reviews

- ❑ Airway or other patient-specific concerns (special meds, health conditions affecting recovery, etc)
- ❑ Patient allergy ❑ No ❑ Yes

Nursing Team Reviews

- ❑ Equipment issues (e.g., gas tanks full, all instruments ready) or other patient concerns

Surgeon Reviews

- ❑ Brief description of procedure and anticipated difficulties
- ❑ Expected duration of procedure
- ❑ Single operative field ❑ Multiple operative fields
- ❑ Need for instruments/supplies beyond those normally used for the procedure
- ❑ Risk of blood loss > 500 ml ❑ No ❑ Yes, and adequate IV access established

Step 2: Process Control—Prior to Skin Incision

Surgeon Confirms

❑ Essential imaging displayed	❑ N/A	
❑ Active warming in place	❑ N/A (Case < 1 hour)	Last Q SCOAP: ____ % missed
❑ Glucose checked for diabetics ❑ Insulin started for glucose > 125	❑ N/A	Last Q SCOAP: ____ % missed
❑ Beta blocker planned postop	❑ N/A (not on preop beta blocker)	Last Q SCOAP: ____ % missed
❑ DVT/PE prevention plan in place	❑ N/A	Last Q SCOAP: ____ % missed
❑ Antibiotic prophylaxis given in last 60 minutes	❑ N/A	Last Q SCOAP: ____ % missed
❑ Antibiotic redosing plan in place	❑ N/A (Case < 3 hours)	Last Q SCOAP: ____ % missed
❑ Specialty-specific checklist needed	❑ N/A	Last Q SCOAP: ____ % missed
❑ Agreed-upon plan to prevent sharps injury	❑ N/A (no sharps)	Last Q SCOAP: ____ % missed

Step 3: Debriefing—At Completion of Case

Surgeon and Nurse Confirm With the Team

- ❑ Before closure: Are instrument, sponge, and needle counts correct?
- ❑ Name of procedure and if applicable, how is the specimen labeled (correct patient name)?
- ❑ Special instructions for pathologist (e.g., 12+ negative lymph nodes for colon CA?) ❑ N/A
- ❑ Equipment issues to be addressed ❑ No ❑ Yes, and response plan formulated (Who/What/When)
- ❑ What could have been done better? ❑ Nothing ❑ Something, and response plan formulated (Who/What/When)
- ❑ Beta blocker planned postop ❑ N/A (not on preop beta blocker)
- ❑ What are the key concerns for recovery and management of the patient?

• Adapted from the WHO "Safe Surgery Saves Lives" campaign •
SCOAP is a program of the Foundation for Health Care Quality
www.scoapchecklist.org

Please click on the links above to view more information on the SCOAP website! rev 3/17/09

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Fundamentals of the Marchman Act

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History and Overview

In the early 1970's, the federal government enacted laws creating formula grants for states to develop continuums of care for individuals and families affected by substance abuse. The laws resulted in separate funding streams and requirements for alcoholism and drug abuse. In response to the laws, the Florida Legislature enacted Chapter 396 (alcohol) and Chapter 397 (drug abuse) of the Florida Statutes (F.S.). Key provisions in Chapter 396, F.S., included decriminalization of public inebriation and procedures for involuntary commitment. Key features in Chapter 397, F.S., included funding for programs for individuals involved in the criminal justice system and licensing requirements for drug abuse programs. Each of these laws governed different aspects of addiction and thus, had different Florida Administrative Code (or rules) promulgated by the state to fully implement the respective pieces of legislation. Since persons with substance abuse issues often don't restrict their misuse to one substance or another, having two separate laws dealing with the prevention and treatment of addiction was cumbersome and did not adequately address the problems faced by Florida's citizens.

In 1993 Representative Steven Wise of Jacksonville introduced legislation to combine Chapters 396 and 397, F.S., into a single law (Chapter 397) that clearly spelled out legislative intent, licensure of service providers, client rights, voluntary and involuntary admissions, offender and inmate programs, service coordination, and children's substance abuse services. The statute was named the "Hal S. Marchman Alcohol and Other Drug Services Act of 1993" -- generally referred to as the Marchman Act. The Act was named after Rev. Hal. S. Marchman, a tireless advocate for persons who suffer from alcoholism and drug abuse.

To implement the new statute, the Florida Department of Health and Rehabilitative Services (HRS) created Chapter 65D-30 of the Florida Administrative Code. This administrative rule contains licensing and other credentialing standards for provider agencies and individual practitioners serving persons with addictions.

Legislative Intent

The 1993 Florida Legislature studied the issues surrounding the use and abuse of alcohol and other drugs and made provisions in the Marchman Act for:

- Development, within available resources, of a full continuum of substance abuse prevention, intervention, and treatment services. The system will emphasize access to the least restrictive environment of optimum care, appropriate to the individual in need.
- Protection and respect for the rights of clients, especially for involuntary admissions.
- Services shall be purchased through community-based private not-for-profit providers working with local governmental programs and involving a wide range of agencies from both the public and private sectors.
- Assistance for substance abuse impaired persons, primarily through health and other rehabilitative services. Services will be designed to relieve the police, courts, correctional institutions, and other criminal justice agencies of the additional burden of care that interferes with their ability to protect people, apprehend offenders, and

maintain safe and orderly communities.

Related Legislation

The Marchman Act most closely resembles the Florida Mental Health Act or "Baker Act" which was enacted in 1971. The Baker Act is Florida's mental health statute and contains provisions for voluntary and involuntary placements for assessment, stabilization, and treatment for persons with mental health disorders. The definition of mental illness in the Baker Act specifically excludes intoxication and substance abuse impairment. This created the need for similar legislation for substance abuse and impairment.

Historically, there has been a significant difference between the use of Baker Act and the use of Marchman Act placements for involuntary care. For example, in 2006 there were 82,414 individuals admitted for involuntary examination under the Baker Act due to mental illness. During a similar timeframe, there were 4,186 individuals admitted to involuntary assessment, stabilization, or treatment due to substance abuse or impairment. Placement in a Baker Act facility is typically done by law enforcement (nearly 50 percent) and is reflective of the criminal justice system's greater familiarity and understanding of the Baker Act. In addition, there is a greater availability of secure evaluation and treatment settings for those with primary mental health disorders, than for those with substance abuse disorders. Some Baker Act placements are due to signs and symptoms of active substance abuse or withdrawal that resemble those of mental health disorders – anxiousness, hallucinations, disorientation, or flat affect. Training for law enforcement, the judicial system and the community is often needed to expand knowledge and use of the Marchman Act as a means for involuntary service placements.

Marchman Act Placement Criteria

Involuntary Admissions

The Marchman Act encourages persons to seek treatment on a voluntary basis and to be actively involved in planning their own services with the assistance of qualified professionals. However, denial of addiction is a common symptom, raising a barrier to early intervention and treatment. As a result, treatment often comes as a result of a spouse, employer, doctor, judge or other person with influence over the addicted individual's life making the intervention needed for substance abuse services.

The Marchman Act establishes a variety of methods under which substance abuse assessment, stabilization and treatment can be obtained on an involuntary basis. There are five involuntary admission procedures. Three of the procedures do not involve the court, while two require direct petitions to the circuit court. The three non-court procedures are:

Protective Custody
Emergency Admission
Alternative Involuntary Assessment for Minors

The law also offers two court-related procedures, including:

Involuntary Assessment and Stabilization
Involuntary Treatment

Regardless of the court-involved or non court-involved nature of the proceedings, the same criteria for involuntary admission apply. To be eligible for involuntary service placement an individual must meet the following criteria for admission:

There is good faith reason to believe the person is substance abuse impaired and, because of such impairment has lost the power of self-control with respect to substance use; **and either**

Has inflicted, or threatened or attempted to inflict, or unless admitted is likely to inflict, physical harm on himself or herself or another**; or**

Is in need of substance abuse services and, by reason of substance abuse impairment, his or her judgment has been so impaired that the person is incapable of appreciating his or her need for such services. The individual's refusal for care does not mean that he or she is unable to make rational decisions with regard to care.

Protective Custody

Protective custody is used by law enforcement officers when a person is substance-impaired or intoxicated in public and is brought to the attention of the officer. The purpose is to allow the person to be taken to a safe environment for observation and assessment to determine the need for treatment. A law enforcement officer may take the individual to their residence, to a hospital, a detoxification center, or addiction receiving facility, or in certain circumstances, to jail. Minors, however, cannot be taken to jail.

Emergency Admission

This procedure permits a person who appears to meet the criteria for involuntary admission to be admitted to a hospital, an addiction receiving facility or a detoxification facility for emergency assessment and stabilization. A physician, spouse, guardian, relative, or any responsible adult who has personal knowledge of the individual may initiate this procedure. In the case of a minor, a parent, legal guardian or legal custodian may initiate the procedure for emergency admission. Individuals admitted for involuntary assessment and stabilization under this provision must have a physician's certificate for admission, demonstrating the need for this type of placement and recommending the least restrictive type of service that is appropriate to the needs of the individual.

Alternative Involuntary Assessment for Minors

This procedure provides a way for a parent, legal guardian or legal custodian to have a minor admitted to an addiction receiving facility to assess the minor's need for treatment by a qualified professional. Following the initial 72-hour evaluation period, the attending physician may extend the minor's stay by 48 hours, with the total placement not to exceed 5 days. Upon conclusion of this timeframe, the minor must be either referred for further treatment or discharged.

Involuntary Assessment & Stabilization

This procedure involves filing a petition with the Clerk of Court. The person's spouse, guardian, any relative, a private practitioner, the director of a licensed service provider, or any three adults with knowledge of the person may file the petition. If the person is a minor, a parent, a legal guardian, a legal custodian, or a licensed service provider may file the petition. The court can schedule a hearing to take place within 10 days or can issue an ex-parte order immediately. The person can be admitted to a hospital, an addictions receiving facility or a detoxification facility for assessment and stabilization for up to 72 hours to determine the person's need for treatment.

Involuntary Treatment

This procedure involves filing a petition with the Clerk of Court after the person has been involved in at least one of the four previously mentioned procedures. The person's spouse, guardian, any relative, a private practitioner, the director of a licensed service provider, or any three adults with knowledge of the person may file the petition. The individual may be admitted to treatment for a period not to exceed 60 days. If the need for treatment is anticipated to be longer, renewal of the order may be petitioned prior to the expiration of the initial 60-day period.

visions of Protective Custody. This means individuals placed in treatment under a Marchman Act may voluntarily leave treatment at any time and the only legal recourse, in the absence of a criminal offense, is for a judge to issue a contempt of court charge and impose brief jail time. The lack of secure capacity creates a "revolving door" of individuals through the legal and treatment systems.

Improving Capacity: Florida's substance abuse system of care has limited resources, further diminished through state budget reductions in recent years. An overall lack of services including assessment, stabilization and treatment, even for those under a Marchman Act, makes placements difficult. The Department of Children and Families is exploring opportunities to create regionalized or statewide Marchman Act facilities. The facilities would be secure and staffed with adequate resources to meet the needs of individuals requiring involuntary placements. This option, while expensive, would help improve client outcomes and reduce costs to the system of care through decreases in hospitalizations and treatment episodes. Use of "regional" or "statewide" facilities would draw on the resources of several communities and ensure a utilization rate sufficient to make the facility financially viable. There would be logistical challenges, including transportation for the individual to and from the facility and linkages to step-down treatment and support in their home community following discharge from a Marchman Act facility. Additional funding for the Department of Children and Families would be needed to develop and purchase this capacity.

Extending Length of Care: Another option is extending assessment and stabilization period from 72 hours to 120 hours. Since the average length of time to properly stabilize an addicted individual is at least 5 days, this extended time would allow for opportunities to provide motivational enhancement for individuals to encourage treatment following stabilization and case management efforts to locate appropriate placement.

Co-occurring Capacity: The Department of Children and Families currently has three assessment and stabilization centers for adolescents that are a combination of Crisis Stabilization Units (mental health) and Addiction Receiving Facilities (substance abuse). These facilities were not financially viable as separate units and lacked the capacity to effectively assess and treat children and adolescents that presented with co-morbid conditions. These facilities can be accessed through voluntary and involuntary placements pursuant to either the Baker Act or the Marchman Act.

As part of the Department's Florida System of Care initiative, all Baker Act and Marchman Act programs will be developing co-occurring capabilities through self-assessment, enhanced training, and integration of care. The Department is examining all policies, protocols, and guidelines to produce a necessary "shift" to assessing and treating co-morbid disorders through integrated care settings. This will change the focus of assessment, stabilization and treatment to become more welcoming and engaging, regardless of an individual's point of entry into the system of care.

Portions of this article were adapted from the Florida Department of Children and Families' Marchman Act Handbook - 2003, developed by Phil Emenheiser and Martha Lenderman.

Baker Act data was taken from the 2006 Florida Mental Health Act (The Baker Act) Report by the University of South Florida, Louis De La Parte Florida Mental Health Institute.

Voluntary Admissions

A person, whether adult or minor, who wishes to enter treatment for substance abuse may apply to a service provider for voluntary admission. Within the financial and space capabilities of the service provider, a person of any age must be admitted to treatment when sufficient evidence exists that the person is impaired by substance abuse and the medical and behavioral conditions of the person are not beyond the safe management capabilities of the service provider.

Client Rights

The Marchman Act provides an array of statutorily protected rights of persons seeking and or receiving substance abuse services as well as due process rights of those persons for whom involuntary interventions are sought. These include:

Individual Dignity – client must be respected at all times and cannot be deprived of constitutional rights.

Nondiscriminatory Services – service providers cannot deny access to care on the basis of race, gender, ethnicity, age, sexual preference, disability, or severity of substance abuse history.

Quality Services – services must be suited to the individual's needs in the least restrictive available environment, with opportunity for the individual to actively participate in planning his/her treatment.

Communication – all clients have the right to contact with family/friends via telephone, mail, or in-person.

Care and Custody of Personal Effects – all clients have the right to possess clothing and personal effects. Providers may take temporary custody of personal effects for medical or safety reasons.

Education of Minors – all minors in a residential treatment/care setting shall be provided education and/or training appropriate to their needs.

Confidentiality of Records – all records that pertain to the identity, diagnosis, prognosis and service provision to the client shall be confidential in accordance with the Health Insurance Portability and Accountability Act (HIPAA) and 42 Code of Federal Regulations, Part II.

Counsel – all clients have the right to counsel for involuntary proceedings for assessment, stabilization and/or treatment.

Habeas Corpus – a client in involuntary status may have their parent, guardian or attorney petition the court for a writ of habeas corpus to question the cause and legality of such retention and request release of the individual.

Liability and Immunity – service provider staff that violate or abuse rights or privileges of clients are liable for damages. Staff acting in good faith, reasonably and without negligence are free from liability, civil or criminal.

Improving the Process

There are several strategies under consideration to improve the capacity and utilization of Marchman Act beds for assessment, stabilization, and treatment in Florida. Each approach, despite its many benefits, has its own unique set of challenges, especially in times of economic uncertainty.

Secure Placements: Marchman Act placements are typically handled through civil court proceedings rather than criminal proceedings which limits the use of secure or "locked" placements that keep an individual from leaving care prematurely and against medical advice. The use of secure beds to physically hold an individual in treatment presents a variety of legal, ethical and financial issues. Florida has limited "secure" placement options for involuntary placements; primarily jail under the pro-

CYBER DOCTORS

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Introduction
When my parents lived in Chicago in the 1950's, it was not uncommon for my mother to call our family doctor, about me or one of my siblings, to discuss a medical issue. The doctor would direct the sick child to cough into the phone. A prescription was then called in.

Patient care at a distance is certainly not a new practice. There are many examples in our history illustrating this concept. In 1642, Theophraste Renaudot, a French physician and philanthropist, created a patient booklet with lists of symptoms and simple body diagrams. The patients would check off the symptoms they were experiencing from the list and used the diagrams to identify the body parts that were troubling them. This innovative booklet enabled a patient to receive a diagnosis and treatment by post without a personal visit to the physician. Other doctors also engaged in such practices, such as William Cullen (1710-1790) of Edinburgh, Scotland and John Morgan (1735-1789) of Philadelphia, who were both equally active with postal consultations.[1]

In more recent years, due to the vast improvement of modern technology, care at a distance has become more sophisticated and developed into what we now know as telemedicine. This article proposes to explore current applications of telemedicine, the benefits, and some of the associated compliance and legal risks hospitals have to contend with when practicing telemedicine.

Definitions
The American Telemedicine Association (ATA) defines telemedine as "the use of medical information exchanged from one site to another via electronic communications to improve patients' health status." Medical information can now be communicated via the internet, video conferencing equipment, and satellite technology. Telemedicine is as basic as a telephone call between two providers discussing the case of a patient or as complex as using satellite technology for robotic surgery.

The terms telehealth and telemedicine are often used interchangeably. Telemedicine is most often defined as focusing on clinical services and the curative aspect, whereas telehealth has a broader meaning and can refer to clinical and non-clinical services, such as medical education, administration, and research, in addition to clinical services.

Other terms used in the industry, are the "originating site" which is the site the patient receiving the service is located in, as opposed to the "distant site" being the site where the physician providing the service is located. Also, services where both parties are interacting at the same time with a communications link between them are called "real time" services or synchronous telemedicine. In contrast "store and forward technology" refers to the asynchronous transmission of medical information to be reviewed at a later time.

Current Applications
The dramatic growth of technology and the internet has provided great benefits to healthcare. Consumers all over the world have a wealth of health information at their fingertips and can receive diagnostics and purchase pharmaceuticals. Among the many applications of telemedine, a few are described below:

Teleradiology/Telepathology - One of the most common applications of telemedicine is teleradiology and telepathology. A smaller hospital, for example, with limited staffing resources may contract with a bigger hospital for the purposes of interpretation and/or consultation of tests for trauma patients after hours. Radiological patient images, such as x-rays, cat scans, and MRIs, are transmitted from the originating site to the distant site. This saves time and improves patient care by allowing hospitals to access radiology services 24/7. Teleradiology can be accomplished with an international distant site as well. In fact, outsourcing teleradiology services overseas (in countries such as India, Israel, and Australia) is becoming popular to cover the night hours along with radiologists in other US time zones, hence the term of "nighthawk" radiology services. Similarly, telepathology activities occur to provide urgent services at sites without a pathologist. Both teleradiology and telepathology are instrumental in providing consultative services with immediate access. This can be extremely beneficial to physicians in rural areas or for a physician seeking a second opinion in emergency situations.

Telephone & Online Patient Consultations – Patients consulting their physicians over the phone or by e-mail via the internet is not a new practice, but until recently there were no CPT codes to report these services. The CPT codes for telephone services have been updated for 2008 to 99441, 99442, and 99443 and are based on the amount of time spent discussing the medical issue. And in 2008, the CPT code 99444 became available to report online services. According to the AMA Current Procedural Terminology (CPT), the services can only be reported for an established patient and only once for the same episode of care in a seven-day-period. The service must include all other communications such as related phone calls, prescription and lab orders. The e-mails must be kept in permanent electronic or hardcopy storage. Even though the guidelines are strict, the assignment of these CPT codes is very encouraging for telemedicine providers as it is a start towards acknowledging these types of services for reimbursement purposes in a time where phone and internet communications have so many appeals to patients.

Just as note, the above CPT codes were the only existing "tele" codes, before July 1, 2008, as all other telemedicine activities are reported using the same CPT codes as the service conducted without telemedicine. Effective July 1, 2008, the AMA introduced new CPT Category III Codes to report remote-real time interactive video-conferenced critical care services. The codes are 0188T and 0189T. The creation of new CPT codes to accurately capture telemedicine activities will probably increase every year.

Telemarker - A special portable phone used in Israel can assist in the determination of a real heart attack. The process is simple, if a patient is experiencing chest pain, a simple self blood test (called Telemarker) is performed. The test can detect the presence of two proteins, which are bio- chemical precursors of a heart attack. The device sends the information to a center through a modem and the doctor can analyze the results and determine if there is a real medical emergency. This device avoids unnecessary hospitalizations and reduces unnecessary costs.[2]

iPath, a telemedicine network developed at the University of Basel, allows publication and discussion of medical cases for second opinion consultations. iPath is a secure teleconsultation tool enabling virtual communities of care professionals to exchange advice about the management of clinical cases in several expertise domains. The network has been active since 2001 and is used in 15 French-speaking African countries, including Mali, Mauritania, Morocco, Tunisia, Senegal, Cameroon and

the Ivory Coast.[3]

Telesurgery – On September 7, 2001, a team of French surgeons located in New York performed a gall bladder removal, with the Zeus Robotic System (at this time no longer on the market), on a 68 year-old woman located in Strasbourg, France, 4000 miles away. Operation "Lindbergh" took 45 minutes and was the first robotic transatlantic telesurgery. The procedure was successful with no complications and the patient was discharged two days after the operation.[4] Telesurgeries (also known as remote surgeries) have not yet occurred with patients in the U.S., however robotic systems are being used for surgeries with a physician in the same room as the patient. The Food and Drug Administration (FDA) first cleared the da Vinci Robotic System in 2000 for general laparoscopic surgeries such as a gall bladder removal and for treatment of severe heartburn. Since then, use of the system has increased and expanded into several other surgical areas. The da Vinci Robotic System allows surgeons to operate from a distance with a minimally invasive approach using small incisions. The robotic system includes a post with multiple arms which is positioned over the patient. The surgeon is seated across the room from the patient with arms inserted in a console and is manipulating the robot's arms looking at magnified 3D images of the surgical site. Remote surgery is still considered investigational within the U.S. and "should not be performed except under IRB approval and by persons thoroughly familiar with the technology".[5] Nevertheless, the revolutionary event of Operation "Lindbergh" supports the incredible potential of telesurgery bringing new opportunities to the delivery of patient care. Telesurgery is hoped to enable surgeons, some day, to operate from remote locations to help fallen soldiers in a battlefield or even astronauts in space.

Benefits of Telemedicine

The internet is dramatically changing the way consumers access health information, receive diagnostics and purchase pharmaceuticals and plays a key role in expanding the reach of telemedicine. Telemedicine appeals for a host of reasons:

Increased Access to Healthcare - Telemedicine increases access to healthcare in a variety of situations; the ED physician can seek a second opinion quickly, the isolated community can access a specialist when there is none in the area, the understaffed hospital can contract radiology services after hours and support emergency services.

Cost Savings to Patients - Telemedicine offers certain conveniences, such as allowing the patient to contact his /her family doctor without leaving home or to use the Telemarker test to save a trip to the emergency room. Internet communications are convenient and efficient for simple medical problems and save both time and money. The healthcare consumer nowadays is much more informed, educated, and accustomed to using electronic sources to gather and transfer information and more likely to ask for advice by e-mail or phone.

Cost Savings to Providers - Providers also benefit from telemedicine. Travel time for providers can be significantly reduced as well. Many radiologists have opted to get the applicable equipment installed in their home when participating in teleradiology services saving on transportation expenses with the additional attraction of flexible working hours.[6]

Improved Patient Outcomes - Telemedicine provides quicker delivery of care, which leads to improved continuity of care. Doctors can get a more accurate diagnosis of their patients with the quick access to a second opinion by teleconsulting with a specialist.

Cutting Edge Opportunities - Finally, state of the art equipment such as remotely controlled surgical robots are opening up many future opportunities

for research, the military, and NASA.

Compliance and Legal Issues
The telemedecine industry faces many challenges. Hospitals and other providers need to conduct due diligence before engaging in any telemedicine activities. Here are some of the issues:

Interstate Licensing Issues - The essence of telemedicine is practicing medicine without borders. Technology enables the provider to render an opinion or interpret a test on a patient living down the road as easily as one living in a different state or across the world. However, when telemedicine is practiced across state lines, licensure becomes an issue. The patient's physical location, i.e. the "originating" site, identifies the location where the health care is provided; so a provider must abide by the laws of that state. In many cases, this may mean that the provider has to get licensed in that state. This can be quite burdensome for a telemedicine provider who may have to fill out multiple licensure applications and pay multiple registration fees in order to practice. In addition, each state has its own licensure laws regulating telemedicine with varying degrees of restrictions or exemptions. In Arizona, licensure requirements do not apply if a doctor licensed in another state, engages in an episodic consultation about a patient with a doctor licensed in Arizona. Montana, on the other hand, prohibits the practice of telemedicine without a telemedicine certificate issued by the State Board of Medical Examiners. [7&8] Some states have not determined how they want to address the out of state providers licensure issue. It is not just a physician issue, hospitals may be viewed as "aiding and abetting" the physician who is practicing telemedicine without a license in another state. A hospital must carefully review each state's requirements with their Legal Department before engaging in any kind of telemedicine involving physicians in other states.

Several medical specialties such as the American College of Radiology (ACR) have developed guidelines for telemedicine activities to ensure the protection of the patient. On the topic of overseas contracting for teleradiology, the ACR recommends that the overseas radiologist "be licensed by the state(s) and credentialed by the U.S. hospital(s) that contracts for their services as stated in the American College of Radiology Teleradiology Technical Standards." The interpreting physician should also be covered by medical malpractice insurance. Hospitals should conduct due diligence when entering in contractual arrangements with teleradiology companies.

Discussions are underway to try to resolve these licensure dilemmas. The 2001 Telemedicine Report to Congress outlined different alternatives to address these issues including assessing the feasibility of developing common licensure application forms.

Credentialing Issues – Another dilemma for which solutions are not clearly defined by the regulations are credentialing issues. Must a telemedicine provider be credentialed in the state the patient is located? Various credentialing organizations such as Joint Commission of Accreditation (JCAHO) have provided some standards for telemedicine, which indicate that a licensed practitioner who is responsible for the care of a patient via a telemedicine link is subject to the credentialing and privileging processes of the originating site. However, the originating site can use the credentialing information from the distant site, if the distant site is a JCAHO–accredited organization (Standard MS.13.01.01). JCAHO does not address all areas of telemedicine services. Consultative services, for example, fall outside the scope of the JCAHO telemedicine standards.[9] And what about the teleradiologist who is unaffiliated with a particular hospital and practices independently? Telemedicine is still an underdeveloped medical-legal frontier.

Security and Privacy Issues
Privacy, security and confidentiality issues are not unique to telemedicine. Similar to any other electronic transactions, hospitals must ensure that adequate precautions are taken when transmitting protected health information (PHI) out of the hospital networks. Since telemedicine activities can be broadcasted anywhere, the concerns are perhaps more prevalent. The America Medical Association (AMA) has developed guidelines for physician-patient e-mail communications. Advances in technology have brought great benefits as well as drawbacks in this area.

Informed Consent
Physicians practicing telemedicine must also consider informed consent requirements, which vary from state to state. In some states, the informed consent requirements do not apply if the patient is not involved directly in the telemedicine activity (such as consultative services). In addition, the physician home state may have different informed consent requirements than the state where the patient resides. The treating physician should explain to the patient not only the risks associated with the telemedicine service, but issues such as which state the telemedicine provider is licensed/credentialed in, the process for follow up care, the equipment required, and the operating staff that may be required at the originating site and at the distant site.[10]

Telemedecine Equipment
The technology involved with a telephone or simple videoconference hookup for telemedicine services is easy to use and readily available. However, depending on the type or equipment or technology used in the telemedicine service, the provider may be required to abide by state and federal regulations related to the use of such equipment. The Federal Food and Drug Administration (FDA) has the responsibility for regulating the safety and effectiveness of medical devices and therefore may regulate software and hardware used to practice telemedicine. Also, telemedicine providers must also consider state regulations. Some states have instituted specific rules governing the use of the internet, e-mail and similar technologies when treating patients. Hospitals and telemedicine providers need to review FDA and state regulations in telemedicine arrangements in reference to equipment, related technologies and the use of the internet in the treatment of patients.

Reimbursement Issues
The lack of reimbursement for the provision of this mode of treatment is an obstacle to the expansion of telemedicine. Congress has taken some action in the Balanced Budget Act (BBA) of 1997 where some Medicare reimbursement for telehealth services was authorized. Congress has further directed CMS to establish a payment methodology for telemedicine services in rural shortage areas if certain conditions are met.[11]

Medicare - The Medicare Policy Benefit Manual has specific guidelines for coverage and payment for telehealth services. The list of services covered are; consultations, office visits, individual psychotherapy, pharmacologic management, psychiatric diagnostic interview examination, end stage renal disease related services, individual medical nutrition therapy, and most recently added in 2008, neurobehavioral status exam. The CPT codes used to report telehealth services are no different than regular services performed without the use of a telecommunications system (with the few exceptions already mentioned for telephone and online consultations and remote-real time interactive video-conferenced critical care services). The originating site must be located either in a rural health professional shortage area (HPSA) or in a county outside of a metropolitan statistical area (MSA). Authorized originating sites are limited to a physician's office, a hospital, a critical access hospital, a

rural health clinic, a federally qualified health center. On July 16, Congress passed H.R. 6331, expanding Medicare coverage beginning January 1, 2009, to include skilled nursing facilities, in-hospital dialysis centers, and community mental health centers as telemedicine sites.

The guidelines further state: "For Medicare payment to occur, interactive audio and video telecommunications must be used, permitting real-time communication between the distant site physician or practitioner and the Medicare beneficiary. As a condition of payment, the patient must be present and participating in the telehealth visit." The payment amount is equal to the reimbursement of the service without the use of telemedicine. There is one exception to the interactive telecommunications requirement in the case of Federal telemedicine demonstration programs such as the ones conducted in Alaska or Hawaii. In those cases, Medicare payment is permitted for "store and forward technology".[12]

Telephone calls and online consultations- Medicare does not pay for telephone calls or online consultations at this time. In fact, the Medicare Benefit Manual Medicare, Chapter 15 states that telephone call services are considered an integral part of the physician services and there is no separate payment. Though this article does not focus on non-federal payors, it is worth mentioning that Aetna and CIGNA HealthCare are already paying some physicians for online patient consultations.[13]

Homehealth - Federal regulations require face-to-face visits for home health, and telemedicine cannot be used as a substitute for those visits. However, a telemedicine encounter may be used as a supplement to the required face-to-face visits. Medicare Benefit Policy Manual Chapter 7 can be reviewed for further detail.
Teleradiology Outsourced - With respect to teleradiology outsourced to a different country, CMS prohibits payments to providers outside the United States. Hospitals with such arrangements would have to pay the overseas radiologists directly. The ACR has voiced concern about the interpretation of radiology images outside of the U.S., because of the risk that a U.S. radiologist would be signing off on the "ghost-read" radiographs without a careful review.[14]

Medicaid - The Centers for Medicare & Medicaid Service (CMS) has not formally defined telemedicine services for the Medicaid Program, however, in some states, Medicaid reimbursement is available for certain services.

2009 OIG WorkPlan
It is noteworthy that some form of telemedicine auditing is included in the 2009 Work Plan. The OIG will be reviewing the appropriateness of Medicare claims for long-distance evaluation and management services:
"Pursuant to the CMS "Medicare Benefits Policy Manual," Pub. No. 100-02, ch. 15, § 30, a service may be considered a physician's service if the physician either examines the patient in person or is able to visualize some aspect of the patient's condition without a third person's judgment. Although services provided by means of a telephone call between the physician and the beneficiary may be covered under Medicare, there are certain services that require a face-to-face visit. Previous OIG work identified instances of physicians billing for services that would normally require a face-to-face examination for beneficiaries who lived a significant distance from the physician. We will also examine factors that contribute to the submission of long-distance physician claims".

Per the Medicare Benefit Policy Manual, Chapter 15, Section 270.2, "the use of a telecommunications system may substitute for a face-to-face, "hands on" encounter for consultations, office visits, individual psychotherapy, pharmacologic manage-

ment, psychiatric diagnostic interview examination, end stage renal disease related services, and individual medical nutrition therapy". However, since the CPT codes used are, in most cases, the same as non- telemedicine encounters, it is unclear how the OIG will pull the data for this review.

Conclusion

Telemedicine plays a critical role in providing access to healthcare, especially in underserved areas. Providers must ensure that the risks of providing telemedicine services do not outweigh the benefits, carefully enter into agreements with the assistance of their Legal Department, and should develop telemedicine policies.

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