Computers, Medicine and the Law
Medicine

• Traditionally
  – The place where medicine was practiced and who was practicing was obvious
• Licensure regulated by the states
• Credentialing regulated by the institution
• Federal overrides
Vision

- Dr. Theresa Myers (neurologist) is conducting rounds in Coffee Creek Idaho. She pulls up x-rays and labs on her patient Barb Collins. Asks local PA to describe changing tremor. Then asks pt. To walk across room, write her name. Concludes Parkinson’s is worse, changes medicine. Looks out window at downtown SLC.
Vision

• Top neurologist provides direct care for underserved areas and consults with local MD’s via teleconferencing links and email.
Barriers

- Inadequate information infrastructure and uncoordinated planning
- Regulatory distortions, limitations on demand and fragmented demand
- Reimbursement policies do not compensate for telemedicine
- Physician licensing and credentialing rules discouraging telemedicine within states and across state lines
- Concerns about malpractice liability
- Concerns about patient information confidentiality
Infrastructure planning and development

• Uncoordinated regulatory and infrastructure development
  – Telecommunications regulation not geared towards telemedicine
  – Neighboring states with different agendas/development status
Telecommunications regulation

• Limited competition in some areas can lead to prohibitively high rates
• Small rural networks/users can’t compete
• Suggested remedies
  – State utility regulation
  – Mutual interest groups
    • MD’s, other practitioners, patients, hospitals etc
Telemedicine

• Standards
• Licensure
• Credentialing
• Malpractice
Safety/standards

• American College of Radiology
  – Has practice guidelines for teleradiology
• Standards under development
  – American Medical Association
  – American Telemedicine Association
  – American Nurses Association
ACR teleradiology standards

• Goals
  – Providing consultative and interpretative radiological services in areas of demonstrated need
  – Making radiologic consultation in facilities without on-site radiologic support
  – Providing timely availability of images and interpretation in emergent and no emergent clinical care areas
ACR

• Goals
  – Facilitating interpretation in on-call
  – Providing sub-specialty interpretations as needed
  – Enhancing education for practicing radiologists
  – Promoting efficiency
  – Sending interpreted images to referring MDs
ACR

• Specifications
  – Acquisition or digitization
  – Compression
    • Lossy vs. lossless
  – Transmission
  – Display
  – Archiving
  – Security
  – Reliability
ACR

- Licensing
- Credentialing
- Liability
- Documentation
- QC, safety, infection control, patient education
Safety/Standards

• Governmental players
  – FDA, FTC
Governmental action

• National communications and information infrastructure policy
  – Telecommunications bill of 1996
    • Carriers shall provide services to rural rates at same rates as urban rates
  – National Information Infrastructure
  – High performance Computing and Communications
    • Basic research, advanced technologies and networks: telemedicine, VR tools for surgery, CPR and digital imaging software
Governmental action

• State programs
  – Midwest, Great Plains and the South
  – Western Governors’ Association
  – Growing number of states have explicit telemedicine planning or developmental efforts
Licensure

• In the US, the states provide for licensing
• Licensure laws originally designed for the states to protect people from charlatans and untrained individuals pretending to be professionals
• Out of state practitioners must obtains licenses in the states in which they practice
• Consultation exception
Licensure issues

• License
  – Costly, hassle factor, face-to-face interview, testing

• Maintaining multiple licenses
  – Time, research (varying requirements), paperwork, travel, cost

• Varying obligations from state to state (confidentiality for example)
Licensure options

• National license
  – National telemedicine license
• Exemptions for telemedicine license
• No additional license for telemedicine
  – It is therefore analogous to transporting the patient to the site of the MD
• No additional license since the consulting MD retains responsibility for the patient
Licensure options

• Uniform regional licensure program
• Institutional or network license to all of the MD’s in a network
• Endorsement
• Mutual recognition
• Reciprocity
• Registration
Credentialing

• Institutional procedures determining whether providers may be employed and what their scope of practice
  – Must an individual be credentialed at home institution as well as institution originating consultation
Malpractice

• Definition
  – Deviation from the accepted medical standard causing injury to a patient for whom the provider has a “duty of care”

• Current policy
  – malpractice governed by state law
  – Laws vary as to duty of care, damages and (previously) standard of care (used to be regionally defined)
Malpractice issues

• Has the practitioner formed a provider-patient relationship via telemedicine
• Who is liable (consulting or referring MD)
• If sued, will the practitioner be presented with same legal issues as an MD in a standard lawsuit
• What are the risks, and therefore liabilities associated with the use of technologically advanced equipment
• Where is the practitioner practicing
Malpractice policy options

• National malpractice standard
• Very little discussion between government and carriers in regard to telemedicine
• Example
  – Georgia MD who practices in two other states
    • State 1 physician friendly, low awards
    • State 2 plaintiff friendly, high awards
    • Under existing rules, MD could be sued in state 2 for problem occurring in Ga
Privacy, confidentiality and security

- Informational privacy, data confidentiality, data security
- Computer based records
  - Make searches convenient
  - Easier collection and updating
  - Individual patient data access
- Solution: HIPAA
Reimbursement

• Fee for service
  – No current provision
  – Fears that fee-for-service would lead to escalation of costs
  – Medicare reimburses for face-to-face and telephone consultations
Reimbursement issues

• Lack of data pertaining to the value of telemedicine compared with traditional services
• Uncertainty about whether reimbursement would lead to excess service
• Potentially large increases in costs if telemedicine improves access to care in underserved areas
• Barriers to the sustainability of telemedicine in rural areas
Reimbursement

• What would be covered
• How procedures would be coded
• How do you set payment level
• How payment would be apportioned for consultation involving an attending MD and a remote specialist
• How are non-MD practitioners paid
• Should payments be divided into professional and facility potions and how split
Regulation of medical devices

- Devices subject to regulation by FDA
- Examples
  - Radiographic equipment
  - Remote surgery
  - Remote decision support
Other issues

• Anti-kickback
  – There is an incentive for telemedicine partners to refer to one another because they are mutually interdependent
  – Does this violate anti-kickback legislation

• Anti-trust
  – Do MD’s within a telemedicine network violate anti-price fixing laws
Other examples

• Online prescribing
  – Prescribing to unseen patients
    • Viagra, baldness medication, diet pills

• Online sales so far OK
HIPAA revisions

3/27/2002
- Bush administration rolled back some of the provisions of HIPAA
  - Eliminate consent requirement
  - Requiring providers to make good faith effort to secure a signed acknowledgement
  - Incidental disclosures (overheard conversations) not a violation when a good faith effort has been made
  - Providers may provide information about minors to parents when the state law is silent
  - Consolidating some of the required authorization forms