Hot Topics in Technology: 3D, Telemedicine, & Robotics

Victoria Vance, Esq.
Chair, Health Care Practice
Tucker Ellis LLP
Victoria.Vance@tuckerellis.com
Regulation of Medical Devices

Medical Devices:

- Devices made using 3D printing are subject to FDA regulation
- FDA has approved more than 85 3D printed medical devices
- FDA classifies devices:
  - Class I, II, and III based on risk profile
  - Escalating levels of premarket reviews/approvals
- Limited regulatory exemptions available:
  - Humanitarian Device Exemption; Investigational Device Exemption, and Custom Device Exemption
FDA Device Regulation

• FDA issued DRAFT guidance: “Technical Considerations for Additive Manufacturing” (March 2016)

• Manufacturer obligations
  • Register with FDA
  • List their devices
  • Comply with General Controls
  • Meet Quality System requirements (including design controls and supplier controls)
  • Device testing considerations
3D Printing: So What’s the Risk?

What is the Health Care Provider’s Role?

Design

Software

Material – Printer

Product

Patient
Shifting Legal Liability Paradigm

• **Strict Liability** – for commercial product manufacturers, manufacturer of component part, assembler, installer and seller

• “**Product**” – generally defined as “tangible personal property distributed commercially for use or consumption” (Restatement (Third) of Torts, Prod. Liab. §19(a))

• May apply to the printer and the finished device

• But what about the design process? Who is the seller?
Potential Exposures for Health Care Providers

- FDA regulatory process – only for commercial firms that manufacture, repackage, relabel and/or import devices sold in the U.S.

- Strict Liability for product – traditionally, only attaches to commercial sellers, not providers treating individual patients. But liability may expand if provider prints devices for outside sales.

- Potential liability for defective design & construction – if provider gives the patient specs used to create the device, or originates the design
Potential Exposures for Health Care Providers

- Long Term Integrity & Viability – of implanted products & materials
- Negligence – liability for breach of standard of care; or carelessness in product design, presurgical planning, or printing
- Standard of Care – will 3D printing and personalized treatments become the new SOC?
Potential Exposures for Health Care Providers

- Physician as “Learned Intermediary”
  - Duty to warn
  - Duty to heed warnings
  - Duty to give Informed Consent


- Institutional Liability: policies, procedures, purchasing, training, credentialing, supervision & controls (IRB, Bioethics)
3D Printing Applications for Providers

- Surgical planning
- Resident training and medical research
- Designing customized implants (bones, joints, stents)
- Vascularized tissues and human organs
- *In Situ* bio-printing during surgery
Other Legal Issues

- Security of technology—risk of counterfeit models, theft of product
- Cyber-Security—of CAD files, software programs
- Patent & Copyright protections
- Patient Privacy of personalized data & HIPAA
- Property rights in the models, tissues, devices, implants
• 3D reproduction of donated bodies and organs – to use for teaching and research; raises issues of consent and donor intent

• Access – will cost factors limit the availability of 3D personalized medical products?

• Safety – will the ability to test products for safety & efficacy prior to use still exist?

• “Human Enhancement” – making replica body parts and organs to achieve greater strength, functionality, longevity
Insurance Perspective

• “Developments in 3D Printing for Medical Purposes,” Pulse Newsletter Health Care Practice, Willis Towers Watson (April 2016)
  *Identifies recent developments in 3D printing and offers risk management recommendations*

• “3D Printing in Medicine – Implications for Insurance,” Swiss Re (18 April 2016)
  *These new healthcare technologies will require careful insurance analysis and novel solutions*
## Underwriters’ Checklist

- **Is 3DP being used? If so, how?**
  - Surgical planning/mapping
  - Implanted tissues, joints, bones, other
  - Medication delivery systems
  - Other

- **Role of Provider in 3DP**
  - Design
  - Software coding
  - Material Specifications
  - Construction--Printing
Underwriters’ Checklist

- Institutional / Operational Documents?
  - All contracts, agreements with printers, suppliers, designers, vendors
  - All indemnification provisions (is provider indemnitor or indemnitee?)
  - Is provider listed as an “additional insured” on supplier, designer, printer, vendor insurance

- Institutional Clinical Oversight?
  - Informed Consent Process: policies, procedures, forms
  - Product testing processes, records, systems
  - Interaction with FDA, IRB
Telemedicine
Scope of Practice & Services

• Remote monitoring of ICU patients
• Tele-stroke monitoring
• Remote neonatal monitoring of high risk deliveries
• Telepsychiatry
• Telebariatrics for pre- and post-op visits
“Telehealth” also includes

• Texting between patient & provider
• New devices: PT/INR home self-testing device, and digital stethoscopes
Market for Telemedicine

Health systems, ACOs, physician practices, home health care agencies, nursing homes, school clinics, and retail clinics, work places, and prisons
Patient Preference

In 2016 Kaiser Permanente CEO reported it sees more patients online than in person.
Benefits of Telemedicine

MAN, THIS TELEMEDICINE THING IS GREAT--I DON'T EVEN HAVE TO PUT MY PANTS ON!
Benefits

Access to expert care 24/7
Efficiency for patients & providers
Better management of chronic disease states
Improved quality of care
Cost effective – especially in era of bundled payments and value-based care
Enhance continuity of care, post-discharge management
Challenges - Limitations

Licensure – providing care across state lines
Quality of care – when the doctor can’t exactly “see you now”
Compliance – fraud & abuse
CMS – reimbursement rules
Cyber & security
Interstate Licensing Issues

In a FSMB survey, Telemedicine was ranked as #1 regulatory topic for State Medical Boards in 2016.

The Interstate Medical Licensure Compact – will enable physicians to practice in multiple states:

- 18 states adopted the Compact
- 8 states and D.C. have legislation pending
- The IMLC Commission began accepting applications April 2017 from qualified physicians
State Regulation

• Telemedicine-related legislation introduced – pending – passed in virtually every state:
  • In 2016: 150 bills introduced in 44 states addressing:
    • Reimbursement & private payer laws
    • Interstate licensure
    • Medicaid program requirements
Some state telemedicine regulations restrictive; raise antitrust concerns: see Teladoc v. Texas Medical Board litigation battle, resolved Feb. 2017, Texas S.B. 1107 now pending

Several states ban prescribing of abortion-inducing meds via telemedicine

- Idaho settled lawsuit brought by Planned Parenthood to repeal such restrictions (Jan. 2017)
Telemedicine affiliation arrangements have the potential, with requisite intent to induce improper referrals, and trigger kickbacks.

OIG Advisory Opinions
- No. 98-18
- No. 99-14
- No. 04-07
- No. 11-12

Telemedicine arrangements are permissible if structured appropriately to reduce the risk of prohibited kickbacks.
(July 2016) Danbury psychiatrist paid $36K to settle whistleblower allegation of submitting false claims for “telehealth” services provided to Medicare beneficiaries over the phone, instead of in person.

Services did not qualify for CMS reimbursement: patients not in rural health shortage area and provider did not use audio-video real time technology.

United States ex rel. v. Anton Fry, M.D. and CPC Associates, Inc., U.S. District Court, Dist. of Conn., Case No. 3:14-cv-1516 (AWT)
Telehealth False Claims Cases

(July 2015) $8M False Claims Act settlement with Jacksonville, FL compounding pharmacy. Concern that suspect prescriptions came from three-party “telemedicine” arrangements, involving marketing companies, directing patients to physicians.

United States v. Blanding Health Mart Pharmacy, Middle District of Fla. (July 15, 2015)
CMS Telehealth Services Fact Sheet for CY 2017

- Defines “originating site” and “distant site practitioners”
- Describes required interactive audio & video telecommunication systems
- Lists approved Medicare Telehealth Services (HCPCS/CPT Codes)
- Detail claim submission requirements
Reimbursement

Telehealth coverage and reimbursement policies

- Medicaid only
- Medicaid and private payers
- None

Source: National Conference of State Legislatures
Quality of Care Concerns

- Sufficiency of remote exam vs. hands-on exam
- Accuracy of assessment, diagnosis & prescribing
- Completeness of encounter
- Timeliness of services (i.e. interpretation of radiology)
- Delay in recognizing urgent/emergent conditions
- Documentation of encounter
Practice Guidance

• FSMB “Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine” (April 2014)

• AMA “Guidance on Ethical Practice in Telemedicine” (June 2016)

• Follow Institution & Practice Group Guidelines
Liability Risks

• Adequacy of informed consent
• Equipment malfunction (resolution, clarity, data transmission)
• Patient/consumer detrimental reliance on wellness & mobile apps
• Language barriers or low health literacy
• Mistaken identity: patient, provider, or practicing beyond scope of licensure
Litigation Considerations

- Venue & Jurisdiction: where will suit be filed?
- eDiscovery – preservation of relevant evidence, images, transmission data, metadata
- Evolving “Standard of Care”
Cyber & Security Concerns

- Breach of privacy
- Security & storage of data
- Integration with EMR
- Access controls
- Costs of upgrades
- HIPAA Business Associate Agreements for vendors & service providers
Cybersecurity Recent Events

Guidance

FDA “Postmarket Management of Cybersecurity in Medical Devices,” issued Dec. 28, 2016

Manufacturers urged to proactively address cybersecurity risks throughout a product lifecycle, develop comprehensive cybersecurity risk management program, and set forth framework for reporting cybersecurity vulnerabilities to FDA according to patient risk.
Cybersecurity Recent Events

(Jan. 2017) FDA & Department of Homeland Security warned of cybersecurity vulnerabilities in St. Jude Medical’s Merlin@home wireless transmitter – used with line of implanted cardiac devices (ICDs).

FDA warning letter issued April 12, 2017 regarding adequacy of company’s cybersecurity risk assessments for high voltage & peripheral devices.
The Risk & Reward of Robotics

“Despite the rapid uptake of robotic-assisted surgery, the usefulness of the technology has been questioned. For many procedures, particularly those in which other minimally invasive alternatives are already available, robotic-assisted surgery has not been shown to reduce complications or improve outcomes, but it is substantially more costly than other alternatives.”

Wright JD et al., “Effect of Regional Hospital competition and Hospital Financial Status on the Use of Robotic-Assisted Surgery” JAMA Surg 2016; 151(7):612-620 (citations in original)
Practice & Procurement: “Medical Arms Race”

- Heavily marketed technology (direct to consumer, physicians, hospitals)
- Substantial costs: $1.5m-$2m for robotic system; extra costs for maintenance, equipment, training & personnel
- Competitive market pressures influence purchase; purchase leads to demand for use
Robotics Risks & Claims

• Outcomes:
  o Unintended laceration/puncture
  o Bleeding/hemorrhage
  o Thermal injury
  o Positioning injuries
  o Retained foreign bodies
  o Infections—cleaning of equipment; maintaining sterile technique
Root Causes Uncovered

- OR staff unfamiliar with equipment & robotic protocols
- Robotics requires new patterns of communication among OR team
- Equipment malfunction, loss of power, data interruption
- Inappropriate patient & case selection
- Increased surgical time
- Surgeon’s training & experience; exposes hospital’s credentialing & privileging process
Root Causes Uncovered

- Inadequate Informed Consent
- Role of manufacture (representative) — in training, supervision, marketing & promotion
- Influence of marketing & competitive pressures to buy and use robot
- Financial pressures and conflict of interest
Case Examples

$6.225M settlement (N.J. March 2016)

• Robotic sling procedure and hysterectomy
• Failure to control robot
• Perforation to bowel, outside field of operation
• Resulted in permanent colostomy
Case Examples

$5M verdict (IL. March 2016)

- Death of 36 yof undergoing robotic hysterectomy
- Tip of trocar lacerated common iliac artery
- Failure to timely recognize bleeding, patient decompensated
- Patient coded and expired
Case Examples


- Robot failed at or before pancreatectomy and islet cell transplant surgery
- Rep in room, allegedly promoting off-label use of device
- Suggested financial motivations to use device
- No medical malpractice claims asserted

**Result:** Product liability claims dismissed
Confidential Settlement (New Jersey, July 2013)

- $375K settlement – urology malpractice
- Plaintiff claims doctor delayed PSA testing and follow-up, causing delay in diagnosis of cancer
- Advanced disease made risky robotic surgery necessary
- Risk materialized: transected iliac artery
Foreign Object Case

*Elsey v. Laury, MD*, D. Oregon (Nov. 2013)

- $110K verdict
- Pieces of daVinci sheath discovered three years following removal of right ovary & fallopian tube, and appendix
- Hospital records reveal robot malfunctioned during surgery; Plaintiff was never informed
- Alleged daVinci should not have been used, as the surgeon lacked proper training or experience with robotic device
Lack of Informed Consent


- $95K settlement
- Death following robotic removal of heart tumor
- Allegations of lack of informed consent regarding risks of robotic surgery: increased risk of bleeding, increased surgery time, increased time on bypass
- Patient not told that robotic surgery was simply an option, and that surgery could be performed using traditional methods
Lack of Informed Consent

_Delong v. Ekunno, MD_, 2016 WL 3537795 (Mo. Cir., March 2016)

- $47K verdict
- Claims of injury following laparoscopic hysterectomy
- Alleged failure to inform patient that robotic surgery would be used to perform the surgery and failed to inform of the risks of using the da Vinci system
Washington State Supreme Court found Intuitive Surgical, Inc. had a duty to warn purchasing hospital of risks associated with “da Vinci” surgical system, rejecting “learned intermediary” doctrine, and vacating defense verdict in wrongful death case.

Training in robotic surgery is fast becoming an essential component of surgical training programs:

- Online robotic training at [www.davincisurgerycommunity.com](http://www.davincisurgerycommunity.com)
- Didactic instruction and readings
- In-house workshops, to learn docking, instrument exchange, console training and bedside training
- Observe live Robotic Assisted surgical procedures
- Serve as Bedside assistant during robotic cases, responsible for docking, instrument exchange, positioning
- Mount Sinai Health System (N.Y.C.) started a Robotics Institute at the Icahn School of Medicine (Jan. 2017)
Robotic Surgery Curriculum

- Successfully complete basic & advanced modules on simulator, inanimate training aids, and live animals
- Serve in role of Console Surgeon, performing progressively advanced surgical tasks
- Assist junior residents in robotic training
- Post-case reviews with attending surgeon

Curriculum Review

- Ongoing assessment and development of training curriculum
- Include objective measurements of operative performance
Privilege & Credentialing Criteria for Robotic Surgery

Challenges:

• Credentialing is performed locally at institutional level

• Surgeons present with varying degrees of experience:
  - Residency/Fellowship trained in robotics
  - Attending level surgeons with robotic experience from prior institution
  - Attending level surgeons new to robotics
Privilege & Credentialing Criteria for Robotic Surgery

- Influential role of industry in training & credentialing programs
- Steep learning curve to gain proficiency
- “Use it or lose it”—need for volume to maintain proficiency
- Evolving development of national consensus guidelines for training & credentialing, across surgical specialties
- Must also train and credential the Surgical Assistants to provide OR bedside care during Robotic surgeries
Resource Organizations

- Society of Urological Robotic Surgeons (SURS)
- Society of American Gastrointestinal & endoscopic Surgeons (SAGES)
- Minimally Invasive Robotic Association (MIRA)
- American Association of Gynecologic Laparoscopists (AAGL)
- AUA Core Curriculum *Fundamentals of Urologic Robotic Surgery*
- Society of Robotic Surgery
- Clinical Robotic Surgery Association
Components of a Robotic Credentialing Program

Prerequisites

• Board Certified or Board Eligible within their surgical specialty or subspecialty

• Unrestricted privileges for the surgical procedure(s) to be performed robotically, with satisfactory complication rates

• Provide Certificate of Attendance at a hands-on training course, or log of cases performed at prior institution over the last 2 years, or Letter from Residency Program Director attesting to successful performance of robotic training, with case list
Components of a Robotic Credentialing Program

Training

• Preclinical didactic course
• Complete approved on-line training
• Observe live robotic-assisted surgeries
• Complete bedside training
• Complete hands-on training with inanimate training aids
• Demonstrate competency on robotic simulator
Components of a Robotic Credentialing Program

Provisional Privilege Track—BASIC ROBOTIC CASES

- Operate with experienced assistant (X cases) →
- Proctored cases (X cases) →
- Peer Reviewed/Chart Review cases (X cases) →
- Perform basic cases without complications (X cases)
Components of a Robotic Credentialing Program

Provisional Privilege Track—ADVANCED ROBOTIC CASES

• Take advanced training courses (online, in simulator)
• Proctored (X) cases with Advanced-Trained Assistant →
• Peer Review of cases (X cases) →
• Maintain minimal volume of cases per year
Components of a Robotic Credentialing Program

Monitoring Privileges

- To maintain skill: require a minimum volume of cases/year
- Demonstrate proficiency annually on a robotic simulator
- Submit to proctored surgery of X cases, checklist of results to be submitted to credentialing office
- Bedside assist at robotic surgeries at least quarterly
- Take CMEs in robotic surgery
Components of a Robotic Credentialing Program

Biannual Review/Reappointment Process

• Review volume of cases over prior two years

• Proctor and/or Peer Review a selection of cases

• Repeat training if there is a gap in cases or to address complication/skills issues
Hospital Infrastructure to Support Robotics Program

• Surgical Leaders
  • Proctor Surgeons
  • Mentor Surgeons

• Equipment
  • Dedicated ORs
  • Simulation Lab and Training equipment

• Surgical Team
  • Robotic Surgical Coordinator
  • Nurses trained in robotics
  • Technical Support Staff
Hospital Infrastructure to Support Robotics Program

Oversight and Supervision

• **Robotics Peer Review Committee** – multi-disciplinary, to oversee and implement credentialing guidelines, review patient & case selection criteria, monitor surgical performance to ensure adequate outcomes and volumes

• **Ongoing Quality Assurance** – to ensure appropriate use of technology and patient safety

• **Institutional Policies & Procedures** – Including *Robotic Surgery Informed Consent*
Taking Stock of Robotic Surgery: Outcomes Measures

- Length of stay
- Blood loss
- Complication rates
- OR time
- Conversion to open; conversion to laparotomy
- Robotic case volumes
- Post operative pain scores
- Presentation to ER within 2 weeks
- Readmission within 30 days
Underwriters’ Checklist

- Number of robot systems in use; type, model, age, purpose
- Policies & Guidelines for Credentialing & Training of surgeons, assistants and OR staff
- Outcomes Measures & Metrics for Robotic Procedures
- Operational Infrastructure in Place?
  - Robotics Peer Review Committee
  - Robotics OR Committee
  - Robotics trainers, mentors, proctors
- Patient Safety Satisfaction Scores
- Nursing and Staff Satisfaction Scores
Resources

A bibliography of references and source documents for 3D Printing, Telemedicine & Robotics is available at today’s conference.

Also available upon request: Victoria.vance@tuckerellis.com