Introduction of New Procedures/Technology: Training, Credentialing, and Privileging

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Outline

• Regulatory Oversight

• The baseline: Credentialing and privileging

• New procedures and technology: Training and privileging

• The future
To earn the right to practice medicine, a candidate had to prove himself by treating three heretics. If all lived, he was considered fit to practice. If all three died, he was denied the right to practice.
Definitions

Training—Acquisition of skills necessary to perform a new procedure *competently*

Credentialing—Process by which hospitals confirm the qualifications of providers

Privileging—Process by which hospitals authorize providers to perform specific patient care activities
Regulatory Oversight: Who Owns This?

Training—ACGME, ABMS/ABO (MOC)

Credentialing/Privileging—BORM, Joint Commission, CMS

Introduction of New Procedures—?, payers

Introduction of New Devices—FDA, payers
Credentialing and Privileging standards
MS.4.00-MS.5.10

- The hospital collects information regarding each practitioner’s current license status, training, experience, competence and ability to perform the requested privilege (MS.4.10).
- The decision to grant or deny privileges or to renew them is an objective, evidence-based process (MS.4.15).
- The medical staff defines the circumstances requiring monitoring and evaluation of a practitioner’s professional practice (MS.4.30).
- The medical staff provides the oversight for the quality of care, treatment and services by recommending members for appointment to the medical staff (MS. 4.60).
The Front End: Initial Credentialing

- Investigate and assess the professional and personal background

- MD, residency, board certification, licensure, DEA, malpractice, Cori check, NPDB, adverse professional actions, malpractice
The Front End: Initial Privileging

- Chief/Chair considers training and experience and scope of practice as defined by board
- Chair and Medical Staff approve core and advanced privileges
- Role for initial precepting/proctoring, provisional privileges with Focused Practice Performance Evaluation (FPPE)
The Front End: Precepting/Proctoring

• Preceptor role is to help learner acquire new skills. Assesses skills and provides feedback. Assists in the procedure and available to take charge

• Proctor role is to assess skills and report back to privileging. Generally an observer who does not participate
The Front End: Challenges

• Significant variability in training programs
• Few validated direct assessment tools
• Variability of learning curves
• Limits of transferrable skills
• Competence v. proficiency v. mastery
The Back End: Recredentialing and Reprivileging

- Examination of outcomes with Ongoing Practice Performance Evaluation (OPPE) at intervals of more than once a year
- Recredentialing at 2 year intervals
- Outcomes—morbidity and mortality, LOS and readmissions, appropriateness, PCO
- Process—volume, blood utilization, PSI, medical record completion, SCIP adherence, ER availability, patient complaints, malpractice cases, etc.
The Back End: Challenges

- Wide variation in criteria
- Little risk-adjusted physician-specific data
- Access issues particularly for emergency procedures
- Physicians work at multiple facilities
- Threat of legal action
What about New Procedures/Technology?
THE DOCTOR'S WORLD; When Patient's Life Is Price of Learning New Kind of Surgery

By LAWRENCE K. ALTMAN, M.D.
Published: June 23, 1992

"SEE one, do one, teach one."

That is the classic doctors' description of the way new procedures and operations are taught.

But the credo seems destined for deserved oblivion.

Alarmed about rising numbers of deaths and serious injuries from a new method of gallbladder surgery, in which surgeons use miniature video cameras and instruments inserted through tiny incisions, the New York State Health Department has demanded tighter regulations. It has directed hospitals to be stricter in deciding which surgeons can perform the procedure and to pay more attention to their results.
Surgical robot da Vinci scrutinized by FDA after deaths, other surgical nightmares

The high-tech robot is being used in surgeries for prostates, gallbladders and wombs, but reports of problems have emerged, ranging from sliced blood vessels to patients being hit in the face.

THE ASSOCIATED PRESS / Tuesday, April 9, 2013, 10:34 AM

Surgeons say the advantages of the da Vinci robot include allowing them to operate sitting down, using small robotic hands with no tremor. The FDA is looking into problems and deaths that may be linked with robotic surgery.
New Procedures/Technology: Challenges

• No standards for what is really “new”
• No national review process for new procedures
• FDA review for devices less rigorous than for drugs?
• No real oversight of training and often by default falls to device manufacturers
• Standards for privileging take time
• Need to stay competitive may trump safety
Taylor v. Intuitive 2013

• Intuitive advised hospital on privileging criteria
• Surgeon had taken Intuitive’s course and been precepted for 2 cases
• Alleged that Intuitive failed to provide adequate oversight, training, and information on risks and decision-making
• Washington State jury ruled in favor of the defense, no negligence on the part of Intuitive
Adoption of Sentinel LNB in Kentucky

Percent of General Surgeons Practicing Breast Surgery and Performing SLN Biopsy

Number of Cases Before Stopping Axillary Dissection among Rural Surgeons

Number of Cases Before Stopping Axillary Dissection among Non-rural Surgeons

The Breast Journal 2005
Optimism Is A Force Multiplier
Advanced Procedures and Technology Committee

Purpose:

• To establish a mechanism for reviewing requests for clinical services or new technology that is not currently offered or used at the hospital

• Upon completion of review, recommend whether the procedure requested is:
  1. An extension of current privileges
  2. An advanced procedure or technology that will require additional training and privileging
Advanced Procedures and Technology Committee

Process:

• Physician/service submits a request with information regarding the procedure, indications, benefits, risks and necessary equipment, training, and privileging criteria.

• Multidisciplinary committee reviews and assesses whether the facility has a need for the treatment or device and recommends a training/privileging plan. Eventually reviewed and approved by Medical Staff Executive Committee/BOT.
ROBOTIC GYNECOLOGIC SURGERY: PATIENT SAFETY AND ADVANCED TECHNIQUES

Establishing a Robotic Credentialing Process

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Special Article

Guidelines for Privileging for Robotic-Assisted Gynecologic Laparoscopy

AAGL Advancing Minimally Invasive Gynecology Worldwide

DISCUSS

You can discuss this article with its authors and with other AAGL members at http://www.AAGL.org/jmig-21-4-JMIG-D-14-00082
Ladder to privileging for basic procedures.

1. 15 Basic Cases w/o Complications or Issues
2. 5 Cases Peer-Reviewed
3. 2 Cases Proctored

Ladder to privileging for advanced procedures.

1. 20 cases per year
2. 2 cases with an Advanced Assistant Surgeon
3. 5 cases Peer Reviewed
4. Advanced Training Course
5. Advanced Simulation
people before the robot

- **Robotic Executive Committee** is the administrative foundation of a robotic surgery program
- **Robotic Steering and Safety Committee** of surgeons in place by the time the robot is purchased
- **Robotic Operations Committee** to oversee/improve daily operations when the program is up and running
REQUIREMENTS FOR INITIAL PRIVILEGES

- Specific surgical privileges (e.g. laparoscopic hysterectomy, laparoscopic prostatectomy, etc.)
- SAGES FLS (Fundamentals of Laparoscopic Surgery)
- Proof of Robotic Proficiency
- Preceptorship (by Expert robotic surgery proctor)

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PROOF OF ROBOTIC PROFICIENCY (EITHER)

- **Formal standardized post-residency training:**
  - Dry Lab Practicum and Animal Lab Practicum with industry certification
  - Case observation (minimum 3)
  - Evidence of full proficiency at digital simulation (Morristown protocol)

- **Formal postgraduate-level training**
  - Minimum of 15 cases with >20% console time within 12 months
  - Evidence of full proficiency at digital simulation (Morristown protocol)

- **Privileges at accredited US hospital**
  - Chairman letter: minimum of 10 cases within 24 months
PRECEPTORSHIP

- **Minimum** of 3 precepted cases (1 if prior privileges)
- **BWH Expert Preceptor by default**
  - Designated by Dept. Chair and Director of Robotic Surgery
  - Preceptor is first surgeon on case (bills for case) and trainee is assistant
- **Massachusetts Licensed Preceptor - second choice**
  - Only if BWH Expert preceptor not available
  - Limited institutional license can be obtained. Surgeon pays fee.
- **Out-of-State preceptor - third choice**
  - As above. Institutional license not an option.

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ANNUAL RENEWAL OF PRIVILEGES
(two month grace period granted by default)

- \( \geq 12 \text{ cases/year} \): No action required
- 5-11 cases/year: Pass Morristown protocol
- < 5 cases/year: Pass Morristown protocol
  - Expert-proctored for one case
- 0 cases/year: Privileges are lost, must re-apply
Advanced Procedures and Technology Committee

Challenges:

• Criteria for review
• Expertise, turf, value, ethics
• Establishing a new training paradigm
• Time and $
The future ain’t what it used to be.

Y. Berra
The Houston Methodist Institute for Technology, Innovation & Education (MITIE<sup>SM</sup>) is an innovative virtual hospital and hands-on clinical training facility for healthcare professionals seeking to maintain excellent procedural skills and acquire new proficiencies. We aim to improve patient safety through these educational pursuits and to conduct research on skills acquisition and technological development.
PERSONAL BEST
TOP ATHLETES AND SINGERS HAVE COACHES. SHOULD YOU?

BY ATUL GAWANDE

Gawande A New Yorker 2011

No matter how well trained people are, few can sustain their best performance on their own. That’s where coaching comes in.

ILLUSTRATION BY BARRY BLITT
Surgical Skill and Complication Rates after Bariatric Surgery

John D. Birmeyer, M.D., Jonathan F. Finks, M.D., Amanda O’Reilly, R.N., M.S., Mary Oerline, M.S., Arthur M. Carlin, M.D., Andre R. Nunn, M.D., Justin Dimick, M.D., M.P.H., Mousumi Banerjee, Ph.D., and Nancy J.O. Birmeyer, Ph.D., for the Michigan Bariatric Surgery Collaborative

Variation in surgeon technical skill for 20 bariatric surgeons performing laparoscopic gastric bypass using OSATS
A. Complications

Surgeon Skill

![Graph showing the relationship between surgeon skill and complications](image)

- Any Complication: p<0.001
- Surgical Complication: p<0.001
- Medical Complication: p=0.001

B. Resource Use

Surgeon Skill

![Graph showing the relationship between surgeon skill and resource use](image)

- Reoperation: p<0.001
- Readmission: p=0.010
- ED Visit: p=0.004

Relationship of surgeon technical skill and risk-adjusted complications (A) and resource use (B)
When you come to a fork in the road, take it.

Y. Berra