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Collaboration Benefits Leaders and Insureds

Combined, nearly 75 percent of cases involved emergent or otherwise unplanned care, and most cases involved care provided in the emergency department. Patient outcomes were nearly always serious—most involved death or significant permanent injury. Most diagnostic errors SHAM observed were related to the traumatology specialty (46.7 percent of cases). In those cases, SHAM identified the most frequently missed diagnoses as either fracture or dislocation (43.0 percent). ProAssurance observed the specialty most frequently associated with diagnostic errors was emergency medicine (37.2 percent) where most patients presented with abdominal or gastrointestinal pain (19.1 percent).

The main causes SHAM found contributing to diagnostic error allegations included: failure to order additional tests or exams (57.6 percent), poor clinical examination, medical background not reviewed (42.4 percent), misinterpretation of X-rays exams, blood tests or EKGs (32.3 percent), and no requirement of specialist (15.1 percent). ProAssurance identified main causes contributing to diagnostic error included failure to order additional testing (21.7 percent), improper interpretation of a study (20.3 percent), inadequate physical exam (13.0 percent), and failure to seek consultation of a specialist (13.0 percent).

	SHAM	ProAssurance
Failure to order additional testing	57.6%	21.7%
Inadequate physical exam of the patient	42.4%	13.0%
Improper interpretation of a study	32.3%	20.3%
Failure to seek specialist consultation	15.1%	13.0%

More thorough documentation of the diagnostic process, especially the differential diagnosis, may have assisted in a more effective defense of those claims.

Of the 150 total claims included in the study, 43 came from ProAssurance and 107 came from SHAM. Patients associated with the claims were 55 percent female and 45 percent male. Most of the patients involved were adults with a median age of 54 (ProAssurance) and 41 (SHAM). Other contributing issues outlined by investigators included outdated protocols, understaffing, non-availability of physician, delays in writing medical reports, access to patient records, and access to test or lab results. Additionally, investigators observed opportunities for improvement in communication between providers and nursing staff, documentation (including EHRs), and tracking and follow-up processes for test results.

By studying these claims, the Companies identified distinct differences but overall similar results. ProAssurance and SHAM will continue to study closed claims as they update and develop new patient strategies for their insureds.

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Key Considerations is published twice annually by ProAssurance's Risk Resource Department
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KEYconsiderations
For Healthcare Organizations

PROMOTING PATIENT SAFETY • PROVIDING SOUND ADVICE • PLEDGING TREATED FAIRLY

VOLUME 11 • SUMMER 2018

Robotic-Assisted Surgery

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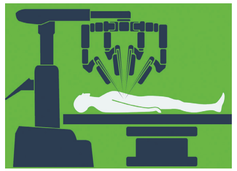

If you have questions on this topic, please contact a Risk Resource Advisor at 844.223.9648 or RiskAdvisor@ProAssurance.com.

A Perfect Storm

An active 67-year-old retiree entered the hospital for what he thought would be a routine prostatectomy. The urologist recommended robotic-assisted surgery (RAS), and the patient and his spouse agreed to proceed. The patient did not know this would be the surgeon's first independent robotic surgery. The planned five-hour RAS evolved into a 13-hour open surgery. The patient experienced a succession of complications including kidney failure, sepsis, stroke, cognitive deficits, a torn rectum, and blood loss requiring several transfusions. He experienced permanent incontinence, required a colostomy, and was debilitated until he succumbed to heart disease four years later.

Experts testified at trial that "confidence" with the device is not achieved until a surgeon has completed 150 to 250 procedures.[1] Prior to performing this procedure, the surgeon had participated in only two proctored robotic prostatectomies—before the hospital granted the surgeon the privilege to independently perform RAS.

Surge in Popularity

"Robot-assisted surgery currently is performed at more than 2,025 academic and community hospital sites nationwide, with growth in excess of 25% annually."[2] While there are at least a dozen surgical robotic companies, Intuitive Surgical, Inc., which manufactures the da Vinci® Surgical System, dominates the market. According to Intuitive Surgical's website, since 2000, more than three million patients have experienced RAS worldwide, using a da Vinci Surgical System. "Every 60 seconds, somewhere in the world, a surgeon uses a da Vinci Surgical System to bring a minimally invasive surgical option to a patient."[3]

With the proliferation of robotic surgery, hospitals may feel pressured to purchase robotic systems. They may also encourage physicians to promote this technology to patients as a means to recoup the investment. However, safe implementation into clinical practice remains a priority. In an effort to maintain quality care, institutions want to ensure that appropriate patient counseling and informed consent for RAS happen consistently. Compliance can be measured by auditing informed consent materials and intermittently interviewing patients.[4]

When making decisions, patients rely on physicians for advice. They expect an objective overview of risks, benefits, and alternatives including the probability of unexpected outcomes. An editorial in *The Lancet* notes, "In medicine, the discomfort of uncertainty, desire to constantly improve, failure to recognise personal biases, and susceptibility to aggressive marketing can lead to innovation being embraced without rigorous evaluation."[5] By not requiring evidence of benefit, hospitals and healthcare organizations may risk the use of inferior techniques or limit the adoption of successful ones.[6]

[1] *Josette Taylor v. Intuitive Surgical Inc.*, FindLaw for Legal Professionals (February 9, 2017), http://caselaw.findlaw.com/wa-supreme-court/1777420.html, accessed February 17, 2018.

[2] "Committee Opinion No. 628: Robotic Surgery in Gynecology," The American College of Obstetricians and Gynecologists, Obstetrics & Gynecology, March 2015, vol. 125, issue 3, p. 760-767, reaffirmed 2017, https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Robotic-Surgery-in-Gynecology, accessed April 2, 2018.

[3] "Moving Surgery Forward," https://www.intuitivesurgical.com, accessed March 29, 2018.

[4] Tara Kirkpatrick, MD, and Chad LaGrange, MD, "Robotic Surgery: Risks vs. Rewards," AHRQ PSNet Patient Safety Network, September 10, 2016, https://psnet.ahrq.gov/webmm/case/368/robotic-surgery-risks-vs-rewards, accessed February 16, 2018.

[5] "Robotic surgery evaluation: 10 years too late," The Lancet, February 2016, http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31586-0/fulltext, accessed on February 16, 2018.

[6] Ibid.

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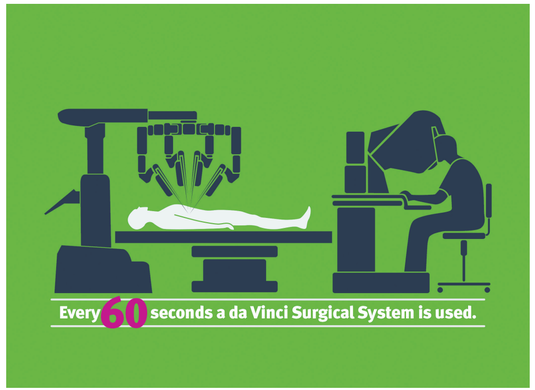
Robotic-Assisted Surgery

Developing Standards

The skyrocketing interest in RAS could lead patients and hospital personnel to believe that surgeons using this equipment have appropriate training, credentials, and expertise—and that privileges have been granted to surgeons meeting minimum competency criteria. In both 2014 and 2015, the ECRI Institute listed robotic surgery complications due to insufficient training requirements on its Top 10 Health Technology Hazards list.[v] Currently, there is no consensus on the appropriate type and duration of training for credentialing surgeons to perform RAS. Requirements also vary widely between facilities. "The lack of a standardized training curriculum lends itself to serious disparity in the quality of robotic training depending on trainee location and specialty."[vi] Repetition is the hallmark of proficiency, no more so than in surgery. Yet, some hospitals require surgeons to be proctored for just a few robotic surgeries before granting privileges to perform independently.

Several professional societies have made their own recommendations for physician credentialing. The American Urological Association (AUA) and the American College of Obstetricians and Gynecologists (ACOG) have shared their views regarding physician training. Robot-assisted laparoscopic prostatectomy accounts for 85% of all prostate surgeries performed in the US.[vii] Taking into account this high volume of urological procedures, robotic surgery has been included in the AUA's Core Curriculum for urology residencies. Urologists completing a residency and/or fellowship training program should complete a minimum of 20 cases; these can be pediatric and/or adult robotic surgical cases. However, the trainee must have console time for a key portion of the procedure with at least ten cases.[viii]



Gynecologic procedures comprise 52% of total RAS.[ix] ACOG has also made its opinions known. In a recent publication, ACOG has stated that robotic surgery is not the only or the best minimally invasive approach for hysterectomy; nor is it the most cost-efficient. "Adoption of new surgical techniques should be driven by what is best for the patient, as determined by evidence-based medicine rather than external pressures."[x] There may be some advantages to the use of robotics in complex hysterectomies, especially for cancer operations that require extensive surgery and removal of lymph nodes.

The Proof is in the Outcomes

In the constant endeavor to improve care and decrease costs, analysis of patient outcome data is a key factor. "Payers, hospitals, and clinicians around the world are increasingly measuring and reporting patient outcomes to improve care."[xi] Outcomes measurement has been considered a critical element of healthcare reform. "Major players—including Medicare and Medicaid in the U.S., the National Health Service in the UK, the National Health Care Institute in the Netherlands, and several leading European university hospitals—have all made great strides in this area."[xii]

Does the surge in popularity of RAS coincide with more favorable post-operative outcomes? "Reporting in *The Lancet*, Robert Gardiner, M.D., of the Royal Brisbane and Women's Hospital in Brisbane, Australia, found there was no significant difference in urinary or sexual function at six weeks or twelve weeks after prostate surgery."[xiii]

Key Considerations

In an effort to promote quality care, hospitals might consider:

- Sending the surgeon and RAS team through formal technical training together so they can work with the specific instrumentation and each other.
- Verifying specific RAS skills along with the number of completed surgeries when evaluating credentials and awarding privileges.
- Reviewing RAS information in patient materials and on the organization's website and other social media to ensure there are no guarantees or promises about patient outcomes.

[v] "ECRI Institute Announces Top 10 Health Technology Hazards for 2014," November 4, 2013, https://www.ecri.org/press/Pages/2014-Top-10-Health-Technology-Hazards-Report.aspx and "ECRI Institute Announces Top 10 Health Technology Hazards for 2015, November 25, 2014, https://www.ecri.org/press/Pages/ECRI-Institute-Announces-Top-10-Health-Technology-Hazards-for-2015.aspx, both accessed April 2, 2018.

[vi] Benjamin T Carpenter and Chandru P Sundaram, "Training the next generation of surgeons in robotic surgery," Dove Press Ltd., August 3, 2015, https://www.dovepress.com/training-the-next-generation-of-surgeons-in-robotic-surgery-peer-reviewed-fulltext-article-RSRR#ref4, accessed on February 16, 2018.

[vii] "Robotic Surgery (Urologic) Standard Operating Procedure (SOP)," Board of Directors, American Urological Association, 2017, http://www.auanet.org/guidelines/robotic-surgery-(urologic)-sop, accessed February 16, 2018.

[viii] Ibid.

[ix] Robotic Surgery: Arm yourself with the latest information on pricing, performance, clinical efficacy, and safety, 2015, https://www.ecri.org/Resources/ASG/Robotic_Surgery_Infographic_MS15369_web.pdf, accessed February 16, 2018.

[x] "The American College of Obstetricians and Gynecologists, loc. cit.

[xi] Elisabeth Hansson, Arne Köhler, Nicolai Skarsgård, and Stefan Larsson, "How to Define Health Care Outcomes," BCG Perspectives, September 21, 2015, https://www.bcgperspectives.com/content/articles/health-care-payers-providers-how-to-define-health-care-outcomes/, accessed February 16, 2018.

[xii] Ibid.

[xiii] Jacek L. Mostwin, MD, DPhil, "Prostate Cancer Surgery: Choose Carefully," HealthCentral, September 23, 2016, https://www.healthcentral.com/article/prostate-cancer-surgery-choose-carefully, accessed February 16, 2018.

Collaboration Benefits ProAssurance Insured Hospitals and Healthcare Organizations

In 2015, ProAssurance began a unique collaboration with a French medical professional liability insurance company, Société Hospitalière D'assurances Mutuelles (SHAM). SHAM is well-known in France and throughout Europe for its leading risk management and patient safety services. Like ProAssurance's Risk Resource Department, SHAM's Risk Management Services Department helps insureds identify risks and provides risk management and patient safety strategies. ProAssurance and SHAM both perform on-site assessments, convey risk management news and information, and offer education for physicians and other healthcare providers.

This issue of Key Considerations reports results from two studies jointly conducted by ProAssurance and SHAM: "Addressing and Preventing Physician Burnout in France and the United States" and "Closed Claims Retrospective Study of Diagnostic Error Claims."

Physician Burnout in France and the United States

ProAssurance and SHAM recognize physician burnout is a patient safety issue worthy of continued investigation, management, and prevention. The Companies performed a literature review looking for a link between physician burnout and professional liability claims. Although the literature did not support a definitive and causal relationship, it identified signs and symptoms associated with burnout —inattentiveness, lethargy, fatigue, and lack of follow-through—in some patient care situations. Dr. Frederic Fuz, Head of Risk Management Services for SHAM, explained, "It is very difficult to relate the claims we handle with possible burnout of physicians. All the more, this relationship is rarely alluded to or investigated by experts. Nevertheless, it seems obvious that the burnout of doctors must be at the origin of a certain number of medical errors considering the symptoms related to the pathology: fatigue, disintegration, disorganization, or addiction."

***Burnout** is a long-term stress reaction marked by emotional exhaustion, depersonalization, and a lack of sense of personal accomplishment.*[xiv]

The literature supports the need for a specific focus on burnout in physicians as opposed to other professionals. Burnout can affect any professional, but physicians appear uniquely susceptible. At any given time, nearly one third of physicians currently practicing in the U.S. may be experiencing the effects of burnout.[xv] Physicians are 15 times more likely than other professionals to experience burnout.[xvi] In 2011, 45 percent of U.S. study respondents reported experiencing at least one symptom of burnout; in a 2014 survey, the number grew to 54 percent.[xvii] Dr. Fuz echoed similar findings from France, where approximately 50 percent of physicians experience burnout symptoms at some point in their careers.

Physician burnout is a patient safety risk affecting the number of physicians and the quality of patient care. The loss of physicians to burnout may hasten a looming physician shortage.[xviii] Physicians who no longer enjoy practicing medicine and cannot find relief may quit, leaving fewer practicing physicians to care for growing patient populations. Burnout symptoms also may affect a physician's skill and judgment, as evident in reviews of many unexpected outcomes and near misses. Helping physicians prevent and address burnout should increase the number of practicing physicians and improve the quality of patient care.

ProAssurance and SHAM support their insured hospitals' and healthcare organizations' efforts to prevent and address physician burnout. These organizations can assist their physicians by collecting, organizing, and sharing available physical health, mental health, and healthy lifestyle resources. Stanford University, for example, created an online resource library. Its options include health and lifestyle assessments; wellness-supporting classes and activities; and crisis support resources: coping with grief and loss, managing concerns about a colleague, and physician peer support programs.[xix] Some organizations offer classes and reading materials on setting appropriate limits, maintaining a work-life balance, and conflict resolution.

Healthcare organizations support the prevention of burnout by promoting healthy lifestyle decisions. They can make nutritious foods available, support schedules that allow an average of 7 to 9 hours of sleep per night, and promote exercise and physical activity. Organizations should encourage creative outlets including hobbies, sports, and leisure activities, as well as taking vacations.

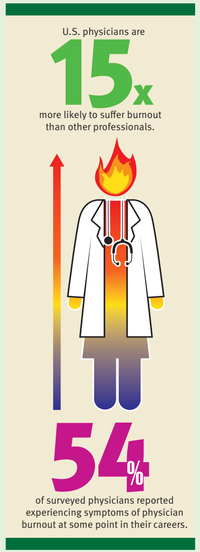
Like healthcare organizations, ProAssurance advocates for physician wellness. Dr. Hayes V. Whiteside, Senior Vice President, Risk Resource, and Chief Medical Officer for ProAssurance, noted, "ProAssurance is aware of the many pressures physicians face in today's difficult and rapidly changing healthcare environment. Our profession is going through massive upheaval, and ProAssurance wants to help physicians successfully manage the challenges—to thrive in their noble calling."

ProAssurance supports physician burnout prevention and treatment through the ProAssurance Endowed Chair for Physician Wellness at the University of Alabama at Birmingham School of Medicine. This academic chair underscores our pledge to protect and advocate for America's physicians.

As medical professional liability insurers, ProAssurance and SHAM recognize the increasing seriousness of physician burnout; they will continue to support hospitals' and healthcare organizations' efforts to support the well-being of physicians, improve patient safety, and provide quality patient care.

Joint Closed Claims Retrospective Study of Diagnostic Error Claims

ProAssurance and SHAM collaborated to study American and French malpractice claims with two objectives: to further support the Companies' current patient safety strategies and identify learning needs of physicians and hospital staff.[xx] All claims analyzed occurred in the hospital setting, included an allegation of diagnostic error, and closed in 2014 with an indemnity payment (settlement or plaintiff's verdict). Study factors included incident date, location of injury, medical specialty, patient demographics, patient medical condition, care provided, and patient outcome. The Companies analyzed medical records, expert witness testimony, records of trials, and other legal proceedings. Investigators then identified common contributing factors. SHAM's study revealed significant patient health or medical histories were present in 20 percent of claims, but not considered by the treating physicians in 10 percent of claims. The ProAssurance study showed the patients' medical histories were clinically pertinent in almost 24 percent of claims, but not always considered in the diagnostic process.



[xiv] Elaine Cox, MD, "Doctor Burnout, Stress and Depression: Not an Easy Fix," April 12, 2016, https://health.usnews.com/health-news/patient-advice/articles/2016-04-12/doctor-burnout-stress-and-depression-not-an-easy-fix accessed September 29, 2017.

[xv] Ibid.

[xvi] Tait D. Shanafelt et al. "Changes in Burnout and Satisfaction With Work-Life Balance in Physicians and the General US Working Population Between 2011 and 2014, Mayo Clinic Proceedings, Volume 90, Issue 12, 1600-1613, https://ezcare.jbs.elsevierhealth.com/action/showCitFormats?pii=S0025-6196%2815%2900716-8&doi=10.1016%2Fj.mayocp.2015.08.023&code=jmcp-site accessed September 29, 2017.

[xvii] "Physician Supply and Demand Through 2025: Key Findings," AAMC https://www.aamc.org/download/426260/data/physiciansupplyanddemandthrough2025keyfindings.pdf accessed September 29, 2017.

[xviii] http://medicaleconomics.modernmedicine.com/medical-economics/news/what-price-physician-stress-and-burnout?page=0,2

[xix] This study and the reported results are for educational purposes only, do not represent the views of ProAssurance or SHAM, and are not intended for any other purpose.

[xx] https://www.ahrq.gov/professionals/clinicians-providers/ahrq-works/burnout/index.html

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