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Perspective

Computer Assisted Surgery: Unintended Consequences

By Don Urbanowicz, Urbanowicz Consulting
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How CAS Will Impact Physician's Livelihoods

Computer-assisted surgery (CAS) and robotics are making in-roads across all surgical specialties from urology to spine. First embraced by "tech-savvy" neurosurgeons 20+ years ago for removing unreachable tumors and other malformations deep in the recesses of the brain, CAS has been embraced by some orthopedic surgeons — for guiding the placement of total joints. And more recently, robotics has been garnering attention as a technology which may improve surgeon accuracy and patient outcomes. Already one major player, **Stryker**, has put a stake in the robotics ground **acquiring** MAKO Surgical. **Globus** followed by **acquiring** Excelsius. Other transactions are likely to come.

However, along with these hi-tech approaches come unintended consequences that could lead to push-back on adoption particularly if these new technologies hit the physician's wallet. One such example in the news is an anesthesia monitoring technology being introduced by JNJ. By automating the sedation of patients undergoing colon-cancer screenings, JNJ could potentially eliminate a big source of income for anesthesiologists by effectively removing them from the surgery suite.
Orthopedic surgeons will be financially impacted as well, although to a much lesser degree. Given the orthopedic companies focus on new technologies that improve efficiencies and procedural throughput, reduce error rates and risks and "improve the surgeon experience" with robotics, the end result will likely be a continuing decline in surgeon reimbursement. Since the early 1990's, Medicare reimbursement to surgeons for hip replacement surgery has dropped over 30%. CMS further reduced reimbursement by an additional 4% in 2014. Expect the trends to continue.

The Issue

According to the Wall Street Journal (WSJ), Johnson & Johnson (JNJ) will initiate a limited launch of the Sedasys System, a first-in-kind, computer-assisted system that automates the sedation of patients undergoing colonoscopies, in early 2014.

Physician anesthesiologists and certified registered nurse anesthesiologists are warning that taking them out of sedative administration (and out of the surgery suite entirely) could be detrimental to the patient's safety.

What Is Sedasys?

Sedasys, which will be marketed by JNJ's Ethicon Endo-Surgery, is a computer-assisted, personalized sedation (CAPS) system. It has been designed to enable non-anesthesiologist physician-led teams to administer minimal-to-moderate propofol sedation by integrating drug delivery with patient monitoring.

The System received FDA Premarket Approval in May of 2013 for use on healthy adults who require mild-to-moderate levels of sedation during colonoscopies. Sedasys was commercialized for colonoscopy use in Canada and the European Union several years ago.

JNJ is confident the Sedasys System has the potential to redefine the way sedation is administered for eligible patients. The Company's principal Sedasys investigator feels that the technology will empower health care facilities to more effectively use their limited resources to deliver value in the increasingly resource-constrained US health care environment.

How Does Sedasys Work?

Patients are connected to Sedasys and sedated intravenously. While connected, a patient's condition is monitored by CAPS, which measures oxygen levels, for example. If an issue arises, CAPS alerts the physician and "takes action" – such as increasing oxygen supply and stopping the anesthesia, and resumes only if the patient's condition normalizes.

Patients also wear an earpiece in case they drift into too deep a level of sedation and require awakening. In that case, CAPS "tells the patient" to wake up through the earpiece.

What About Propofol?

CAPS delivers propofol – a proven, powerful sedative. Propofol can result in sedation as deep as general anesthesia, but it may also have serious side effects. A patient receiving propofol could suddenly slip into general anesthesia, with the patient either abruptly losing blood pressure or stopping breathing – requiring emergency intervention. The gastroenterologists who conduct colonoscopies may select from a variety of drugs to sedate patients. However, propofol is widely used because it both takes effect and wears off quickly.

What Are The Clinical Benefits Of Sedasys?

Data included in JNJ's PMA application demonstrated that the System reduces the risks associated with over-sedation. Patients who received sedation with Sedasys experienced fewer and less significant oxygen desaturation events than patients in the control group – who received traditional sedation with benzodiazepines and opioids.

The data also demonstrated that patients sedated with the Sedasys System recovered faster than the control group – with 99% recovered from the effects of sedation within 10 minutes – and the patients were highly satisfied.

In addition, physicians were significantly more satisfied with administration of sedation they provided to patients in the Sedasys System group compared to sedation provided to patients in the control group.

What Are The Economic Benefits Of Sedasys?

A RAND Corp. study, sponsored by JNJ, reported that $1.3 billion was spent on 12.5 million gastroenterology probes in the US in 2009. The study suggested that $1.1 billion of the spending was for low-risk patients who didn't need an anesthesiologist to administer propofol.

Per the WSJ, health-plan CDPHP in NY claimed that anesthesiologists' services usually cost more than the $200 to $400 generally charged by physicians performing the actual colon-cancer screenings. According to a research letter published by JAMA Internal Medicine in July of 2013, an anesthesiologist's involvement usually adds $600 to $2,000 to the procedure's cost.

Sedasys is projected to cost $150 per procedure. Hospitals and clinics would not purchase CAPS; instead each would pay the $150 "user fee" only when the System was utilized. The cost would likely cover the disposables used, maintenance and all other costs of performing the procedure with the exception of the sedative drug.

Reimbursement would vary, but insurers are expected to pick up most or all of the tab. JNJ is hoping the potential savings from using Sedasys appeals to hospitals and clinics and drives CAPS revenues. The JNJ CEO stated that Sedasys "is a great way to improve care and reduce costs".

The Anesthesiologists Point Of View

The WSJ reported that anesthesiologists feel "the gastroenterologists and regular nurses who perform colon-cancer screenings lack specialized training and can't focus solely on the sedated patients health".

CAPS "could endanger some patients because it uses the powerful drug propofol, that could be used improperly". Sedasys "will be used on risky patients who should have an anesthesia professional present in case of emergency".

They also worry “that if the anesthesiologist isn’t in the (OR) room, he might not be able to get to an emergency fast enough to prevent harm”. They mentioned that according to JNJ, “facilities where the Sedasys is used should have an anesthesia professional immediately available for assistance or consultation, a vague requirement that generally limits the machine’s utility and cost-effectiveness – and only means the professional needs to be present in the facility”.

In addition, “It is always best for propofol to be administered by a qualified anesthesia professional. Since a machine is not able to prevent or manage loss of consciousness, we have serious concerns. Substituting a machine for a dedicated anesthesia expert involves unknown costs and risks”.

The chair of the American Society of Anesthesiologists (ASA) committee on Sedasys opined, “Everyone is so hot on technology, but you have to balance the fiduciary duties of the company with the physicians interest in ensuring the highest quality and safest care for the patient”. An anesthesiologist added, “There’s really no substitute for physician-centered care”. Another concurred, “If a patient ends up dying because of preventable circumstances, that’s not acceptable because we are trying to save money”.

After unsuccessfully lobbying the FDA for a number of years to prevent approval of the System, ASA is urging its more than 50,000 members to tally the number of times CAPS is used and the number of emergencies that arise to develop a national database measuring the System’s safety.

Anesthesiologists – Targeted By “Number Crunchers”?

Anesthesiologists are among the highest-paid physicians who have long fought health care “number crunchers” who target their specialty (rightly or wrongly) to reduce costs. PayScale.com reported that their annual salary of $286,000 is ninth among all physicians and third among non-surgeons.

By automating the sedation of patients undergoing colon-cancer screenings, JNJ could eliminate a big source of income for anesthesiologists.

JNJ’s Position

The physician-developer of Sedasys claims that CAPS is limited to healthy patients who aren’t at risk for problems and that the System has mechanisms to monitor patients and make rapid adjustments, such as increasing oxygen –- tasks typically performed by anesthesiologists.

JNJ states that it will adopt a cautious approach. It will train doctors and nurses to use Sedasys – and teach them to deal with propofol’s cardio-respiratory effects. In addition, the Company will ensure that only appropriate patients are treated with CAPS and an anesthesiologist or nurse anesthetist be on site when the System is in use.

In an effort to further protect patients, JNJ plans to introduce Sedasys slowly – in select hospitals and clinics. The Company will also conduct two post-approval studies to monitor the use of the technology in actual clinical practice following its limited rollout.

Conclusions

The dispute over Sedasys may be a signal that more health care battles are on the way. While efforts to reduce health care spending have created opportunities for medical device companies, it is apparent that select new technologies will disrupt the status quo for physicians – including their livelihoods.

The WSJ reported that JNJ is developing a device that could "remove" the anesthesiologists from *another* procedure – insertion of tubes into the ears of children looking for relief from infections. ENT physicians will be able to insert the device with a simple push-of-the-button – and eliminate having children anesthetized in an acute care setting.

Clearly, physician anesthesiologists and certified registered nurse anesthesiologists will be carefully watching the peer-reviewed journals for data that further validates the utility and safety of the Sedasys System – as well as JNJ's potential ENT-related technology!

Don Urbanowicz is Principal of Urbanowicz Consulting, an advisory firm with a musculoskeletal focus seeking to enable clients to achieve strategic and transaction-related goals by capitalizing on market opportunities. UC offers a unique perspective on how large global companies approach strategy, valuation, negotiations, due diligence and integration, and a thorough understanding of achieving success throughout all phases of the transaction process.
Please learn more online at www.urbanowiczconsulting.com, and contact Don Urbanowicz at durbanowicz@du-llc.com.