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Fundamental Use of Surgical Energy (FUSE) – Closing a Gap in Medical Education

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Abstract

Traditional medical education curricula for students, residents and trainees do not address the rapidly growing number of technological devices that are fundamentally changing health care delivery today. This is most relevant in those medical specialties that rely heavily on the use of advanced technologies and devices, for example minimally invasive surgery, interventional radiology, gastroenterology, cardiology and anesthesia. Health care professionals in these domains are increasingly sharing procedures that use energy devices of many different designs and functionality without training in their fundamental use and safety. This exposes both operators and patients to increasing risk for injury. The definitive gap in adequate education and training in new technologies prompted the development of The Fundamental Use of Surgical Energy (FUSE) program by a multidisciplinary team of clinicians, nurses, educators and engineers under the leadership of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). The sweeping changes in the surgical and interventional professions due to technological innovation call for the development of additional curricula to close the educational gap on other medically important technologies. The FUSE program and future educational curricula on medical technologies are fundamental to patient care and represent a necessary paradigm shift in traditional medical education.

The medical community stands in the midst of a transformation in the delivery of healthcare. At its core lies a technological revolution that has gained great momentum over the last two decades and has touched and disrupted virtually every medical specialty. This is particularly true for surgery, gastroenterology, cardiology and radiology, which have been radically transformed by the developments in energy application, image guided procedures, robotics, miniaturization, molecular genetics, and wireless control. The availability of advanced instrumentation and specialized facilities allows surgeons, gastroenterologists, radiologists and cardiologists to share the ability to perform therapeutic procedures that were once the unique domain of one specialty. Examples include endovascular repairs for vascular diseases, minimally invasive, robotic assisted and natural orifice procedures, cardiac and oncologic percutaneous ablation procedures, endoscopic antireflux procedures and endoluminal resections. Essential to these new procedures is the availability of a large portfolio of new mechanical and energy driven devices that has changed the treatment approaches to entire disease entities. For the most part, these developments have advanced our ability to provide medical care with ever decreasing complication and mortality rates.

Yet the speed, complexity, and number of new devices introduced annually raises safety and training concerns that are not being addressed by the current regulatory framework.

Efforts to regulate and improve safety of medical devices date back to the mid 1970s with the enactment of the Medical Device Amendments of 1976.¹ This legislation provided a framework for FDA supervision, premarket application approval and completed product development protocol. In 1990 the MDA was replaced by the Safe Medical Devices Act which provided the current legislative framework for the regulation of medical devices. These government regulations and the additional work from voluntary and nonprofit organizations such as the Association of the Advancement of Medical Instrumentation (AAMI, founded in 1965) and the Emergency Care Research Institute (ECRI, founded in 1968) have been instrumental to our understanding of medical device safety. As a result, a great deal has been learned about medical device safety and how to prevent accidents and fatalities due to inadequate engineering and wiring design. Most importantly, large voluntary and mandatory adverse event reporting databases provide essential information about medical device related accidents and injuries.

This regulatory framework typically lacks specific requirements for training prior to clinical use of new devices, and this lack of knowledge about the functionality, appropriate use and hazards of a device or technology likely increases the chance of adverse events. For example, the Emergency Care Research Institute's (ECRI) top ten health technology hazards for 2015 include complications due to insufficient training in robotic assisted laparoscopic surgery. Given that modern medicine and, notably, interventional medicine is highly reliant on technology and devices, it is necessary to address their safety through targeted educational activities. This concept is certainly true for energy devices, the distinct subgroup of energy powered medical devices that are used in procedural-based specialties to dissect, cut, coagulate, seal and ablate tissues in the operating rooms, endoscopy suites and in radiologic interventions.

Since a safe device cannot guarantee device safety, adverse events related to energy based devices appear to occur commonly and with increasing frequency. The extent of harm is concerning as the vast majority of adverse events due to energy devices are almost all preventable. According to the Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE), 178 deaths and 3,553 injuries related to radiofrequency electrosurgical devices were reported in the last 20 years (Fig. 1). The most common causes for injury and death were thermal burns (N=2,353; 63%), hemorrhage (N=642; 17%), mechanical device failure (N=336; 9%), and fire (N=294; 8%). Thermal injury was the most common cause of mortality (N=70; 39%). Even more concerning is the observed steady rise in the number of injuries and death over time. The ECRI noted in its 2005 Health Devices publication on electrosurgical safety the re-emergence of hazard and risk of burn due to laparoscopic and high-current procedures.² Unrecognized energy device-related burns carry mortality, morbidity and significant medico-legal costs.^{3,4}

Outside the US, similar observations and needs assessments have been made. The French national database on adverse events in surgery (Evénements Porteurs de Risques, EPR) maintained by the French federation of gastrointestinal and digestive surgery (Fédération de

Chirurgie Viscérale et Digestive - FCVD) contains over 7500 registered adverse events reported voluntarily by 900 surgeons over a period of 6 years (2009-2014). Overall 2345 events occurred in the operating room, with 648 (24%) related to the use of energy devices, including 51 operating room fires and 423 unintended skin or organ burns. The majority of injuries resulted from the use of monopolar radiofrequency instrumentation and to a lesser degree bipolar radiofrequency and ultrasound devices. In some instances injury detection was delayed, particularly if the injury occurred secondary to current diversion caused by faulty instrument insulation (72 cases). These events resulted in several re-operations and some patient fatalities. The lack of knowledge about the proper use of the device and absence of training were revealed as the primary causes of these events. With this in mind, the FCVD has decided to focus its risk management agenda for 2016 on training in the use of energy sources in the operating room. (Personal communication, Dr Jean-Francois Gravié, FCVD, France.)

Teaching safe and appropriate use of technology is not part of traditional medical education. To this day, the vast majority of operators of these devices obtain their knowledge and proficiency through industry representatives or simply by observing another surgeon using a device.⁵ Relevant textbooks rarely address fundamental knowledge on energy-based devices. Few if any goals and objectives of major medical school surgical clerkships or post-graduate training programs address the use of energy-based devices in the operating room and endoscopy suite. *The Manual of Surgical Objectives* (4th edition, 2001) from the Association for Surgical Education does not contain any learning objectives specific for the appropriate use and safety of energy-based devices. At the same time, the number of times in which a potential adverse event may occur is very high. It has been shown that a surgeon activates an energy-based device during one surgical procedure on average over 100 times. With several million procedures performed annually in operating rooms and endoscopy suites in the United States alone, even small absolute risks can translate into large numbers of adverse events.⁶

The risk is further compounded by the development of complex instruments designed for minimally invasive procedures. These instruments require thinly-insulated long handles that may fray with reprocessing causing current diversion and that use angulations that place instruments in close proximity which facilitates direct current coupling. The minimally invasive surgical approach inherently creates “blind spots” that increase the risk for undetected, and therefore, particularly dangerous injuries and burns. The exponential rise in the number and diversity of surgical and endoscopic energy-based devices available for use also contributes to risk. For much of modern human history, true cautery was the only available energy device for physicians. The first radiofrequency electrosurgical instrument was invented about 100 years ago and radiofrequency electricity was the sole energy source for surgical devices for most of the 20th century. It is only in the last two decades that we have witnessed the equivalent of an explosion in type and design of energy-based devices used for human intervention. Today, operators can choose from a dizzying number of end effectors and many different types of energy sources that include ultrasonic devices, microwaves, water jet, and most recently true cautery instruments.

It is, therefore, not surprising that most health care professionals may not have sufficient knowledge about the detailed functionality, hazards and safe use of these devices. A survey conducted in the early 1990s by the American College of Surgeons demonstrated that many surgeons did not know the optimal power settings for electrosurgical instruments.⁷ In 2011, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) tested the knowledge on functionality and safety of energy devices in 48 experienced surgeons.⁸ For these experienced surgeons who use energy devices daily, the median number of correct answers was only 59% (IQR 55-73%). Common incorrect answers related to operating room fires, interference with pacemakers, thermal profile of bipolar instruments and correct handling of the dispersive electrode or “pad”. Of note, the knowledge of the tested experienced surgeons was no different to that of junior surgical residents tested in the same way. Similar findings have been reported among practicing gynecological surgeons with a zero initial pass rate during a test on electrosurgery.⁹

The existence of a global gap in medical education regarding the safe use of energy devices is undeniable. Because energy-based devices are used across many medical specialties and by other health practitioners, such curricula ought to be widely applicable. Over the past four years and under the leadership of SAGES, a multispecialty group of physicians and nurses partnering with professionals and specialists from general surgery, hepatobiliary surgery, gynecologic surgery, urologic surgery, anesthesiology, gastroenterology, operating room nurses, and engineers have created the “Fundamental Use of Surgical Energy”TM, (FUSE) program. FUSE is an independent, multidisciplinary educational program for energy-based devices in both traditional “open” surgery and for minimal access procedures typically directed with an endoscope, including, but not limited to laparoscopy, thoracoscopy, and the endoluminal gastroenterological procedures such as colonoscopy, and upper GI endoscopy. The primary goals of FUSE serve to educate practitioners in the principles of the safe use of energy-based devices, to foster best practices, and to optimize patient safety. Secondary goals include provision of an adaptable platform for continuous training and education on future surgical energy devices, creation of a standard process to educate providers and nurses who are often unfamiliar with existing devices, and establishment of mandatory training standards for energy-based surgical device and operating room fire safety.

Completed in 2014, the FUSE program contains the first formal curriculum designed to teach medical and allied health professionals about the principles and safe use of energy-based devices. It is structured into 10 major educational domains (Table 1) and includes an online multimedia learning module (free at <http://www.fuseprogram.org>), a standard textbook (The SAGES Manual on the Fundamental Use of Surgical Energy, 9) and a high-stakes certifying exam (FUSE certification exam). Integrated into the online curriculum is the ability to obtain Continued Medical Education (CME) credits for physicians and Continuing Education Units (CEU) for allied health professionals. The high-stakes certification exam was developed using standard psychometric processes and has been validated based on a determination of the minimal acceptable knowledge required for the safe and effective use of energy-based devices. This exam is made available at several test centers throughout the country and at the annual meetings of both the American College of

Surgeons and SAGES. At this time over 230 FUSE certified surgeons and allied health professionals throughout North America have become FUSE certified.

In summary, technological innovations and advanced energy-based devices are changing the way surgeons, interventional radiologists, anesthesiologists, internists and nurses perform a wide spectrum of medical procedures. The lessons from FUSE should be a call for the development of additional curricula to close the educational gap that exists for other medically important technologies, such as robotic-assisted surgery, natural orifice surgery, image guided interventions, wearable technology, implantable devices, wireless medical devices and others. Clearly, the radical changes in the surgical and interventional professions due to technological innovation remain fundamental to patient care and will continue to evolve rapidly. Therefore, educational curricula that focus on safety and use of complex medical technology may represent an important and necessary paradigm shift in traditional medical education.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1. Electrosurgery Device Adverse Event Reports Submitted to the FDA. Number of device reports (y axis) per year spanning Jan 1994 to Dec 2013

Table 1

Learning objectives and major Domains of the FUSE educational curriculum

	Domains (10)	Learning Objectives (63)
1	Fundamentals of electrosurgery	7
2	Mechanisms and prevention of adverse events	20
3	Monopolar devices	4
4	Bipolar devices	5
5	Radiofrequency for soft tissue ablation	4
6	Endoscopic devices	4
7	Ultrasonic energy systems	5
8	Microwave energy systems	2
9	Energy devices in pediatric surgery	3
10	Integration with other medical devices	9