

From the Editor's Desk...

JSS Technical Editor
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Efficacy

“Efficacy” is defined by Webster as “the power to produce an effect.” A good example of the use of this word is found in the science of pharmacology, where the maximal effect of a drug is referred to as either “maximal efficacy” or simply “efficacy.” Consider two drugs that are available for pain relief. Aspirin can provide relief up to moderate pain intensities, while morphine relieves almost all levels of pain. Therefore, the opiate has a much greater efficacy for pain reduction (of course, there are side effects that must be considered).

A more complex example of efficacy is given by Dr. Siddhartha Mukherjee in his book *The Emperor of All Maladies*, where he describes an intellectual battle that lasted for many decades within the war on cancer. Radical mastectomy became the treatment of choice for breast tumors during the late 19th and early 20th centuries. The major proponent of this approach was Baltimore surgeon Dr. William Stuart Halsted. In 1927, a London physician, Dr. Geoffrey Keynes, reported results showing that local surgery, combined with radiation, had the same positive outcome (i.e., efficacy) as radical surgery. The American surgeons ridiculed the less-invasive approach and nicknamed it the “lumpectomy” in an effort to be condescending.

The work of Keynes was largely suppressed by the Halsted descendants for several decades. It was not until 1981 that a scientific study with proper statistics definitively showed that the radical mastectomy and “lumpectomy” had the same efficacy. The hundreds of thousands of radical procedures performed over decades saved lives in many cases; however, they had a high cost to patients in terms of greater pain and suffering than would have been incurred with less-radical measures of the same efficacy.

I have often wondered about the efficacy of system safety methods with respect to safety-critical software. Do the methods work and, if so, is there another approach that has the same efficacy but is perhaps better in some way (such as in the surgical approaches described above)? This question is addressed by the first technical paper in this issue, “Planning the Unplanned Experiment: Towards Assessing the Efficacy of Standards for Safety-Critical Software,” by Patrick J. Graydon and C. Michael Holloway. The authors point out that, “while software in industries such as aviation has a good safety record, little is known

about whether standards for software in safety-critical applications ‘work’ (or even what that means).” They say it is often argued that software is fit for safety-critical use because it conforms to an appropriate standard. Since we do not know if a standard “works,” however, such reliance is an unplanned experiment. The authors do not have a definitive answer but identify several approaches for further research that may help resolve the question.

The second technical paper in this issue, “Management of Risk and Benefits for Medical Devices” by Bijan Elahi, describes the application of system safety concepts to medical devices. This paper addresses the balance of risk and benefit as they apply to medical devices and discusses some aspects of analysis, such as risk perception, that differ somewhat from other types of systems.

In the TBD column this month, Charles Hoes describes some wide-ranging ideas about what the International System Safety Society (ISSS) should be doing and how these things might be accomplished. These ideas are to provide value to our members and enhance the profession. This article should promote some vigorous discussion about future directions of the ISSS.

The Design-Based Safety column by David MacCollum recounts the “Snake Oil Salesmen” of the Old West. MacCollum gives a number of examples of safety-related activities from modern times he views as “snake oil safety.”

In his System Safety in Healthcare column, “White House Wants System Engineering for Safety and Reliability in Health Care,” Dev Raheja describes a recommendation by the President’s Council of Advisors on Science and Technology. He explores possible barriers to the implementation of this idea, as well as what more could be done from the system safety point of view.

In his Notes On Society History column, ISSS Historian Rex Gordon explains the “Pathfinder Award.” This new award was approved at the Society’s Executive Council meeting on August 28, 2015.

I welcome your thoughts on the articles in this issue and any other matters that you are interested in. Please email me at cmuniak@stevens.edu.

Regards
Chuck

In Memoriam

James Howard Wiggins, Sr.



James Howard Wiggins, Sr. of Arab, Alabama, passed away at the age of 77 on March 3, 2016 at his home.

He is survived by his wife of 10 years, Mary Ann Gober Wiggins; sons, James Wiggins, Jr. (Sarah) and Michael Glenn Wiggins; daughters, Cathy Hallman (Tim), Malesa Webb (Glenn) and

Teresa Gail; five grandchildren, one great-grandchild; his brother, Dave Herman; and his sisters, Alinda Ballard Davis and Sandra Fuller. James was preceded in death by his father, Robert Howard Wiggins; his mother and step-father, Grace Ward Herman and Milton Herman, and a sister, Norma Whittler.

James, who served as the ISSS president from 2007 to 2009, was born on November 20, 1938 in Keewanee, Mississippi and graduated high school in Hitchcock, Texas. He also served in the Vietnam War and was in the U.S. Navy, where he worked on diesel and nuclear submarines and surface ships. He ultimately achieved the rank of Lieutenant Commander and later retired from the U.S. Navy. He went to the University of Texas and earned his BS degree in aerospace engineering. During his career as an engineer, he worked for Boeing Microcraft, Allied Signal, Honeywell and Raytheon, and was also an independent consultant to the aerospace industry. He later founded Technical Analysis Inc. (TAI), which brought him to NASA and U.S. government agencies in Huntsville, Alabama, where he retired.

He was a member of the Warrior Creek Missionary Baptist Church.

Daniel L. Welch

Dr. Daniel L. Welch, Ph.D., CPE, passed away on December 21, 2015 at his home in Silver Spring, Maryland. He is survived by his sons, Robert and Dennis; his grandchildren, Bobby, Trinity, Calvin and Abigail; and his step-grandchildren, China, James, Jericho, Bella and Jude.

Daniel was an engineering psychologist who applied general systems theory to the human factors engineering analysis, design, test and evaluation, and operation of complex systems. He strove to design systems that people could operate efficiently, effectively, safely and rewardingly. He participated in the design of numerous systems, including nuclear power plant control rooms, nuclear submarine control party stations, aviation naviga-

tion and communications systems, and complex computer interfaces. Daniel did his undergraduate work in psychology at Seton Hall University, graduating magna cum laude in 1973. He received a master's degree in general experimental psychology from Towson State College, and a second master's and doctoral degrees in applied experimental psychology (human factors) from The Catholic University of America. Between 2001 and 2015, Daniel served as principal human factors engineer for TetraTech AMT, a technical assistance contractor for the U.S. Federal Aviation Administration. Prior to that, he worked with several local government contractors, including Carlow International, SAIC and Andrulis Research Corporation. For six years, he operated his own consulting practice.

Preston Lee Parker

Preston Lee Parker passed away on December 4, 2015, joining his loving wife, Dotty. He was born in Spring Hill, Louisiana, to the late Preston and Mabel Parker. Preston retired as a fully decorated colonel from the Air Force Reserve in 2001, and in 2014, from civil service as the technical director of system safety at Eglin Air Force Base. Preston graduated from Louisiana Tech University with a bachelor's degree in engineering, followed by a master's degree in engineering from Texas A & M University. Survivors include his daughter, mother-in-law, father-in-law, sister-in-law, brother-in-law and other family members in Louisiana.

As beautifully stated by the Naval Ordnance Safety and Security Activity (NOSSA): "Preston will truly be missed by the weapons safety community; he was a mon-

ument to our profession and a true hero for the safety of the warfighter. Preston provided an unparalleled service to the United States Air Force (USAF) and to the country both in uniform and as a civil servant during a career that spanned 46 years. Preston began his career in an active duty role as a 2nd Lieutenant in the Air Force, culminating in his civil service role as the technical director for systems safety at the Air Armament Center at Eglin Air Force Base, Florida. As the Air Force's Executive Secretary for the Non-Nuclear Munitions Safety Board (NNMSB) virtually every weapon delivered by the USAF, to include the Joint Service weapons, benefited from Preston's wisdom. His passing is a loss for the warfighter, the weapons safety community and for the country. Preston, you will be missed."