

UAB Grand Challenge: iWAG the Paradigm Shift: Level the Playing Field. Standardize and Validate the Delivery of Emergency Medical Care

Point of Contact: Dr. Linda B Thompson MD FAACEP FAAEM
UAB SOM Assistant Professor Emergency Medicine
Email: lbthompson@uabmc.edu
Cell Phone number: 205-612-8672

Problem: Medication errors annually lead to **7,000 deaths** and **injure 1.3 million people** in the United States leading to a yearly cost burden of approximately **\$16.4 billion**. Although medication errors pose significant risks to adults, it is estimated that errors with potential to cause harm are three times more likely to occur among children. Adverse drug events are often associated with complex dosing regimens involving “high-impact medications” administered in the Emergency Department (ED) for life-threatening conditions (Stroke, Cardiac Arrest, and Sepsis). These high-impact medications cause 40.9% of the medication errors that result in death. The doses of these high-impact medications are based on weight. Medical emergencies requiring these medications often involve patients who cannot communicate their weight. Most of these patients are lying in the supine position and unable to stand on a scale. Providers must therefore visually estimate adult weight, use a height measurement to estimate pediatric weight, or resort to pre-set doses when administering life-saving medicines. Research has shown that visual weight estimation can be 30% inaccurate, and height-weight estimation can be 70% inaccurate. The pre-set doses established in the 1970s are still in use and basically are a “one size fits all” dosing regimen. This allows a 90lb person to receive the same medicine dose as a 500lb person. Accuracy of the pre-set dose rule has never been evaluated. Most pre-hospital settings and many ED settings in Alabama as well as nationally lack a practical, commercially available portable weight scale device capable of accurately measuring weight in critically ill supine patients. Research has determined that lack of available patient weight is directly connected to medication errors and related consequences. **Lack of a practical, commercially available portable weight-measuring device is a significant barrier to providing safe and quality medical care in many Alabama as well as national ED and pre-hospital settings.**

Solution (Outcomes & Plan): The proposed project will address these barriers by developing and validating **an Integrated Weight Assessment Gauge (iWAG)** for obtaining weight in non-verbal, critically ill patients in the recumbent position. This project is highly significant as it will produce the **first-ever** portable weight

scale designed specifically for the unique ED and pre-hospital settings, thus enabling accurate weight measurement and proper medication dosing for non-verbal supine patients requiring emergent medical care. This will ultimately lower the risk of medical complications or death caused by improper medication dosing. The iWAG device will also help ED providers better manage persons with physical disabilities and deformations by providing an alternate method for obtaining weight without standing on a traditional scale. Furthermore, **the most intriguing and possibly the most ground-breaking application** of this device will be in the arena of adult resuscitative medicine. This device will now make it possible to investigate The American Heart Association Adult Cardiac Life Support (ACLS) pre-set medication dose protocols which have never been validated since their inception in the 1970s. For the **first time in modern medicine**, this technology will enable studies to be performed comparing the pre-set medicine dose protocols versus weight-based dosing protocols. This could revolutionize the **world-wide** delivery of resuscitative medicine. A proof-of-concept iWAG design was first developed in 2013 by UAB faculty-mentored undergraduate students from UAB's Department of Biomedical Engineering. This project seeks to advance this rudimentary iWAG design and produce a portable, cost-effective weight scale for evaluation against calibrated "gold standard" scales in the clinical setting. Our multidisciplinary team includes emergency medicine physicians and professional engineers from the UAB-based Engineering Innovative Technology Development Group (EITD). The UAB-EITD group includes a multidisciplinary team of engineers with an extensive track record for assembling complex integrated systems for critical functions in a number of NASA applications. The UAB-EITD group will be responsible for design, fabrication, and testing of the proposed iWAG device. Industrial design consultants will collaborate with UAB-EITD engineers with the focus on developing a commercially viable device. After the final iWAG system is thoroughly tested and validated for accuracy and safety in the UAB-EITD's laboratory, it will be delivered to the UAB-ED team. The UAB-ED team will perform an observational study to validate the iWAG weight measurement accuracy and functionality in the clinical setting. Outcomes of this pilot project will be used to further enhance iWAG technology and design and compete for extramural funding to support larger-scale outcomes research projects to clarify impacts of accurate weight-based medication dosing of high-impact medications. We anticipate further development of the iWAG device and a future larger-scale validation study will be supported by NIH-STTR funding opportunities (e.g., PA-12-089).

Potential Team Members:

Linda B. Thompson, MD Principal Investigator: Dr. Thompson is an Assistant Professor and attending physician at UAB Dept. of Emergency Medicine with over 30 years of clinical experience. Dr. Thompson will oversee the overall operations and progress of specific aims. Dr. Thompson will lead efforts to translate pilot outcomes to future extramural support based on the technology and preliminary data collected in this study.

Erik P. Hess MD MSc: Professor and Vice Chair for Research Department of Emergency Medicine. He obtained a medical degree from the University of Alabama School of Medicine and completed residency training in emergency medicine and fellowship training in critical care medicine at the Mayo Clinic. Dr. Hess also completed a fellowship in clinical research at the University of Ottawa where he obtained a Master of Science in Epidemiology. Dr. Hess' primary areas of academic interest include risk stratification, patient-centered shared decision making and risk-communication in the emergency department. He has authored over 100 publications – many of which have included a mentee as first author -- and mentored over 25 clinicians, with mentee outcomes ranging from presentations at national and international academic meetings to successful attainment of residency and faculty positions in academic emergency medicine to preparing competitive applications for extramural funding. His work has been funded by the American Heart Association, the Foundation for Informed Decision Making, the Greenwall Foundation, the Emergency Medicine Foundation, and the Patient Centered Outcomes Research Institute. His role will be to oversee the project and provide mentorship.

Alan W. Eberhardt, PhD: Professor and Associate Chair of Education Department of Biomedical Engineering. Dr. Eberhardt has been involved with the development of the proof-of-concept prototype since 2013 and has extensive experience with biomedical engineering.

Samuel R. Misko, MSEE Co-Investigator: Mr. Misko is an Electrical Engineer and Project Manager at UAB Engineering and Innovative Technology Development (EITD) Group and will oversee and assist all development efforts to implement the proposed prototype device. He has over 8 years of professional experience in electrical engineering and project management, and specializes in the development and evaluation of instrumentation,

measurement techniques, and all aspects of embedded system design. Mr. Misko currently manages multiple pilot scale medical device projects and has successfully instituted a hybrid process at UAB EITD that combines aspects of AS9100 quality control and NASA standard engineering processes with Agile Development features to produce a methodology that can rapidly produce robust complex system prototypes for pilot scale projects.

EITD ME II Engineer: UAB EITD employs a number of professional engineers with extensive professional experience in the area of Mechanical Engineering. This individual will be responsible for the development and integration of the key mechanical components of the device (i.e. air mat, pressure transducer interface, air management hardware, gurney/backboard integration, etc.). There are a number of EITD personnel that could fulfill this role, but any selection of personnel must be cleared by the EITD section manager at the time of the award.

EITD CS Student Engineer: UAB EITD employs a number of part-time student employees that possess proficiencies in the area of Computer Science. This individual will be responsible for the development of firmware that will control and interface with all peripheral components to facilitate the key features of the device (i.e. measurement, user interface, etc.).

EITD EE Student Engineer: UAB EITD employs a number of part-time student employees that possess proficiencies in the area of Electrical Engineering. This individual will be responsible for the development of hardware and harnesses to implement the key features of the device (i.e. measurement, user interface, air management control, etc.)

UAB-ED Research Assistant: This individual will be responsible for assisting Dr. Thompson with the design, setup, execution, and data collection throughout the project in support of the clinical testing of the device. This individual will also assist Dr. Thompson with project reporting and development of strategies and materials to facilitate the pursuit of follow-on research proposals for future, extramural support.

Dorsey Cox, IDSA: Mr. Cox is the founder of STREAM and has over 25 years of experience in Industrial Design with 17 patents and others pending - with specific expertise ranging from innovative designs of consumer and medical products to office furniture.

Sean Simmons, IDSA: Mr. Simmons is the founder of Objective Design and has over 30 years of experience in Industrial Design and has consistently positioned his company to identify, define & mine opportunities, and strategies, for innovation & improvement within all product aspects; including product markets, technologies, utility, ergonomics, user interface, manufacture &

aesthetic conformation. Mr. Simmons has developed medical device products for many clients range from bone growth stimulators for Zimmer to capital equipment such as the first MRI for Fonar.

UAB EITD will utilize Mr. Cox and Mr. Simmons' expertise in this project is required to assist with the development of solutions to a number of unique project challenges. These challenges are expected to include: the development of a novel design and fabrication technique for the air filled component of iWAG technology; development of iWAG prototype form/ fit/ function from a human-technology interface perspective based on the development of use scenarios; and to guide higher level device design trade-off decisions to ensure viability of device commercialization from a design for manufacture and part/ component/ service sourcing perspective. Their design evaluation process will include the functional perspectives of many to measure the effectiveness of a solution idea including users and service persons (Human), to physical improvement over alternative product systems (technical), to appropriate material and manufacturing strategies (production), to product lifecycle strategies for post-consumer waste (recycling). They will assist with the scripting of scenarios to uncover challenges from multi-discipline perspectives to minimize misdirection of client resources and streamlines project efforts toward sustainable performance features that insure user satisfaction.

Please note that UAB EITD personnel labor hours will be directly impacted by the contributions of the listed consultants. That is, the more consultant expertise utilized in the areas of—custom design for manufacturing, optimization of design for human-technology interaction, and part sourcing—the fewer hours will be required by the UAB EITD project staff. For this reason, both

Dr. Joel H. Dobbs: Executive I Residence UAB Collat School of Business He has been involved with Dr. Eberhardt and the undergraduate biodesign courses and is committed to assisting with future patent applications and exploring option in the private sector to bring the iWAG device to market.

David Allison PhD with the UAB Nutrition Obesity Research Center, Kenneth G Sagg MD MSc with the UAB Center for Outcomes and Effectiveness Research and Education, David A. Brown PT, PhD, FAPTA with the UAB Center for Disability Health and Rehabilitation Science and Robert W. Hergenrother PhD with Southern Research Institute: Each of these individuals with these various UAB centers have shown

interest in this research and are willing to discuss future involvement and possible financial support.