Statement

For the Record

Of

Gauss Surgical, Inc.

to the

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

Re: "Improving Maternal Health: Legislation to Advance Prevention Efforts and Access to Care."

September 10, 2019

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Gauss Surgical appreciates the opportunity to provide testimony to the U.S. House of Representatives Committee on Energy and Commerce for the hearing on "Improving Maternal Health: Legislation to Advance Prevention Efforts and Access to Care" and to offer our perspective on the important issue of reducing pregnancy-related morbidity and mortality.

We believe that the Federal Government should strongly explore and consider supporting the adoption of adjunct technologies to improve perinatal safety. In this statement, we highlight a proven Artificial Intelligence (AI) enabled mobile technology solution that is playing a meaningful role in improving detection and treatment of Postpartum Hemorrhage, the leading preventable cause of maternal mortality in the United States.

Hemorrhage is the Leading Preventable Cause of Maternal Mortality in the United States

The United States has the highest maternal mortality rate in the developed world.[1] According to the Centers for Disease Control and Prevention, 60% of pregnancy-related deaths are preventable.[2] Postpartum hemorrhage is a leading cause of preventable maternal morbidity and mortality.[3] To address this problem, organizations such as the American College of Obstetrics and Gynecology and the California Maternal Quality Care Collaborative recommend use of standardized hemorrhage management protocols to facilitate appropriate care of patients suffering from postpartum bleeding.[4,5]

On August 21, 2019, The Joint Commission, the body that accredits approximately 77% of hospitals in the United States, announced a perinatal safety guideline[6] that requires accredited

hospitals to "develop written, evidence-based procedures for stage-based management of pregnant and postpartum patients who experience maternal hemorrhage" incorporating "the use of an evidence-based tool that includes an algorithm for identification and treatment of hemorrhage" This new standard will go into effect July 1, 2020.

Ineffective Blood Loss Monitoring Hinders Hemorrhage Management

Widely accepted clinical protocols for hemorrhage detection and response rely on the ongoing, quantitative evaluation of cumulative blood loss as the lynchpin for triggering interventions to manage bleeding at predetermined levels or "stages" of blood loss.[7]

However, traditional approaches to assessing blood loss, such as visual estimation and manual weighing of blood-soaked sponges, are known to be unreliably subjective, inaccurate, labor-intensive, and confounded by the presence of fluids other than blood (e.g., irrigation, amniotic fluid).[8-11] These difficulties have severely limited providers' ability to recognize and respond to hemorrhage in a timely manner. [12]

As Laura Ungar reported in a July 2018 USA TODAY investigation[13],

> *"In July, a USA TODAY investigation revealed that thousands of women in the U.S. suffer life-changing injuries or die during childbirth because hospitals, doctors and nurses ignore basic best practices known to head off disaster.* ***Experts say half of those women's lives could be saved if doctors and nurses took simple steps, including measuring blood loss during and after delivery*** *and giving timely treatment for high blood pressure."*

Artificial Intelligence (AI) Enabled Technology Can Significantly Improve Hemorrhage Recognition and Response

Gauss Surgical, Inc., a leading healthcare Artificial Intelligence (AI) company based in Menlo Park, California, has developed an actionable solution that leverages cost-effective mobile technology and recent advances in AI to accurately estimate blood loss during both vaginal and cesarean deliveries. The company's Triton technology is a mobile application for the iPad that enables providers to assess blood loss in a way that is objective, accurate, and available in real-time during or after a delivery. The Triton App is FDA cleared as a Class II medical device, and is currently used by leading U.S. hospitals performing approximately 250,000 deliveries per year.

The Triton mobile application uses computer vision and machine learning algorithms to accurately estimate blood loss from digital images of blood-soaked sponges captured by the iPad as part of the routine sponge counting process. Similarly, the mobile application captures and processes images of the suction canister using sophisticated algorithms. As each new sponge or canister is scanned, the cumulative blood loss for the patient is displayed, providing doctors and nurses with clear insight into a critical aspect of the patient's condition. The technology seamlessly integrates into the busy workflow of a delivery room, operating room, or patient care unit.

Clinical Evidence Suggests Substantial Improvement in Hemorrhage Recognition and Response with the use of Technology

Several clinical studies have documented the accuracy[14,15,16] of the Triton mobile application as well as its ability to improve hemorrhage recognition, affect transfusion decision-making, and appropriately implement hemorrhage response protocols during both cesarean and vaginal deliveries.[17,18]

Earlier this year, researchers at Mount Sinai Hospital in New York published an independent 7,600-patient study in *The International Journal of Obstetric Anesthesia* comparing Triton with visual estimation of blood loss. The use of Triton to support implementation of a stage-based hemorrhage protocol was associated with (i) a nearly four-fold improvement in hemorrhage recognition, (ii) a 34% reduction in delayed interventions to control bleeding in vaginal deliveries, (iii) a reduced transfusion dose in cesarean deliveries, and (iv) significant cost savings yielding a 152% return on investment to the hospital.[18]

Triton provides additional benefits; each hospital's Hemorrhage Protocol can be loaded into the mobile application to alert the care team to hemorrhage stages in real time. This makes it significantly easier for providers to rapidly and correctly implement the proper treatments to improve outcomes, by placing evidence-based protocols at their fingertips based on objective data on the patient's blood loss.

Quantification of Blood Loss with Technology Should be a Required Standard of Care in US Hospitals

Leading maternal health organizations have recommended use of stage-based hemorrhage protocols, and the use of objective, cumulative, quantitative blood loss. However, most hospitals and providers lack accurate, objective data needed to detect and respond to hemorrhage in time to improve maternal health outcomes.

Given that user-friendly and cost-effective mobile medical technology is now available to simplify, streamline, and objectively provide accurate and timely blood loss information, we believe that quantification of blood loss (QBL) should be a required standard of care in US hospitals for every delivery. The Federal Government should also strongly consider supporting the adoption of technology for quantifying blood loss and digital hemorrhage protocols through Medicaid reimbursement incentives and through grant programs to under-resourced hospitals.

Conclusion

Gauss Surgical sincerely thanks the Committee for this hearing and for your commitment to addressing the problem of maternal morbidity and mortality. We deeply support your efforts and welcome the opportunity to work with the Committee and Congress to draft legislation to improve maternal outcomes.

Respectfully yours,

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