

NEWS RELEASE

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Emmes Studies Contribute to FDA Approval of a Medical Device That Estimates the Weight of Infants

Rockville, MD – January 6, 2020 – Emmes today announced that the U.S. Food and Drug Administration (FDA) has approved a prescription-only medical device used to estimate the weight of infants who are up to 90 days of age.

The Mercy babyTAPE is a tape-measure-like device that permits health care professionals to estimate the body weight of preterm and full-term infants when a scale may not be available or practical to use. Accurately estimating pediatric patient weight is important for drug dosing, resuscitation interventions, and nutritional assessments. This easy-to-produce device could be especially useful in emergency or resource-constrained situations such as remote or rural areas, and in developing countries.

The Mercy babyTAPE was developed under the <u>Best Pharmaceuticals for Children Act</u>, which mandates the National Institutes of Health (NIH) to prioritize therapeutic areas in critical need of pediatric-specific treatment information, sponsor pediatric clinical trials, and submit the data for review by the U.S. Food and Drug Administration (FDA) for action on affected products.

Emmes coordinated operations and analyzed the data from the NIH-funded studies for the original Mercy TAPE devices, which are used in children ages 2-16 years. These were the first weight estimation devices developed under the BPCA program and the first weight estimation devices to be cleared by the FDA. The Mercy babyTAPE now brings the same weight estimation process to infants.

All were developed by Dr. Susan M. Abdel-Rahman at The Children's Mercy Hospital of Kansas City, Missouri. According to Dr. Abdel-Rahman, "We now have a suite of low-cost, easy-to-use tools that take the guesswork out of estimating weight, one of the most important vital signs in a child. Combined, the Mercy TAPE and babyTAPE permit weight estimation from birth through adolescence in settings where this information is critical for delivering the best medical care possible."

Dr. Anne Lindblad, president and chief executive officer of Emmes, added, "The development of the TAPE devices is a wonderful example of collaboration between government agencies, researchers and industry. It's an honor for Emmes to partner with an outstanding researcher like Dr. Abdel-Rahman."

About Emmes

We collaborate with our clients to produce valued, trusted scientific research. Our team members at Emmes are passionate about making a difference in the quality of human health, and we have supported more than a thousand studies across a diverse range of diseases since our formation in 1977. Our research is contributing to a healthier world. For more information, visit the Emmes website at <u>www.emmes.com</u>.