Medtronic Initiates PRODIGY - a Global Study to Identify Those at High Risk for Opioid Induced Respiratory Depression, a Preventable Form of Respiratory Compromise

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Medtronic

DUBLIN - May 31, 2017 - Medtronic plc (NYSE: MDT) recently launched PRODIGY, a 1,650-patient global study, to identify individuals at high risk for opioid induced respiratory depression (OIRD), a form of respiratory compromise. It is the first study to assess the clinical and economic benefits derived from the use of pulse oximetry (a device that measures oxygen saturation and pulse rate) and capnography (a device that measures carbon dioxide in exhaled air and respiration rate), in patients receiving opioid medication on hospital general care floors. The first patient was enrolled in the PRODIGY study at The Ohio State University Wexner Medical Center.

The study is titled PRODIGY (PRediction of Opioid-induced respiratory Depression In patients monitored by capnoGraphY), and is a prospective, multi-center, post-market, global study conducted at 16 sites.

Through the development of a risk assessment scoring tool, the study will seek to identify patients at increased risk for respiratory compromise. It will evaluate hospital ward patients receiving opioids for post-surgical or non-surgical pain who are continuously monitored with capnography and oximetry. The study will also help inform clinicians' understanding of the true incidence of respiratory compromise, which may be underestimated. The scoring tool will be used at the trial sites, with the goal of wider adoption across more hospitals following completion of the study.

Respiratory compromise is a potentially life-threatening, progressive condition negatively impacting a person's ability to breathe. Patients with OIRD experience a decrease in the effectiveness of ventilatory function, an ability to breathe, after opioid administration.[1] This condition is rapidly becoming the third-most costly hospital inpatient expense in the U.S., and dramatically increases the likelihood of adverse patient outcomes and cost of patient care.[2] Not only is respiratory compromise common and dangerous, it has been very difficult to predict.[3-5]

The continuous monitoring of a patient's oxygen and carbon dioxide levels will also allow PRODIGY to identify other causes of respiratory compromise in patients on the general care ward. Currently, ward patients' breathing is monitored manually, and typically is no more frequent than every four hours.

"The PRODIGY study allows us to deepen our understanding of the development of respiratory compromise, including OIRD, and determine strategies for earlier detection and prevention," said Dr. Frank Overdyk, lead investigator of the PRODIGY study and a staff anesthesiologist at the Roper St. Francis Health System in Charleston, S.C.

In addition to Dr. Overdyk, the study is being led by Prof. Wolfgang Buhre, chair of the department of anesthesiology and pain medicine at Maastricht University Medical Centre, located in the Netherlands; and Dr. Ashish Khanna, staff intensivist and assistant professor of anesthesiology at Cleveland Clinic Lerner College of Medicine of the Case Western Reserve University, located in Cleveland, Ohio. Dr. Overdyk and Dr. Khanna are paid members of the Medtronic clinical advisory board for PRODIGY. Professor Buhre is not a paid consultant; all consulting fees for Prof. Buhre are paid to the University of Maastricht.

"The PRODIGY study is indicative of our commitment to bring attention to respiratory compromise - an under-recognized, serious health condition that's preventable," said Vafa Jamali, senior vice president and president of the Respiratory & Monitoring Solutions and Early Technologies businesses, which are part of the Minimally Invasive Therapies Group at Medtronic. "Information is powerful and the ability to identify patients at risk for respiratory compromise who could benefit from continuous capnography and oximetry monitoring - may improve patient safety throughout the hospital."

Additional information about the PRODIGY study can be found at: https://clinicaltrials.gov/ct2/show/NCT02811302.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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