Closed-Loop Anesthesia: Invention or Innovation?

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Abstract Content: Transportation and energy industries have leveraged automation extensively in the past decades [1]. The quest for automation has also penetrated medical device industry, particularly in critical care settings where there is an abundance of physiological monitors combined with an ever-increasing clinician cognitive overload and burnout [1-4]. In recent years there has been a surge of medical devices in field of anesthesia and critical care that not only automate routine tasks but have evolved to take on more diagnostic and therapeutic responsibilities to care for patients. Such devices may be referred to as Physiological Closed-Loop Controlled (PCLC) medical devices [1]. FDA defines PCLCs as system of devices that incorporate physiological sensor(s) to manipulation physiological variable(s) through actuation of therapy that is conventionally made by clinician [1]. Automated anesthesia, mechanical ventilation and fluid resuscitation are examples of PCLCs. This technology has the potential to provide timely, consistent, and distraction-free therapy to the patient [2] potentially leading to efficient maintenance of physiological variables within a prescribed range, reduction of human errors, alarm fatigue, clinician burnout, and ultimately improved patient outcomes. PCLCs are *en route* towards becoming an innovative technology with potential for positive impact on the safety and effectiveness of care delivery in anesthesia and critical care settings. The major hurdles for the process of taking PCLCs from invention to innovation can be combination of factors including lack of or slow clinician adoption [5] and absence of a standardized regulatory approach due to PCLC complexity. Opportunities to overcome these challenges include careful benchmarking of advanced PCLC systems such as Artificial Pancreas System in which adoption of automation is more mature [1,6]. Furthermore, new and novel regulatory tools such as the Early Feasibility Studies Program [7] and Parallel Review Program [8] can be leveraged to generate evidence needed for regulatory as well as reimbursement approval.

References:

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