A TAXONOMY OF SAFETY ISSUES TO BE OVERCOME IN THE ARTIFICIAL PANCREAS

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Introduction

The artificial pancreas (AP) is a sought after device for the treatment of type 1 diabetes (T1D) aimed at tight glucose regulation in patients to reduce complications. In a recent paper by Doyle et al.[1] it was stated that over 40 clinical studies on the AP were performed in the last ten years. However, many of these studies chose to focus on the efficacy of the AP rather than on the safety. Safety is a crucial part of the developmental process of any medical device and is especially important with the AP because of the long duration of contact with the patient and the severity of the consequences of inappropriate function[2]. The primary aim of this study was to create a taxonomy of all safety issues present in the AP.

Safety and the Artificial Pancreas

System safety as described by Leveson[3] uses systems theory and systems engineering approaches to prevent foreseeable accidents and to minimize the result of unforeseen ones. All losses are evaluated including: human injury or death, destruction of property, loss of mission and environmental harm. The primary concern of system safety is the management of hazards: their identification, evaluation, elimination, and control through analysis, design and management procedures. Although, the AP has made great strides forward in terms of efficacy and the ability to mitigate some system failures. The early identification and classification of hazards has not been done in a formal manner. Only after this first step can corrective action can be taken to eliminate or minimize these hazards.

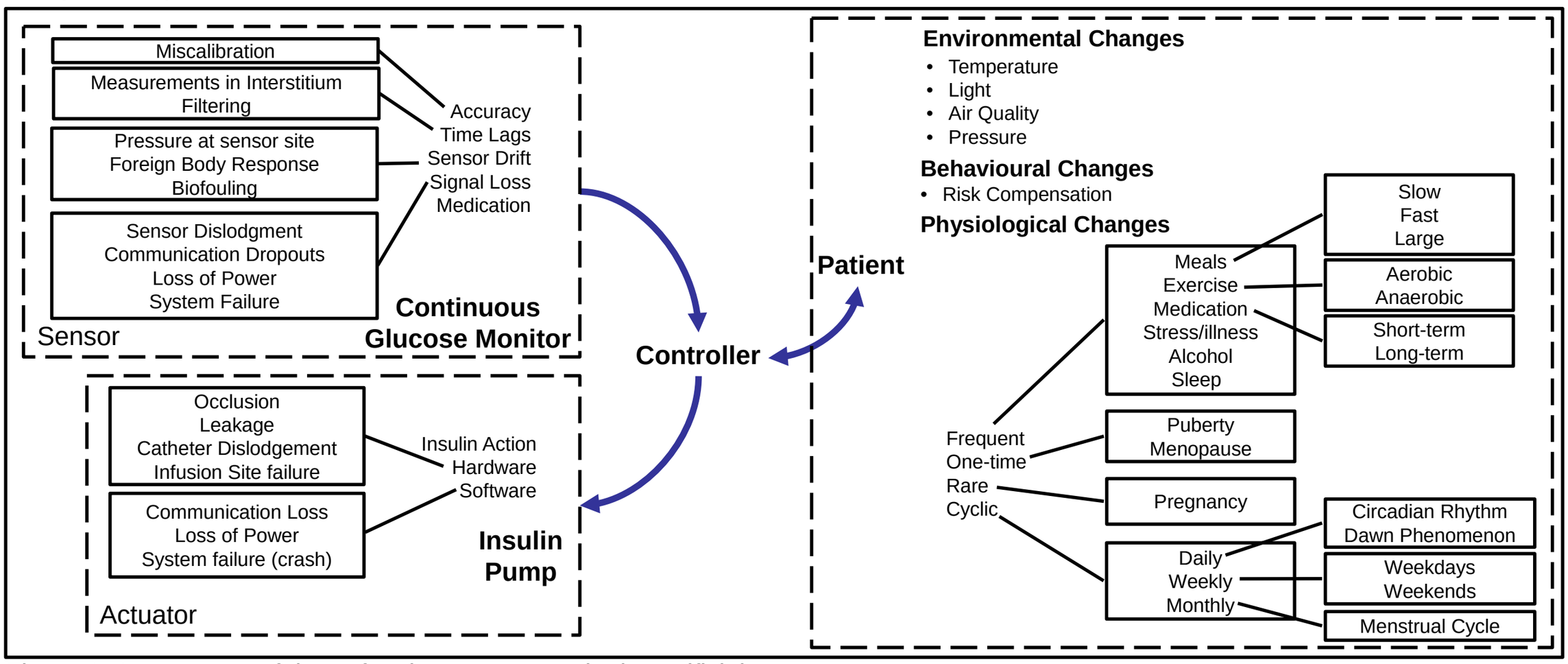

Figure 1. A taxonomy of the safety issues present in the artificial pancreas.

Discussion

Many papers cite the artificial pancreas as having three components: 1) a continuous glucose monitor (CGM), 2) a continuous insulin infusion pump and 3) a controller with an embedded algorithm[4]. However, there is a fourth component to the AP that has not been included by many investigators: the patient[5]. Addressing the component of 'the patient' is especially important when addressing safety issues. Many anomalies can occur due to changes within the patient. These changes can be induced by physical activity, meals, illness, circadian variability and other circumstances that result in substantial changes in the physiological parameters of the patient[6]. These changes, without being identified, could otherwise be mistaken as faults in another component of the system.

This taxonomy depicted in figure 1 includes:

1. Controller: scenarios outside of controller range, alarm fatigue
2. Continuous Glucose Monitor: miscalibration, time lag, sensor drift (pressure-induced sensor attenuation), signal loss (communication loss, loss of power, system failure), inaccurate reading due to foreign substances (i.e. medication)
3. Patient: environmental changes (temperature, light, air quality, pressure), behavioural changes (risk compensation), physiological changes (meals, exercise, stress/illness, alcohol, sleep, puberty, menopause, pregnancy, circadian rhythm, dawn phenomenon)
4. Insulin Pump: slow insulin action, occlusions, leakages, catheter dislodgments, infusion site failures, insulin infusion set failures, signal loss (communication loss, loss of power, system failure)

Ultimately, this taxonomy will allow the identification and classification of all foreseeable safety issues, which in turn will facilitate the development of detection and solutions.

References

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