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Automated Insulin Dosing Systems or Automated Insulin Delivery Systems? It is Time for Consistency

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"What's in a name? That which we call a rose by any other name would smell as sweet"

William Shakespeare

A Lack of Consistency

A system comprised of an insulin pump connected to a continuous glucose monitor, which delivers doses of insulin determined by a software algorithm has been called an "artificial pancreas" and "closed loop system." In place of these previously widely used terms, clinicians, researchers, manufacturers, and the United States Food and Drug Administration (FDA) alike have recently been using two different new phrases to describe this type of system. These phrases are "automated insulin dosing" system and "automated insulin delivery" system (both abbreviated as AID). Given that two different phrases are used to identify the same type of automated insulin system and both phrases have the same abbreviation (AID), in the interest of clarity, we believe it is preferable to settle on a single phrase that consistently identifies the letter D in this abbreviation as either "dosing" or "delivery."

The Medical Literature

Evidence of the current inconsistency of terminology can be found in the medical literature. Many articles written by clinicians have used the words "dosing"[1] and "delivery"[2] to describe automated insulin systems. Many researchers have also described these systems as performing "dosing"[3] or "delivery"[4] of insulin, and on occasion as performing both of these terms[5] in the same article.

Classification of FDA-Cleared Products

Two companies manufacture FDA-cleared, automated insulin systems. They are Medtronic (Medtronic, Northridge, CA, USA) and Tandem (Tandem Diabetes Care, San Diego, CA, USA). Medtronic has developed the MiniMed 630G System, MiniMed 670G System, and MiniMed 770G Systems, which are hybrid closed-loop insulin pumps. Medtronic's websites[6,7] use the phrase "automated insulin delivery" to describe their 670G and 770G products' action, but classify the MiniMed 630G,[8] 670G,[6] and 770G[7] systems as "hybrid closed loop system(s),"[6] "insulin pump system(s),"[6,8] or "insulin pump and CGM system(s)."[9] Medtronic has received Conformitè Europëenne (CE) mark clearance but not FDA clearance for the MiniMed 780G System, which they describe as an "advanced hybrid closed loop system."[10] Medtronic does not use the term "AID system" to describe their automated insulin products on their websites. Meanwhile, Tandem Diabetes Care has also developed an automated insulin system called the Control-IQ. Tandem's website refers to the Control-IQ product as using "automated insulin dosing" software and "advanced hybrid closed-loop technology," [11] but does not refer to their product as an "AID system."

Classification of Products Not Cleared by FDA

Manufacturers of six non-FDA cleared automated insulin products have used a variety of terms to describe their systems, but only one of them refers to their product on their website as an automated insulin delivery system, and none of them refer to their product on their website as an automated insulin dosing system. Three of these products are CE marked and three are not. The manufacturers of the three CE marked products are CamDiab (CamDiab Ltd.,

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Cambridge, UK),[12] Diabeloop (Diabeloop, Grenoble, France),[13] and Inreda Diabetic (Inreda Diabetic, B.V. Noor, Netherlands).[14] CamDiab created the CamAPS FX app, whose name stands for "**Cam**bridge **A**rtificial **P**ancreas **S**ystem."[12] CamDiab's user manual classifies their system as an "artificial pancreas system" and a "closed loop system."[12] However, the company does not describe their automated insulin product as an "AID system" on their website[15] or user manual.[12] Diabeloop created an automated insulin product called the DBLG1. Their website uses the phrase "automated insulin delivery" to describe the product's action, but the company classifies their system as a "hybrid closed-loop system."[16] Their website uses neither the words "delivery" nor "dosing" to describe how they classify their system and the product is not referred to as an "AID system." The Inreda Artificial Pancreas can deliver glucagon as well as insulin. The manufacturer classifies its product as a bihormonal artificial pancreas and does not refer to its product as an "AID" system.[14]

The manufacturers of the three non-CE marked products are Insulet Corporation (Insulet Corporation, Acton, MA, USA), Tidepool (Tidepool, Palo Alto, CA, USA), and Beta Bionics (Beta Bionics, Inc., Boston, MA, USA). Insulet Corporation has developed the Omnipod 5 "automated insulin delivery system," according to a submission to ClinicalTrials.gov.[17] Tidepool uses the phrase "automated insulin dosing" to refer to an advanced sensor-enabled insulin pump system that automatically adjusts how much insulin is being delivered.[18] Tidepool describes their own software product, Tidepool Loop, as an "automated insulin delivery app,"[19] but not as an "AID system." Tidepool hopes to receive a designation from FDA for their dosing software as an interoperable automated glycemic controller, which would also be known as an iAGC.[18] Beta Bionics describes their automated insulin product, the iLet, as a "bionic pancreas," which can deliver glucagon as well as insulin. The company does not refer to their product as an "AID system" on their website.[20]

Automated Insulin Delivery Systems Regulated by Food and Drug Administration

The FDA has been inconsistent in their use of the terms "dosing" and "delivery" to describe automated insulin systems.[21-23] In 2019, the FDA used "dosing" to refer to the controller that determines the dose of insulin in an "automated insulin dosing system" (the Control-IQ), by which they meant a device that was previously known as an "artificial pancreas" or a "closed loop system."[22] In this context "dosing" was intended to connote a system that provides either a specific quantity of insulin or else a system that delivers any unspecified quantity of insulin. However, in 2018[21] and 2020,[23] the FDA used "delivery" (for a device that was previously known as an "artificial pancreas" or a "closed loop system") to refer to a system that delivers insulin automatically (the MiniMed 670G in 2018 and the MiniMed 770G in 2020). In this context, "delivery" connotes a system that provides any unspecified quantity of insulin to a patient.

Definitions

Because of this lack of agreement on consistent terminology, we examine nuances distinguishing the terms "delivery" and "dosing." We believe that if the emphasis for the classification of the product is on determining the correct dose, then the word "dosing" is the best word for the letter D in AID. However, if the emphasis for classifying a product is on infusing an appropriate quantity of insulin into a person, then the word "delivery" is the best word for the letter D in AID. The word "dose" can have either of two meanings: (1) to provide a measured quantity of medication (for example: "You need to dose yourself with five units of insulin to cover your breakfast carbohydrates.") or (2) to administer medication without necessarily intending a specific quantity (for example: "When your blood glucose becomes elevated, then you need to dose yourself with insulin."). If the first meaning is used for a product, then the word "dosing" is more appropriate. If the second meaning is used, then either word (dosing or delivery) is appropriate for an "AID" system because the device may be said to be either delivering a specific quantity of insulin or may be said to be delivering an unspecified quantity of insulin. Furthermore, the second meaning is the more commonly intended concept for the word "dosing" in the context of an artificial pancreas, a hybrid closed loop system, a fully closed loop system, or an automated insulin system that delivers quantities of insulin.

Conclusions

We believe that "delivery" is a more general and preferable term for the "D" in AID, because it incorporates both a specific quantity as well as a non-specific quantity of insulin. "Dosing" is correct if the main purpose of the product is to determine a quantity of insulin (rather than to deliver it), such as algorithm-based software programs. On their websites, Tandem[11] and Tidepool[18] discuss their appropriately named insulin "dosing" software. In those cases, the first meaning of "dosing" is sensible. If the emphasis of the product is more on the act of delivering rather than the act of calculating an appropriate quantity of insulin and the product contains a pump, then "delivery" is a better, more inclusive term because it incorporates both a specific quantity and a non-specific quantity of insulin. We recommend that the abbreviation "AID" system, which at one time referred to an "artificial pancreas" and at another time referred to a "closed loop system," should now be known as an "Automated Insulin Delivery" system. We are less in favor

of the term "Automated Insulin Dosing" system, but that term can be correct in specific contexts. It is now time for the diabetes technology community to come together on selecting a definition of the abbreviation for its most advanced technology: an AID system infusing insulin in the context of an automated process.

Abbreviations

AID, automated insulin delivery, automated insulin dosing; CamAPS, Cambridge Artificial Pancreas System; CE, Conformitè Europëenne; FDA, Food and Drug Administration.

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