A Novel Algorithm to Detect Priming Doses from Smart Insulin Pens

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Background

Insulin Pens are the most used device for administering insulin. Mechanical play between the drive components or an empty needle might prevent correct drug flow. Therefore, patients are advised to prime their pen before injection by delivering small doses until flow out of the needle is observed (**Figure 1**). Since these doses are not injected, they must be excluded from treatment decisions.

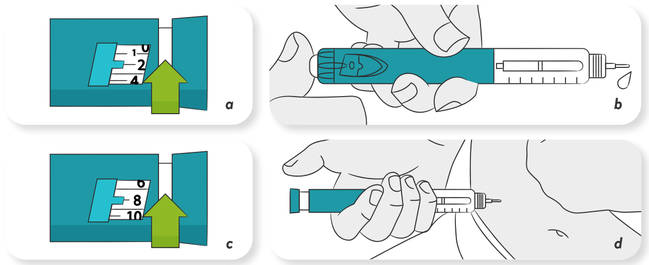

Figure 1: Insulin delivery using an insulin pen in multiple Steps. First, the patient primes the pen (a-b): The patient dials a small dose (e.g. 1 Unit) (a) and delivers the dose into the air ("airshot") until insulin flow out of the needle is observed (b). Then the patient injects insulin (c-d) by dialing the injectable amount (c) and injects into subcutaneous tissue (d).

Problem Description

Smart pens record all doses which makes automatic exclusion of priming events a critical task when used in decision support applications. However, individual priming strategies are diverse (**Figure 2**), which makes automatic separation of primings and injections difficult. In fact, existing algorithms are often incapable of accounting for many of these situations (**Figure 3**).

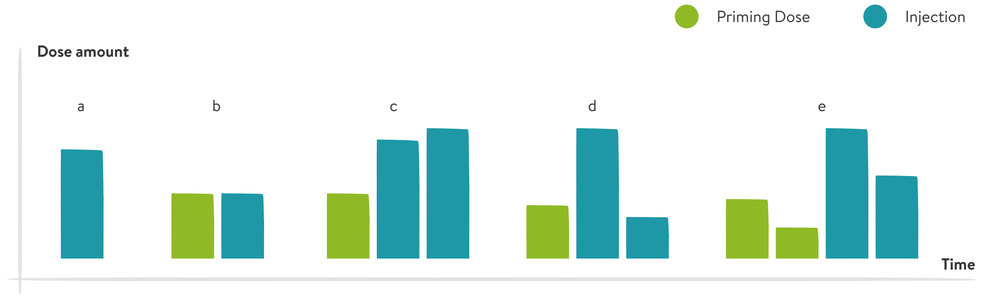

Figure 2: Examples of variability in possible pen event sequences (a-e). Users might (a) not prime, (b) inject the same amount as used for priming, (c, d) split their bolus into multiple injections or (e) perform multiple primings, possibly with different dose sizes.

Methods

We consulted a small group of internal experts and diabetics to understand different priming strategies and edge cases in insulin therapy. This allowed us to learn about relevant factors (e.g., timing, dose amount, order of events, dose splitting). We designed a new algorithm to account for these situations and compared its accuracy on a set of artificial dosing sequences.

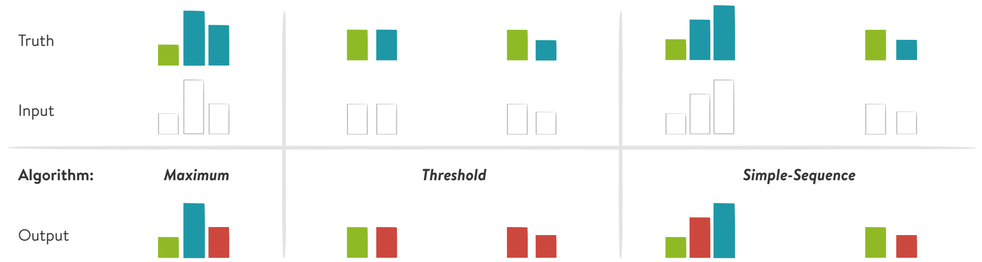

Figure 3: Algorithms failing (red) to correctly separate priming doses from injections:
Maximum algorithm [1]: Only maximum dose is not considered priming. Fails when a bolus was split e.g., in two parts.
Threshold algorithm [2]: doses below threshold are marked as priming doses. Algorithm fails e.g., when priming/injecting with larger/smaller doses. ***Simple-Sequence*** algorithm [3]: Small dose preceding larger dose or the last dose is marked as priming dose. Fails when injections are split, or priming dose is smaller than the threshold.

Results

The algorithm first splits doses into distinct groups of temporal vicinity and then labels the events as primings or injections. It allows multiple primings, dose splitting and boluses below priming thresholds. Overall, the algorithm has a high accuracy (>90%) compared to threshold based and simple sequence (>75%) and the maximum algorithm (>60%) (**Figure 4**).

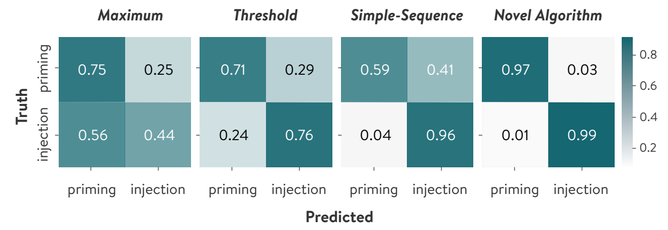

Figure 4: Confusion matrix outlining the performance (detection rates) of different algorithms for the automatic classification of priming doses and injections

Conclusion & Outlook

The correct detection of priming doses is essential for the use of smart pen data in decision support applications. The newly developed algorithm shows promising results. Monitoring pen priming behavior in a broader population will help to estimate algorithmic performance in a real-world setting and should include data from pediatrics and adult patients with type 1/2 diabetes including various therapy forms (basal therapy, conventional insulin therapy).

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1 EP2400883B1 - Drug delivery management systems and methods, 2 US10391235B2 - Device and method for determining information related to a medical device, 3 US9672328B2 - Medicine administering system including injection pen and companion device