Technology to overcome clinical inertia in insulin therapy

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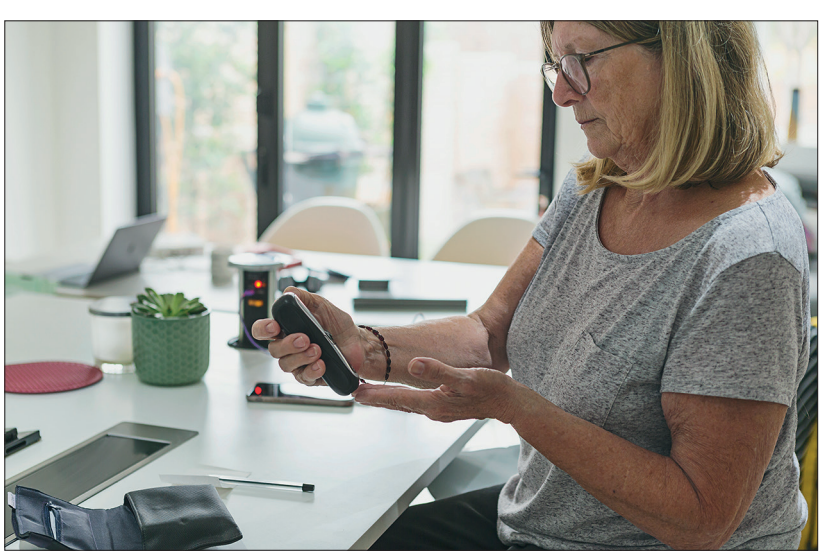
The evidence that lowering of blood glucose concentrations in diabetes can reduce risk of complications is well established; however, many people with type 2 diabetes do not reach recommended glycaemic targets.[1] Type 2 diabetes is typically a progressive disease with stepwise increases in blood glucose-lowering therapy needed to achieve and maintain glucose targets. Data from many health-care systems show that delays occur in intensifying therapies in those who do not to reach glycaemic targets.[2,3] As a consequence, many people with diabetes spend years with poor glycaemic control.

Why does this delay occur? Some obvious challenges exist. Diabetes care is frequently provided in busy generalist or primary care services with numerous competing time demands. Providers and patients might be reluctant to move from oral to injectable therapy (whether insulin or glucagon-like peptide-1 agonists) and there is often a lack of time, confidence, and resources for diabetes education to support providers' training and dose titration. Additionally, specific concerns might exist regarding insulin and potential weight gain and risk of hypoglycaemia.

One potential solution is to use computerised algorithms to inform and drive more frequent insulin dosing decisions. In *The Lancet*, Richard Bergenstal and colleagues[4] assessed a handheld glucose meter (d-Nav Insulin Guidance System, Hygieia, Livonia, MI, USA) with an inbuilt algorithm that can provide insulin dose advice on the basis of measured blood glucose. The device analyses glucose patterns and provides dosing advice direct to patients at the time of injections for four common insulin regimens (once daily basal, twice daily biphasic, and basal bolus with or without carbohydrate counting). In the study, 181 adults (88 women and 93 men)] with insulin-treated type 2 diabetes and sub optimal control (glycated haemoglobin [HbA_{1c}] ≥7·5% [58 mmol/mol] to ≤11% [97 mmol/mol]) were randomly assigned (1:1) to the intervention group, in which patients used the d-Nav device in combination with health-care professional support, or the control group, in which patients continued with a standard meter for glucose monitoring but otherwise received identical health-care professional contact. The primary outcome was change in HbA_{1c} assessed at 6 months.

Glycaemic control improved more in the intervention group than in the control group, with a mean HbA_{1c} decrease of 1·0% (SD 1·0; 11 mmol/mol [SD 11]) versus 0·3% (SD 0·9; 3·3 mmol/mol [SD 9·9]). On average, the algorithm adjusted insulin doses 1·1 times weekly (SD 0·2)—a frequency of adjustment that would be pragmatically unachievable in routine practice. As expected, this increased the frequency of adjustments, resulted in a notable increase in insulin administration in the group using the d-Nav device, with final doses being over 60% higher than in the control group. Interestingly, despite higher insulin doses in the intervention group, weight gain was minimal and the overall frequency of hypoglycaemic events was low in both groups and not significantly increased in the intervention group.

Continuous glucose monitoring was not done, so hypoglycaemia data were largely based on capturing low glucose values during self-monitoring. Notably, the group randomly assigned to use the d-Nav device did more glucose tests, perhaps reflecting the users' perceived value of the device. Importantly, for safety, the algorithm can either decrease or increase doses, and about 15% of dose titrations during the study were to decrease the insulin dose. Although the population studied had a relatively low frequency of hypoglycaemic events, an important question for more widespread future use would be whether automated insulin dose titration would result in increased hypoglycaemia in those at high risk at baseline.



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At face value, the approach looks appealing. The studied population appeared typical for many services, and the ability of the device to cope with different insulin regimens (including those who switched regimens during the study) and to provide advice direct to patients is valuable. The reported metabolic outcomes are similar to those reported in an earlier single-arm service evaluation assessment of the same device in a UK setting[5] and a broadly similar system in which dose advice was fed back to health-care providers.[6]

As expected in the context of a clinical trial, both groups had frequent contact with study team members, with seven face-to-face or telephone contacts over the period of 6 months. The authors are careful to describe the intervention as d-Nav delivered in combination with health-care professional support. During contacts, study teams checked overall wellbeing and health changes, but also assessed use of the device and could suggest alterations in insulin doses. In the real world, if such frequency of contact was an essential requirement for success of the system, it would be challenging for many services.

Finally, and importantly, how comfortable would patients and clinical teams be in allowing an algorithm to manage insulin dose titration? Generally, participants in this study were comfortable with receiving dose advice from the device. The world of type 1 diabetes, with greater complexity of insulin dosing than for type 2 diabetes, is already moving rapidly towards automated closed-loop insulin delivery.[7] Faced with increasing pressures and demands on primary care, a substantial niche seems likely for technology to help in type 2 diabetes.

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