Development of a cost utility model to assess the incremental cost effectiveness of continuous dual glucose ketone monitoring system versus continuous glucose monitoring system in people with diabetes

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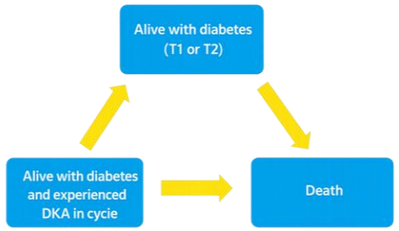
BACKGROUND

- Diabetic ketoacidosis (DKA) is a life-threatening condition that can occur with both Type 1 (T1) and Type 2 (T2) diabetes. DKA results from the accumulation of ketones in the blood and often arises due to insufficient insulin. Those managed with insulin therapy are often most at risk of DKA.
- Hospitalization rates for DKA are rising among people with both T1 and T2 diabetes—though earlier underreporting remains possible[1]. DKA events are not reliably predicted by glucose levels, and early signs of DKA are often non-specific.
- Significant barriers remain to widespread awareness of DKA and ketone self-monitoring via urine or blood testing. Ketone testing may have limited effectiveness in preventing DKA hospitalizations, as it is often initiated after symptoms, when results may only serve as confirmation rather than enabling proactive intervention to avoid hospitalization.
- A recent international expert panel noted that continuous ketone-monitoring sensors (CKMs) could reduce the risk of DKA and address a major gap in care[2]. CKM sensors could empower users to understand their overall risk and provide alerts when ketone levels are rising, enabling proactive interventions to avert DKA.
- A Dual glucose-ketone (DGK) sensor that incorporates both a CKM sensor and a continuous glucose monitor (CGM) could help people with T1 and T2 diabetes manage both glucose and ketone levels, thereby preventing potential DKAs and address a critical gap in care.
- A cost-effectiveness model was developed to compare this new DGK sensor to management with FreeStyle Libre 2 Plus (FSL2Plus) with blood ketone monitoring.

Figure 1: Schematic of Markov model states



METHODS

- The cost-effectiveness model evaluated DGK compared to FSL2Plus with blood ketone monitoring for people with T1 and T2 on multiple daily injections of insulin (T2 MDI). The UK served as the setting of the analysis. A National Health Service perspective was adopted.
- The model conservatively assumed the only additional benefit of DGK relative to FSL2Plus with blood ketone monitoring was a reduction in DKA hospitalizations. With this assumption, a simple, transparent three-state Markov model was developed (Figure 1). A 1-year cycle length was assumed. A lifetime time horizon was adopted with a 3.5% discount rate.
- Transition probabilities from the "alive with diabetes" state to "death" were modeled using UK sex-specific life tables[3]. Standardized mortality ratios were used to adjust mortality probabilities in life tables to reflect mortality in the T1 and T2 MDI population (T1 = 2.8[4]; Male T2 MDI = 1.5[5]; Female T2 MDI = 1.7[5]). Table 1 displays other transition probabilities and utility values assigned to health states. The model assumed those managed with DGK received an annual utility benefit of 0.01.
- Currently, no clinical data exist on the effectiveness of DGK relative to FSL2Plus (or any other CGM) in reducing DKA hospitalizations. In the base case, DGK was assumed to reduce DKA hospitalizations by 50% compared to FSL2Plus with blood ketone monitoring. Sensitivity analyses were conducted to assess the robustness of this assumption.

Table 1: Base case model parameters

Parameter	Value
T1 Demographic data	Mean age 37[6]; Male 52.4%[6]
T2 Demographic data	Mean age 59[6]; Male 56.5%[6]
DKA Annual Transition Probability	Prob. of DKA in T1 2.4%[6] Prob. of DKA in T2 MDI 0.8%[6] Prob. of DKA Death 1.8%[7]
Utilities	Diabetes baseline utility 0.785† DKA disutility 0.05† DGK utility benefit 0.01†
Costs	Annual ketone blood testing £14.61 DKA Hospitalization £2,170[8] Diabetes background cost £2,470[9]

RESULTS

- For people with T1, the model estimated DGK increased average lifetime quality adjusted life years (QALYs) by 0.26 per person compared to FSL2Plus with blood ketone monitoring at an incremental cost of £2,997.
- For people with T2 MDI, the model estimated DGK increased average lifetime QALYs by 0.16 per person compared to FSL2Plus with blood ketone monitoring at an incremental cost of £2,335.
- The estimated incremental cost-effectiveness ratio (ICER) of DGK relative to FSL2Plus with blood ketone monitoring was £11,668 for people with T1; the ICER for people with T2 MDI was £14,944.
- The model found DGK to be cost-effective for both the T1 and T2 MDI populations under the National Institute for Health and Care Excellence willingness-to-pay (WTP) threshold. This conclusion was robust even in a sensitivity analysis where DGK only reduced DKA hospitalization rates by 10%--opposed to 50% in the base case (Figure 2)

Figure 2: Results for T1 and T2 MDI population

CONCLUSIONS

- This analysis indicated DGK was a cost-effective intervention for T1 and T2 MDI population.
- Overall, this analysis supports future reimbursement of the DGK sensor in the UK

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†Assumed

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