KARMA2 🔴🔵

Use of blood ketone meters to improve ambulance hyperglycaemia care.

KARMA2 Summary

Ambulance clinicians usually rely on non-specific clinical signs and symptoms for hyperglycaemia and diabetic ketoacidosis (DKA) care strategies, which are susceptible to error. They do not routinely have access to point-of-care capillary blood ketone meters to assess blood ketone levels in unwell patients. Current Joint Royal Colleges Ambulance Liaison Committee (JRCALC) Clinical Practice Guidelines indicate intravenous fluid therapy should be considered for DKA management if the patient is hypotensive and there is clear evidence of circulatory failure or dehydration.

The KARMA2 stepped-wedge controlled feasibility study was devised to determine whether ambulance clinicians could reliably and safely identify DKA using capillary blood ketone meters and commence fluid therapy in accordance with the study protocol.

Adult patients with hyperglycaemia or unwell patients with diabetes were recruited over a 10-month period, initially into the Control Phase (5-months; usual care) and then the Intervention Phase (5 months; usual care plus blood ketone assessment – 'High-Risk' DKA patients receiving fluid therapy). In addition, ambulance and emergency department (ED) clinicians were purposively sampled to participate in a research interview to explore their experiences of hyperglycaemic emergencies, in particular DKA.

In total, 388 eligible patient participants were recruited into KARMA2. Most had hyperglycaemia (i.e., capillary blood glucose (CBG) greater than 11mmol/l), diabetes (Type 1: 20%; Type 2: 73%) and were conveyed to hospital.

Ketonaemia and DKA: During the Control Phase, the incidence of reported ketonaemia (i.e., elevated ketones present in blood) was 7%. With the use of study ketone meters during the Intervention Phase, this information availability increased to 24%. The incidence of 'High-Risk' DKA (capillary blood ketones (CBK) ≥3.0mmol/l) in the Control Phase was approximately 2%, and 6% in the Intervention Phase. The incidence of hospital-confirmed DKA in the Control and Intervention Phases was approximately 4% and 6%, respectively. Ambulance primary impression codes revealed a high suspicion for DKA as a differential diagnosis: missed patients included those presenting with euglycaemic DKA and complex co-morbidities.

Patient Management: One third of Control Phase and almost half Intervention Phase 'High-Risk' DKA participants were cannulated and received fluid therapy. All except one Intervention Phase 'High-Risk' DKA participant was normotensive, yet most were reported to have signs of circulatory failure or dehydration. Reasons for not commencing fluid administration were unsuccessful cannulation, patient close to hospital, and not within scope of practice. Almost all the 'High-Risk' DKA Intervention Phase participants received a hospital pre-alert. Whilst it was recognised pre-alerting was part of the intervention, it was almost twice that of Control participants.

Hospital management: ED blood glucose and ketone assessment results were obtained for the majority (89%) of participants; however, glycosylated haemoglobin (HbA1c) data was only available for a minority (6%) of participants.

Clinician Interviews: Ten ambulance clinicians and ten ED clinicians were interviewed: ten themes were identified:

• Patient assessment: Ambulance staff reported positive experiences using capillary blood ketone meters and considered them a beneficial diagnostic tool for patient assessment and care:

> '…I think it allows us, as pre-hospital clinicians to make better judgment calls on if we can leave someone at home or if they need to reach out to a GP or whether they need to go to hospital.' **P10**

Difficulties associated with meter use did occur; calibration before use with time-critical patients; error messages with temperature extremes; calibration value falling outside of manufacturer's range.

• Recognising hyperglycaemia: When considering the risk factors for DKA, ambulance clinicians had inconsistent approaches to determining hyperglycaemia:

> '…you always associated it with a 'HI' reading on the, on the BM [blood glucose] machine or, you know, reading in the 30s or, or high 20s.' **P6**

'[It] *is just knowing what's normal for that patient and whether they're outside of what's normal for them and whether their concerns and their family and their carers…*' **P2**

• Current ambulance DKA fluid therapy: Hyperglycaemia/DKA fluid therapy practice appears non-compliant with current JRCALC clinical guidelines:

'*…if their sugars are reading high, I'd probably treat them with fluids anyway.*' **P5**

• Ambulance clinical handovers: Inclusion of ketone status was considered informative and beneficial when safety-netting with primary care or handover at hospital:

'*…it …will be better, ringing up and saying, 'by the way, do you know Mrs X's blood sugars are 18 today and incidentally the ketones are 1.2 and this is what I've done about it.*' **P3**

• Decision support tool**:** Ambulance participants reported improved clinical decision-making and safety-netting with ketone meter use, in particular, conveyance versus non-conveyance:

'*I think it's helped having that discussion with the patient and asking them whether they had been following sick day rules and whether they can…*' **P2**

• Ambulance diabetes education: There is scope for improved hyperglycaemia education for ambulance staff - 'sick day rules' and euglycaemic DKA were unfamiliar for most:

'*I am embarrassed to say I was not aware of sick day rules…*' **P3**

'*I had heard of* [euglycaemia DKA]*, but it's not something I would have been very aware... Probably wouldn't be considering DKA if their blood sugars weren't elevated and stuff.*' **P2**

• Patient engagement: Whilst KARMA2 did not seek the experiences of patients, several ambulance participants indicated they felt positively about meters in clinical practice:

'*…all of the patients have been very receptive… … everybody has been very positive about it.*' **P2**

• Hospital DKA diagnosis and care: Emergency department participants were supportive of ambulance blood ketone assessments and 'High-Risk DKA' pre-alert messaging to expedite hospital DKA management:

'*That information will change a lot of things. …Number one will be where to put this patient… …If I know the ketones are high, they go to Resus. It's clear cut DKA, initiate fluids… Number two, if …it's not DKA, then we can think about the other places where this patient can, er, go.*' **P5**

• Prioritisation of fluid therapy: The importance of paramedic-led cannulation and fluid therapy was recognised by ED participants, facilitating their delivery of DKA care:

'*… if* [ambulance ketone] *reading has already been done and fluids have already been started, it gives us a little bit of time to, um, organise our… Resus area and get our levels safer to bring this patient then in.*' **P19**

• Barriers to hospital DKA care: Resuscitation bed capacity and nursing staff resources were identified as key barriers to hospital-based care. Pre-hospital intravenous access was noted to aid hospital DKA care:

'*I think gaining access is probably the most helpful… obviously it takes time for us to try and gain access… If we've already got one, we can start the treatment.*' **P14**

To date, there has been limited research regarding hyperglycaemia care in the ambulance setting, both in the UK and more widely, so the findings from KARMA2 are much anticipated. Currently JRCALC is updating its Clinical Guidelines for Glycaemic Emergencies, which are being informed by the KARMA2 findings. It is recommending UK ambulance services make capillary blood ketone meters available for frontline clinicians and promotes a standardised approach to blood ketone testing and hyperglycaemic patient care.

COVID-19 did impact participant recruitment so that the study progression criteria for a full-scale trial were not met. Learning could include use of alternative trial design and clinician training mode for future research.