

Use of capillary blood ketone meters to improve ambulance service care of hyperglycaemic patients: protocol for a stepped-wedge, controlled feasibility study (KARMA2)

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Background:

Diabetic ketoacidosis (DKA) is a potentially life-threatening condition associated with diabetes (Type 1 and Type 2), certain medications (i.e. SGLT2 inhibitors), and other health conditions. Hospital-based guidelines advocate immediate start of intravenous fluid therapy upon DKA diagnosis, which does not reliably happen in the pre-hospital setting. Ambulance clinicians do not routinely have access to ketone meters to determine presence of ketones; they rely on non-specific clinical signs and symptoms for care strategies. The aims of this feasibility study are to determine whether ambulance clinicians can reliably and safely identify patients with DKA using capillary blood ketone meters, commence fluid therapy, and gather necessary study data.

Methods:

During an 8-month period (4-month control : 4-month intervention), 120 ambulance clinicians from one UK ambulance service will receive training to determine presence of ketones using capillary blood testing from 800 consenting patients with hyperglycaemia and unwell patients with diabetes. Subsequent patient care will depend on the ketone value obtained: high-risk DKA patients will receive fluid therapy. Twenty ambulance and hospital clinicians will be invited to an interview to share their views of DKA care and the impact of capillary blood ketone meters.

Results:

Information collated will include completion of study training, patient recruitment, intervention adherence, service call activity, and ambulance and hospital patient clinical data. Prevalence and severity of hyperglycaemia, incidence of DKA and ability of paramedics to commence fluid therapy for DKA will be explored. Quantitative findings will be analysed using descriptive statistics, whilst the qualitative study interviews will be thematically analysed.

Conclusions:

Study findings will be used to inform the need and feasibility to proceed to a full stepped-wedge, controlled trial. If warranted, we will develop a research funding proposal evaluating the clinical and cost-effectiveness of ambulance ketone meters and further explore meter provision for improved ambulance patient care.