**Title:** EXPECTED VALUE OF SAMPLE INFORMATION FOR INDIVIDUAL LEVEL SIMULATION MODELS TO INFORM STOP/GO DECISION MAKING BY PUBLIC RESEARCH FUNDERS: A METHODOLOGY FOR THE DAFNEPLUS DIABETES EDUCATION CLUSTER RCT.

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**ABSTRACT**

**OBJECTIVES:** This paper presents a conceptual methodology for calculating the expected value of sample information (EVSI) to inform the decision making of a UK public funder (NIHR) regarding whether to fund the second stage of the DAFNEplus research programme. The first phase of DAFNEplus programme involves redeveloping, piloting and refining DAFNE structured education courses for adults with type 1 diabetes. The second phase aims to test the effectiveness and cost-effectiveness of the revised course (DAFNEplus) versus a standard DAFNE course in a cluster randomised controlled trial (RCT). **METHODS:** To generate prior estimates of effectiveness of DAFNEplus compared to DAFNE and the uncertainty around them, an expert elicitation exercise will be conducted using the Sheffield Elicitation Framework to estimate likely incremental changes at 12 months follow-up in: HbA1c; rate of severe hypoglycaemia; and rate of diabetic ketoacidosis. Five experts will include: medical experts; diabetes educators; psychologists; and potentially patient representatives. Summary statistics from the first phase of DAFNEplus will be presented to the experts. EVSI of the proposed trial will be calculated by conducting a cost-effectiveness analysis of DAFNEplus versus DAFNE using an existing individual level simulation model (the Sheffield Type 1 Diabetes Policy Model), the elicited distributions and Sheffield Accelerated Value of Information Tool (SAVI) by Strong *et al*. The EVSI will compared to the cost of the RCT. **CONCLUSIONS:** Elicitation of likely effects on clinical endpoints and their prior uncertainty, together with individual level simulation modelling and SAVI, makes it feasible to include health economic criteria in stop/go decisions by public funders. To generalise this approach to other diseases and settings, analysts will need to consider: how to synthesise prior evidence; the balance between existing prior data and eliciting expert judgement; the roles and biases of experts to elicit from; and wider decision making criteria of the research funder.

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