

Challenges of Treating to Target - Experiences and views of patients and staff participating in the three-year 4-T trial

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Aim: To understand why patients could not always attain the Treat to Target in Type 2 Diabetes Trial (4-T) HbA1c $\leq 6.5\%$ glycaemic target when adding insulin to oral glucose lowering therapy.

Methods: In-depth interviews with 45 patients and 21 health professionals, recruited from 12 of the 58 clinical centres.

Results: Most patients were committed to taking insulin as recommended by 4-T staff. Although initially anxious about injections, patients were 'insulin receptive' rather than 'psychologically insulin resistant'. This was due to experiences of deteriorating blood glucose control and perceptions that oral glucose lowering agents were no longer working. To avoid hypoglycaemia, patients occasionally altered or skipped insulin doses, sometimes in consultation with staff. Staff felt that the 4-T automated insulin dose adjustment algorithm increased their confidence to prescribe larger insulin doses than in routine clinical practice but all described situations where they did not follow recommendations. Application of a 'one size fits all' glycaemic target was seen as contrary to clinical experience. Staff also expressed concerns that 'tight' glycaemic control might impose an unacceptably high risk of hypoglycaemia that could compromise trust and safety, especially amongst older patients. Patients were usually unaware of the glycaemic targets. Positive staff feedback led some to believe they had been 'successful' trial participants even when their HbA1c exceeded 6.5%.

Conclusions: To understand 4-T glycaemic outcomes it is necessary to move beyond the patient and consider the broader context, including the difficulties staff encountered in balancing and reconciling their 'clinical' and 'research' roles and responsibilities.