

## 1. Background and Aims

Continuous glucose monitoring has been developed to overcome the limitations of traditional blood glucose monitoring methods. Widespread use of new technology in healthcare, such as these devices, is predicated upon their acceptability to people with diabetes.

Acceptability: An individual's willingness to use a device which in turn, depends on several interrelated factors<sup>1</sup>:

- the needs of the individual
- perceptions of safety and utility of the device
- whether the device either supports or undermines personal identity and control over the condition

Although a number of these devices have been introduced, relatively little work has been performed on their acceptability. The work by the DirecNet group in developing a questionnaire of treatment satisfaction has begun to address this gap<sup>2</sup>.

Aim: to examine the relative use and acceptability of the GlucoWatch G2 Biographer (Animas) and the CGMS (Minimed).

## 2. Methods

Design: part of an efficacy RCT

CGMS: fitted on 3 separate occasions during first 3-months  
GlucoWatch: requested to wear minimum of 4x per month and maximum of 4x per week in first 3 months

Participants:

- Insulin-requiring ( $\geq 2$  injections per day) people with diabetes
- Two consecutive HbA1c's  $\geq 7.5\%$

Acceptability, use and skin reactions over the first 3-months of the trial are reported.

Measures:

Acceptability questionnaire developed specifically for the purpose of this trial<sup>\*</sup>.

Questionnaire items assessing the following aspects of acceptability are reported here:

- side-effects
- relative level of interference of the devices
- degree to which they were willing to accept side-effects and interference

Analysis:

Levels of interference with daily activities and acceptability ratings were compared between the groups using Mann-Whitney U Tests. Frequency of use was treated as a further indicator of acceptability and analysed using t-tests and ANOVAs.

## 3. Results

### Sample Characteristics

	GlucoWatch	CGMS
n	100	102
Median Age (IQR)	55 (37 to 66)	53 (42 to 63)
Male Sex (%)	56 (56)	57 (56)
Type 1 (%)	53 (53)	61 (60)
HbA1c Mean (sd)	9.2 (1.5)	9.0 (1.1)

\* Further details available from the authors on request

### Monitor Use (0-3 months)

- 2.5 in the CGMS group (83% of that requested)
- 10 times in the GlucoWatch group (all less than requested)

Number who stopped using monitor by 3-months:

- 11 CGMS and 36 GlucoWatch participants
- 4 CGMS and 6 GlucoWatch chose not to wear devices at all after randomisation

### Skin Reactions

Proportion reporting skin problems amongst those using devices at 3-months:

- 7% CGMS
- 98% GlucoWatch

Median duration of skin problems reported during first 3 months:

- 1 to 4 days CGMS
- 3 to 28 days GlucoWatch

Proportion reporting severe skin reaction during first 3 months (MITRE Skin Scale Score  $\geq 6$ ):

- 0% CGMS group
- 13% GlucoWatch group

### Side-effects:

Three months from baseline, participants were asked whether they had experienced any of 9 specific side-effects (Figure 1). If they responded 'yes', they rated how acceptable these were (1=not at all acceptable to 5=completely acceptable; Figure 2).

Figure 1: Percentage of those using the devices who reported side effects in Phase 1 (0-3 months)

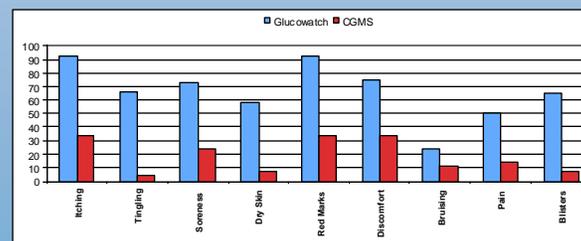
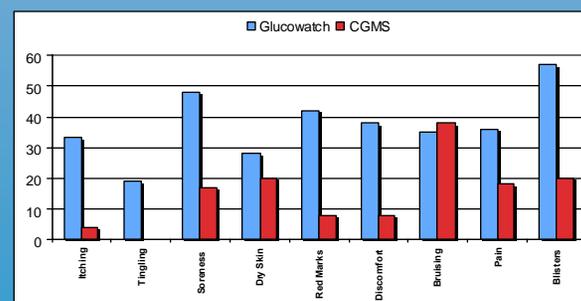


Figure 2: Percentage of those reporting side effects who rated them not at all acceptable



Percentage reporting at least one side-effect:

- 48/76 (63%) CGMS
- 69/71 (97%) GlucoWatch

Percentage reporting 1 or more side-effects and rating at least 1 of these as 'not at all acceptable':

- 8/48 (17%) CGMS
- 44/71 (63%) GlucoWatch

### Interference with Lifestyle

Participants rated the extent to which wearing the device interfered with 9 normal activities on a 5-point Likert scale.

If they reported interference, they were also asked to rate how acceptable this was to them on a 5-point Likert scale.

Approximately 50% or more participants in both the CGMS and GlucoWatch groups stated that wearing the monitor interfered with 5 of these daily activities (washing, exercise, sleep, work and choice of clothes; Fig. 3).

Figure 3: Percentage reporting some interference with their normal activities in Phase 1 (0-3 months)

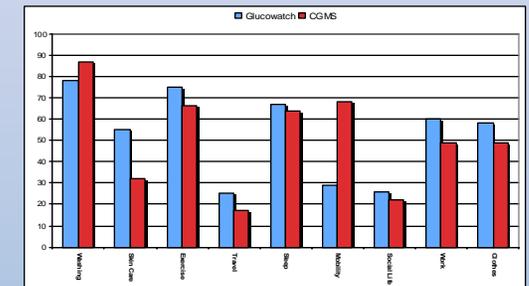
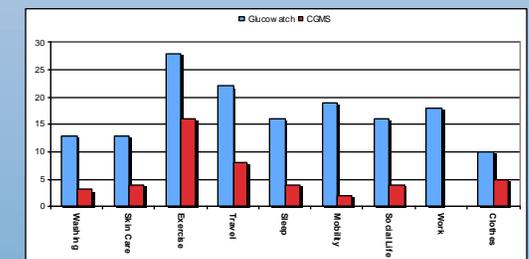


Figure 4: Percentage of Participants Reporting Interference that was 'not at all acceptable'



• GlucoWatch group: significantly greater interference with work (U=541, p=.046) and skin care routine (U=1881, p=.001)

• CGMS group: wearing the device interfered with their ability to move around significantly more than the GlucoWatch group (U=1700, p=.001).

• CGMS group: significantly higher acceptability ratings for interference with bathing routines (U=1383, p=.03) indicating that they were more willing to tolerate this interference than the GlucoWatch group (Fig. 4).

## 4. Summary

The CGMS was more acceptable to participants than the GlucoWatch in terms of both discontinuation rates, side-effects and interference with lifestyle.

Many participants continued to use both of these devices despite reporting significant interference with daily living. This suggests that this is balanced by participants' perception of the potential value or importance of the devices in their care.

This study demonstrates that it is possible to assess the relative acceptability of such devices. This is a crucial aspect in establishing whether a device can be routinely incorporated into diabetes management.

## 5. References

1. McCreadie C, Tinker A. Ageing and Society 2005; 25:91-110.
2. DirecNet Group. Diabetes Care 2005; 28:1929-1935.

## 6. Acknowledgements

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