

Roche Diagnostics© “Diabetes Assistant” Feasibility Study

A feasibility trial of a commercial internet based service used for the management of Diabetes on a group of children and adolescents in New Zealand.

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1 Introduction

Diabetes Mellitus (DM) makes major demands on health-care resources in New Zealand (NZ) with much of these costs spent on the management of diabetic complications (1). In NZ the average incidence of Type 1 DM has doubled over the past three decades. Self-management of diabetes is a challenging task due to its complexity and ever-present barriers to self-care (2). The tight control of blood glucose (BG) levels however is crucial to the prevention of subsequent complications which are ultimately reflected in the large economic burden that arises from poorly controlled BG levels (3). Results from the Diabetes Control and Complications Trial (DCCT) in the United Kingdom established conclusively that achieving near normal BG levels during adolescence can lead to a significant reduction in diabetes-related complications over time (4).

How well children and adolescents are motivated to control their diabetes in their youth, has a direct bearing on the complications they may experience as an adult (5). Therefore, in people with Type 1 DM developing good diabetes management skills and a positive attitude as early as possible is essential (6).

Adolescence is a time in life when increased independence and responsibility is expected of and asked for by the teenager. With this in mind there has been a large drive in recent times to develop new strategies to improve the quality and efficacy of care.

With the arrival of the digital age, the internet has triggered an information revolution and firmly established itself as a valuable tool for the flux of health information (7). The benefits of the internet are in affordability, accessibility and its capability to reach thousands of patients (8).

Glasgow R.E. and colleagues discuss the practical and conceptual uses for interactive computer applications (ICAs) in family practice. (9) Their group focuses on implications that the technology could have on patient self-management and physician-patient relationships. With many ICAs already available, the authors predict that many will play a central role in future health care but also acknowledge that there is also a risk of ICAs being used inappropriately. They urge that those

involved in researching and applying ICAs should be “bold in what they attempt but cautious in what they claim”.

Eng T.R. and colleagues discussed the benefits and challenges associated with evaluating interactive health communication applications in more detail. Evaluation of these services is crucial as inaccurate or inappropriate health information and poorly designed applications can result in detrimental outcomes. The paper explains that the key principles of assessment are that the evaluation should be practical, proactive and have a clear purpose. (10)

A small pilot trial conducted by Cavan and colleagues had patients enter BG measurements manually and then received feedback on alternate insulin doses or meal sizes in order to better control their BG levels. Responses from the participants indicated that while the system was helpful, they felt hindered by difficulties with entering their BG data. (11) A.C. Smith in 2003 explored online health services by incorporating ‘telepaediatrics’ with an outreach program. They were able to reduce travel for specialist hospital staff while at the same time maintaining and at times even increasing patient access to specialist services from remote areas of Queensland/Australia. (12) Although the technology used was different to this study, it is interesting as Australia is renowned for the geographical challenges it presents to the provision of health care.

H.S Kwon looked specifically at using the internet to allow physicians to monitor BG concentrations in their patients. Their study found that patients using the system experienced a significant fall in their HbA_{1C} plasma concentrations over a trial period of 12 weeks. (13) The improvement in the control of the patients’ blood BG was attributed to a number of factors including more frequent physician-patient contact and the fact that patients received medical advice relevant to the most recent BG data possible. It is thought that these factors may have motivated patients to take more responsibility and monitor their BG levels more enthusiastically. In 2004 researchers trailed a wireless, portable system to improve adherence and glycaemic control in youth with DM and found that youth is able to implement new technologies and most of all showed an increased frequency in Self-monitoring of blood glucose (SmoBG) levels. (14) The trail was of short duration (4 weeks) and based on a motivational game style. In relevance to the

current study, an increased sense of responsibility for ones care could be an empowering experience to an adolescent. Perhaps this could be beneficial to adolescents as a group as they typically have the most difficulty managing chronic health conditions. The authors acknowledge that due to the short duration of the trial, the long-term efficacy still needs to be determined.

Unfortunately little literature was found addressing the specific benefits for children and adolescents using internet diabetes support services.

Therefore the aim for this feasibility study was to:

1. Install and evaluate a system that will allow electronic transferring of blood glucose data form an ACCU-Chek* BG meter to a web-database in adolescent's home.
2. Evaluate the ability and consistency of participants to forward the transferred results to their Diabetes care team monthly and 24 hours prior to Diabetes outpatient appointments.
3. Evaluate the benefits for the Diabetes Care team of receiving the participant's blood sugar results prior to their outpatient appointment.
4. Evaluate the understanding and acceptance by the adolescent of the layout and presentation of their BG results.

*ACCU-Chek Roche

2.0 Methods

2.1 Recruitment

The Otago District Health Board (ODHB) paediatric diabetes outpatient clinic register and the diabetes nurse educator (DNE) and Endocrinologist's knowledge of names of children and adolescents owning a personal computer were used as the sampling frame. Inclusion criteria for this study were defined:

- Diagnosed with Type 1 DM for at least 6 months
- The participants family owned a personal computer
- The computer was running on at least Windows98 or higher
- The family had internet access.
- The participant or parent showed computer literacy

A personalised, informal cover letter, study information sheet, consent form and return stamped and addressed envelope were mailed to all children meeting the study criteria that had shown an interest to the DNE or endocrinologist (n=21). The children were asked to return their consent form within seven days if they were willing to participate. If the consent form was not received within nine days, a follow up phone call was made. This phone call was used to clarify questions. A further four (n=8) were approached by the principal investigator (Registered Dietitian) during their pediatric diabetes outpatient appointment.

2.2 Development of Resources

2.2.1 Development of Trouble-shooter information sheet for use of the programme "Diabetes Assistant"*

Trouble-shooter information sheet was designed by the principal investigator with support by the Information Technologist specialised in the software programme "Diabetes Assistant"* in Sydney, Australia. The help sheet was pre-tested by two adolescents without diabetes and one adult after explaining the aim of the study, the importance of self monitoring of blood sugars (SmoBG) and processes that children with diabetes have to take on a daily basis. Some changes were made to the wording of the help sheet after feedback from pre-testing.

2.2.2 Development of Questionnaires

The questionnaire was developed by a research student as part of a summer scholarship, under the guidance of research staff in the Department of Women's and Children's Health, ODHB. The participant questionnaire was divided into several components and was comprised of two parts: one for the participant (Appendix 1) and one for the caregiver (Appendix 2) with the greatest involvement in the management of the participant's diabetes. The questionnaire was piloted on several colleagues and their children to ensure it was intelligible and unbiased (15) and changes were made based on their responses.

Due to the age distribution of the group and the small sample size, it was thought that the results would be more useful and reliable if an interviewer worked through the questionnaire with the participant allowing them to query and clarify any of the participants' responses if necessary. It was thought that this age group would provide better information in a one on one situation compared with that gained from simply posting out a questionnaire. We were mindful of the fact that the presence of an interviewer could potentially influence the participants' responses. To overcome this to some point, the questionnaire was mailed out prior to the interview and the participants were expected to have answered the questionnaire. The interviews were carried out by the principal investigator.

It was anticipated to interview members of the specialist team responsible for the management of the participants during the trial. The team consisted of one Pediatric Endocrinologist, one Diabetes Nurse Educator, one Dietitian and one Pediatric Nurse. They were asked what they thought of the new system, potential improvements and whether or not they thought it had a potential for future use in New Zealand. (Appendix 3)

2.3 Data Collection Procedure

2.3.1 Study Protocol

Participants that returned their consent were contacted by phone to arrange a home visit. Each participant's home was visited by the principal investigator or a research student. The participant was provided with a new "Advantage Accu-

Chek[®] blood glucose meter courtesy of Roche[®]. The commercially available “Diabetes Assistant” software was installed on the participant’s computer and they were shown how to use it. One practice trail of downloading blood sugar results and e-mailing those results to their Endocrinologist was expected and observed by the investigator. A brief discussion and explanation of the trouble-shooter information sheet and expectations on the participant finished off the visit. Participants were instructed to download their BG results on a monthly basis and e-mail those results to the Endocrinologist and or DNE. Additionally, the subject was instructed to send in a full report from the date of commencement of the study twenty four hours prior to a follow up outpatient appointment (three monthly). The research team offered a follow up phone call service after the first months to encourage uploading of results. Although the trial was running for 3 months, access to the “Diabetes Assistant” website was available for 13 months in total, allowing them to continue using the service if they wished. Many of the patients were already using this particular model of meter or one similar and were able to upload pre-trial blood glucose data as well.

2.3.2 Participant Data Analysis

Demographic data and results of a pre-study and post-study glycated Haemoglobin (HbA1c) were obtained from the participants medical records. Treatment regimes (Insulin) were recorded on a spreadsheet and forwarded to the specialist reviewing the participant’s online data. It was assumed that this information would allow the Endocrinologist to make judgments about the participants control and then respond appropriately via email or telephone.

2.3.3 Website Data Analysis:

Data from the website database was accessed with the participants’ permission. Access to BG results was provided via sending results to the Endocrinologist/DNE who then use a password that was send by the “Diabetes Assistant” programme to enter the forwarded BG-results.

2.3.4 Data Analysis of Questionnaires and feedback

The data was analysed by the principal investigator and did not follow a recommended five step process as anticipated to prevent bias. (16) An excel spread sheet was used to analyze demographics, HbA1c, frequency of posting results and questions that allowed answering on a likert scale. Averages were calculated using simple math.

Verbal and written answers were copied and pasted into the appropriate code using excel. (Appendix 4) Frequency and accuracy of mailing of downloaded results were analyzed using excel (Appendix 5) as was frequency of follow up phone calls, quarries and follow up visits by the principal investigator. (Appendix 6) Feedback from the Diabetes Care Team was anticipated to be analysed in the same manner, however due to time constrains only three team members were interviewed.

2.3.5 Data storage procedures

The raw data collected was treated anonymously and confidentially. The data was stored securely in the principal investigator's office during the project. Only the principal investigator had access to the data. On completion of the project all raw data, complete consent forms, interview notes are submitted to the Department of Women's and Children's Health, ODHB. Contact details used during the intervention were deleted from e-mail lists or destroyed upon completion of the project.

3.0 Results

3.1 Sample description

Twenty nine (n=29) potential participants were approached by the principal investigator. Fifteen (n=15) returned their consent and were contacted to arrange set up of the programme “Diabetes Assistant”^{*} and a practice run for uploading of results. One participant (n=1) withdrew during set up stage due to time constraints. One participant was withdrawn for not following the study protocol. Hence, 13 participants (n=13, n=5 male, n=8 female) were enrolled after screening, ages ranging from 7 to 18 years, average age 12.6 years (Table 1).

Most participants were living in Dunedin within a 20 km radius from the Hospital, n=2 lived outside Dunedin, more than 100 km from the hospital.

Two (n=2) children lived with a single parent for most of the week, but had weekends with the other parent or grandparent. This affected their ability to have access to their computer.

All participants were Insulin dependent and no one was administering Insulin via an insulin pump. Insulin type and regimen was adjusted and changed during the period of the feasibility study, hence no analysis was performed on this.

Table 1: Demographic distribution of study group

Female participants			
Age (years)	Living < 20 km radius of Hospital	Living >100 km of hospital	Number of participants
7		1	1
10	1	1	2
12	1		1
13	2		2
14	1		1
15	1		1
Total			8
Male participants			
12	1		1
13	1		1
14	2		2
18	1		1
Total			5

Results as extracted from medical records for HbA1c were from the last follow up visit at ODHB diabetes outpatient clinic prior to commencement of the study. The average HbA1c was 8.88 % and 8.45 % pre- and post-intervention respectively (Table 2).

Table 2: Participants HbA1c results pre- and post- intervention

Participant number	Age (years)	Gender (f=female, m=male)	Pre intervention HbA1c (%)	Post intervention HbA1c (%)
101	14	M	8.1	7.6
102	12	F	7.5	7.8
103	14	F	7.6	7.6
104	15	F	9.1	8.1
105	13	F	8.2	8.2
106	13	F	10.2	11.6
107	10	F	8	7.4
108	13	M	11.7	11.6
109	18	M	8.5	6.5
110	12	M	8	8.9
111	14	M	10.6	Not available
112	10	F	8.7	7.6
113	8	F	9.3	Not available
Average	12.6	n=5 m n=8 f	8.88 %	8.45%

3.2 Technical support requirements

Participants were encouraged to contact the support service for Roche “Diabetes Assistant”* in Australia or the research team if they came across problems during the period of the trial. Table 3.1 illustrates support provided by the research team on request of the participant; whereas Table 3.2 illustrates support provided by the research team as part of follow up arrangements as per study protocol. Table 3.3 shows the number of contacts during the trail combining requested and planned contacts and support, this table also illustrates personal computers systems that were used by the participants.

Table 3.1: Requested support for trouble shooting

Participant number	Age (years)	Gender (f=female, m=male)	Phone call support	Home visit required
101	14	M	2	2
102	12	F	3	2
103	14	F	1	2
104	15	F	0	2
105	13	F	1	3
106	13	F	3	4
107	10	F	0	0
108	13	M	2	0
109	18	M	4	1
110	12	M	1	1
111	14	M	2	2
112	10	F	3	0
113	8	F	3	0
Total			25	19
Average contact per child			1.92	1.46

Table 3.2: Prearranged follow up support

Participant number	Age (years)	Gender (f=female, m=male)	Phone call support	Home visit for set up
101	14	M	1	2
102	12	F	2	2
103	14	F	1	3
104	15	F	1	2
105	13	F	1	1
106	13	F	1	1
107	10	F	1	1
108	13	M	2	1
109	18	M	1	2
110	12	M	1	1
111	14	M	1	2
112	10	F	2	1
113	8	F	2	1
Total			17	20

Table 3.3: Total contact with participant during three months trail

Participant number	Age (years)	Gender (f=female, m=male)	Phone call support	Home visit required	Computer running on
101	14	M	3	4	Windows 98 d.u.c.
102	12	F	5	4	Windows 98 d.u.c.
103	14	F	2	5	Windows XP d.u.c.
104	15	F	1	4	Windows XP b.b.
105	13	F	2	4	Windows 98 d.u.c.
106	13	F	4	5	Windows XP d.u.c.
107	10	F	1	1	Windows 98 d.u.c.
108	13	M	4	1	Windows XP b.b.
109	18	M	5	3	Windows XP d.u.c.
110	12	M	2	2	Windows 98 d.u.c.
111	14	M	3	4	Windows 98 d.u.c.
112	10	F	5	1	Windows 98 d.u.c.
113	8	F	5	1	Windows 98 d.u.c.
Total			42	39	
Average contact per child			3.23	3	

d.u.c. = Dial up connection, b.b. = broadband

3.3 Transfer and mailing of blood sugar uploads

The participants were instructed to mail blood results on a monthly basis and 24 hours prior to outpatient appointment. Results were expected to cover at least one previous month. Ten (n=10 (77%)) reports were mailed to the team after months one of participating in the trail covering the previous month. Followed by five (n=5 (38%)) reports mailed at months 2 of the trail. At month three most participants (n=10) had been booked in for a follow up appointment at one point of the study three (n=3) submitted results on time covering at least the last month of blood results. Only one (n=1) participant mailed the report at month three of the study.

3.4 Questionnaire results and qualitative statements from children

Participants and their parents received a questionnaire within three weeks of study end by mail. An appointment for a brief interview in the participant's home was arranged within the following week. Participants and their caregivers were instructed to answer the questionnaire by the time the interviewer visited. The interviewer checked if all questions were answered and asked prompting questions in regards to their answers and to collate practical feedback for future improvements of the programme. The questionnaire uses a ten centimeter continuous scale. Answers ranged from "Very poor – Average - Very good" as well as tick box questions e.g. yes/no answers to multiple choices. Only little room was made available for written comments for the participant as the interviewer had the opportunity to clarify issues and prompt for more detail. Table 4.1 (Appendix 11) illustrates answers from female participants questionnaire, Table 4.2 (Appendix 8) male participants questionnaires, Table 4.3 combined averages. Table 5 shows results from caregivers questionnaire which in allowed for more verbal comments.

Table 3.4: Questionnaire results for female and male participants combined

Question	Male	Female	Total
1) How did you find the way we told you about the meter and how to set it up? (Very poor [0] – average [5] – very good [10])	8.8	8.3	8.55
2) How did you find downloading your blood glucose results? (Hard [0] – average [5] – easy [10])	8.5	4.3	6.4
3) If you needed help using the website, the people who helped you most were? [1] no help needed, [2] parents [3] siblings [4] friend [5] adult [6] DNE [7] DM team [8] convener [9] free phone Roche (au)	[2]=1 [6]=0 [7]=2 [8]=3	[2]=5 [6]=2 [7]=4 [8]=6	[2]=6 [6]=2 [7]=6 [8]=9
4) Did your parents have a look at your results on the computer? Yes [Y] No [N]	[Y]=4 [N]=1	[Y]=6 [N]=2	[Y]=10 [N]=3
5) Did you look around the web site at all? Yes [Y] NO [N]	[Y]=3 [N]=2	[Y]=2 [N]=5	[Y]=5 [N]=7
6) When did you have a look at your results on the web page? [1] not at all [2] once [3] twice [4] three or more times [5] every day	[1]=1 [2]=1 [3]=1 [4]=2	[1]=0 [2]=0 [3]=1 [4]=3	[1]=1 [2]=1 [3]=2 [4]=5
7) Did you find the way your results were displayed on the web page useful? (Very useful [0] – average [5] – not very useful [10])	2.2	4.0	3.1
8) How much of the information (i.e. graphs etc) do you think you could understand? (none of it [0] – about half of it [5] – all of it [10])	7.9	6.3	7.1
9) Did you find the graphs and pictures of your glucose levels interesting? (very boring [0] – ok [5] – very interesting [10])	6.5	5.6	6.1
10) Was the web site easy to use? (very easy [0] – average [5] – very hard [10])	2.1	4.0	3.1
11) Do you think the time taken to record your blood glucose using the new meter is any different compared to keeping a dairy? [1] new system faster [2] no real difference [3] new system slower	[1]=4 [2]=1	[1]=6 [2]=2	[1]=10 [2]=3
12) How do you think your diabetes control is now that you are using the new system? [1] better [2] same [3] worse	[1]=2 [2]=3	[1]=0 [2]=8	[1]=2 [2]=11
13) If you could choose how you manage your diabetes in future, would you keep using the new way or go back to keeping a dairy? [1] new system [2] back to diary [3] both [4] not sure	[1]=1 [2]=0 [3]=3 [4]=1	[1]=3 [2]=1 [3]=4 [4]=0	[1]=4 [2]=1 [3]=7 [4]=1
14) If you had a friend with diabetes would you suggest they use the web system? [1] yes [2] no [3] not sure	[1]=2 [2]=1 [3]=1	[1]=5 [2]=0 [3]=2	[1]=7 [3]=1 [3]=3

Table 3.5 Questionnaire results from caregiver

Question	Results
Would you consider continuing to use this system after the completion of this study at a cost of \$30.00 per year? [Y] Yes [N] No	[Y]=8 [N]=5
Where you happy with your child using this system? [1] Yes [2] No [3] Uncertain	[1]=10 [2]=0 [3]=3
As a record of blood glucose results to help manage your child's diabetes, which would you prefer? [1] web system [2] paper diary [3] both [4] other	[1]=4 [2]=3 [3]=5 [4]=0

3.5 Opinions and verbal feedback gathered during the interview – Key points

Detailed answers can be found in Appendix 9.

3.5.1 Verbal feedback- participants

Question 2 – How did you find downloading your blood glucose results?

- Time consuming to log in
- Easy to download once connected

Question 5 – Did you look around the web site at all?

Question 6 – When did you have a look at your results on the web page?

- lack of patience to spend time looking at web site as downloading/logging in consumed a lot of time
- parent printed of results to show visual

Question 7 – Did you find the way your results were displayed on the web page useful?

Question 8 – How much of the information (i.e. graphs etc) do you think you could understand?

- Preferred graphs (Trend graph)
- Graph (Trend graph) too busy and complex hard to interpret
- Easy to understand
- Well set you and easy to understand
- Too many lines on the Trend graph looks confusing

Question 9 – Did you find the graphs and pictures of your glucose levels interesting?

- Fine none of it was “kind of wow”...

Question 10 – Was the web site easy to use?

- Too long to open up pages on web site
- Up grade to JAVA- sun was too time consuming
- Up grade to JAVA – sun did not work on computer, hence could not use it after that

Question 11 – Do you think the time taken to record your blood glucose using the new meter is any different compared to keeping a diary?

- Parent writes up diary
- If downloading would work [at all times] would upload results independently and it would be quicker
- Less afford
- Wasn't using my dairy

Question 12 – How do you think your diabetes control is now that you are using the new system?

- Better as parent has more input, as parent encourages to upload results regularly

Question 13 – If you could choose how you manage your diabetes in the future, would you keep using the new way or go back to keeping a diary?

- Web-site or a software program [as long as it worked]
- Wasn't using diary anyway

Other comments from participants:

Question: “Would you like to have an option to add your insulin doses?”

- No – too time consuming to enter
- Prefer to trace daily – need to enter insulin, food and exercise too

Other comments:

- computer too slow
- require broadband connection to speed log-in and download

3.5.2 Verbal feedback – caregiver

Question 1: “Would you consider continuing to use this system after the completion of this study at a cost of \$30.00 NZ per year?”

- Yes, as long as it worked
- Not much of a cost [yes]
- It was useful but too time consuming – another chore – [no]

Question 2: “Were you happy with your child using this system?”

- Very little involvement with the system – independent child
- If child would use it independently yes – but parent involvement was too often required – hence little benefit.

Question 3: “As a record of blood glucose results to help manage your child’s diabetes, which would you prefer?”

- Did not see results as single parent and uploads were only possible on fathers computer [no] unless had a capable computer at both homes
- [no] paper dairy can be used as a guide for Insulin adjustments that were used in the past
- [no] dairy is a quicker daily reference
- [no] we are used to manual dairy, we stick with it

Question 4: “Did you have any concerns about the new system?”

- computer too slow
- tedious to download
- doesn’t include Insulin regiment
- thought forward and helpful to have visual graphs
- too difficult to download results

Question 5: “Do you have any suggestions about how this service could be improved?”

- No connect to internet just download
- Need broadband
- Needs to become faster (computer/programme)

Question 6: “Any other comments?”

- study duration too short to get sufficient experience
- great concept
- graphs fascinating, trend graphs offer good insight
- good visual for child (graphs)
- encouraged child to be involved (previously not recording results in paper dairy)

3.6 Comments and suggestions of clinicians involved in the pilot trial

The study convener attempted to interview the diabetes clinical team involved with the participants. A brief interview was set up for feedback and recommendations. Only the Outpatient diabetes nurse and Diabetes nurse educator were interviewed, a Dietitian reported that her involvement was very minimal and endocrinologist was not available for interviews.

3.6.1 Verbal feedback - clinical team

Outpatient diabetes nurse:

- Little involvement (*by choice*)

Diabetes nurse educator:

Question 1: “What was your initial impression?”

- “.... Anything that would improve the blood sugar control would be an advantage; it is such a difficult medium...”

Question 2: “Problems you could encounter or have come across?”

- Lack of time
- Additional workload
- Lack of computer literacy
- Lack of computer capability (poorly maintained home computers)
- Participants did not “own it”

Question 3: “Any suggestions for future improvements or developments?”

- Downloading results on cell phone (age group 14 + years)
- Easier downloading of results on home computer for older patients

Question 4: - “Ease of use?”

- Not user friendly
- Too time consuming – for patient, clinician, parent
- Too much parent involvement required
- Not quick enough to make adjustment to insulin regiment for this age group
- Emotional/ personalised support lacking

Question 5: “Efficiency?”

- Very time consuming for the patient/parent and the clinical team

Question 6: “Would you like to see the program continue or expand?”

- No

Question 7: “Why not?”

- Too much negative feedback from the families, as it was very time consuming for them and didn’t gain much out of downloading.
-

Question 8: “Did you think it was appropriate for the age group?”

- No – the participants need to be computer literate.

Question 9: “What other age group would be more appropriate?”

- University students age 18- early 30’s.

3.6.2 Verbal feedback - study convener and support person

Study convener (Dietitian) and support person (third year medical student) feedback from experience with the system.

Question 1: "What was your initial impression?"

- Great programme to improve outpatient visits, e.g. making use of time with the patient. The clinician can use last month's results in combination with HbA1c for quick feedback and use graphs as an educational tool.
- Ideal for older children to take control of their own BS and learn from correlations e.g. school days versus weekend day Blood sugar control, exercise and BS etc.

Question 2: "Problems you could encounter or have come across?"

- People own computers; however computers and internet connections not up to date.
- Computers very slow and prone to crash/freeze in homes with more than one child/teenager.
- Time consuming
- Low computer literacy
- Parental involvement needs to be very high – encouraging and reminding to download result

Question 3: "Any suggestions for future improvements or developments?"

- Software program only to download results with option to either e-mail results or print.
- SmoBG: use cell-phone for testing and mailing to clinical team – option to add Insulin dose, exercise and food consumed.

Question 4: "Ease of use?"

- Programme easy to use and understand.
- -logging in to the web-site - time consuming if dial-up
- -downloading time consuming if dial-up
- -e-mailing time consuming if one expect feedback from clinician. The patient would need to add Insulin regimen, exercise and food to receive appropriate feedback. The clinician needs to be available to answer queries quickly to keep the confidence in the patient to use the system which can not always be guaranteed. (e.g. holidays)

Question 5: "Efficiency?"

- Time consuming for household that only has a dial-up connection.

Question 6: "Would you like to see the program continue or expand?"

- Yes, however not as a web-based program but as a software option.

Question 7: “Why not?”

- N/A

Question 8: “Did you think it was appropriate for the age group?”

Age range was from 7-18 years in this study.

- Most appropriate group 15-18 years if not newly diagnosed. However, the participants at that age had no control over the computer available and therefore even that age group wouldn't be appropriate.

Question 9: “What other age group would be more appropriate?”

- Patients that have access to computers at all times with appropriate computer literacy.
- Most suitable age group at 18- mid 30's

4 Discussion

Living with Type 1 DM places a major demand on young people and poor management can result in long term complications. When working with adolescents, creative strategies that meet their needs are important for achieving good metabolic control and self-efficacy in DM management.

This feasibility study was designed to test an existing web-based electronic transfer and communication service for BG results between adolescent/child with DM and health professionals. The study was aiming to install and then evaluate the ability and consistency of participants to forward the transferred blood results in regular intervals. Further the web-site and its layout were to be evaluated by the participants of the study and recommendations for improvement thought.

This study was designed as a feasibility study and numbers of participants were therefore limited to fifteen (n=15) in total. Due to one participant withdrawing (n=1) and one participant being excluded (n=1) only a modest number of thirteen participants were involved. The results should therefore not be extrapolated to adolescents with diabetes in other centers. Although the feasibility study was of short nature and numbers low; the experience, feedback and stories shared were powerful.

4.1 Support requirements during trial

Frequently assumptions are verbalized that children or young adults are more computer “savvy” than the older generation due to their exposure at this young age. However, this study showed the demand placed on the researcher and support persons during the trial for help with set up and updates of the computer programme. Troubleshooting support was averaging on 1.92 contacts via phone and 1.46 home-visits per participant during the three months trial. Additional to troubleshooting support, the researcher allowed for follow up visits, which in combination averaged to 3.23 phone follow-up calls and 3 home visits per participants.

As per study protocol participants used a home computer supporting Windows98 or higher. Five (n=5) had Windows XP, eight (n=8) Windows98. One participant had at commencement of the study a broadband connection. A second participant upgraded from the dial-up connection to broadband within the first week. The researcher found that single parent families had computers that were either not upgraded, regularly “froze” and were extremely slow, this could explain the frustration and lack of patience in the participants experienced. Families with both parents working with children over the age of 10 years in the household appeared to have more upgraded computers that were in better working order. This observational finding agrees with results from the NZ Census of 2001. (17) The most single largest effect on internet connections in a household was found to be held by income, followed by highest qualification and household composition. Households consisting of a couple and children had the highest level of internet access, whereas one-parent households were the lowest. Age of the child was another relevant factor to note, where families with children over the age of 10 years had 56% of internet access. (17) However, these results are based on NZ census for the general population and one should take care not to extrapolate those to the population of people with Type one DM. This particular population in turn either due to their increased costs occurring for the support of a family member with Type 1 DM have a potentially unequal outcome for the census results of 2001 or due to their increased need for information and support choose to make more use of the internet and therefore make access to the internet a priority. No New Zealand based literature was found on this issue.

Blood sugar results were uploaded and transferred at a poor rate, in hindsight in an expected rate, taking into account the problems our participants encountered during uploading or even installing the programme. Ten reports of thirteen (77%) were returned on time covering the expected timeframe of one months follow up. This was followed by five (38%) reports at two months follow up and one report at months three. For outpatient appointments three participants mailed their results on time covering at least one month. This poor outcome could be explained by the interruption the feasibility study had at week 7 of the 12 week intervention. At this point of the study the Website was upgraded from JAVA to JAVA Sun which needed to be uploaded and installed to participant's computers, causing difficulties for the older home computers and computers using dial up connection. Some computers were not able to be upgrade at all and downloading was not possible for three (n=3) participants. Additionally two (n=2) participants caught a virus on their home computer which was not resolved before study end. A further confounding factor to point out was that the study ran during the summer school holidays. Most participants were on vacation and some did not have the opportunity to upload results at times.

4.2 Feedback participants and caregiver

Feedback from participants revealed that while the system of uploading results, compared to keeping a handwritten diary was faster (76%) difficulties with uploading results hindered its use, which is consistent with other research.(11) The display of blood sugar results by graphs, pictures and tables was seen as useful , interesting and information was understood well. Study participants found that the web-site was easy to use, which should not be confused with the frequent support requested as this was clearly linked to the capability of the computer in the individuals home and the lack of speed using dial-up service. This conversely could explain the negative verbal feedback gathered during the interview at study end. Participants and their caregivers complained of lack of patience when uploading results from the meter, entering the web-site and taking time to view individual outcomes. Some participants stated that entering the web-site and uploading results could take more than 30 minutes, which appears excessive for this age group.

Most participants (76%) had parents involved with uploading, printing and viewing of results. Surprisingly, a majority of caregivers (62%) were prepared to purchase access to the web-site at a cost of \$30 (NZ) per annum and were happy for their child to use this system (76%). Comments made by caregivers, related to using the web-based system, were pointing out that parents wish to encourage their child to take an active role in their DM management and did not oppose to spend money as long as it would benefit their BG management. However, most parents felt more confident if the child would use both methods of recording daily BG results (38%), which could place an even further burden and therefore rejection on the child.

The feasibility study, the experience gathered while working with this age group and international literature (5,6) has made it clear that particularly in the adolescent population SmoBG has to be practical, proactive and convenient. A surprisingly frequent answer received to the question of preference of recording blood sugar results by the older subjects (>14 years) were: "I wasn't using my dairy anyway...". This is in accordance with anecdotal information from the Diabetes team with their experience during outpatient clinics. The majority (76%) agreed that "Diabetes Assistant" service of uploading results was faster than manually recording BG results. Comparing this with not recording BG results at all or relying purely on the memory of the BG meter appears a great advantage to support SmoBG.

Only one child (1/13) intentionally forgot the log in password and did not upload results to avoid visualising poor BG control.

Suggestions for improvements of the web-site were not offered readily. This could be explained and was confirmed by the caregiver's feedback, that the study was of short duration (12 weeks) and the teenager and child had very little exposure to the actual web-site. During Diabetes outpatient clinics little use was made of results received from our participants. Participants received limited feedback or suggestions for change of Insulin regimen via e-mail from the Diabetes team due to time constraints and difficulty of making confident decisions, as the clinician did not have the subject's notes accessible at times. Recommendations gathered for improvement were based on the speed of opening the page for "Diabetes

Assistant” web-site, some graphs were at first difficult to interpret. The trend graph report was the most frequently mentioned visual; comments during the interview were “it was hard to figure out” and “...just not really easy...”. However, from observations during the demonstration of the programme by the researcher, the trend graph report appeared to have the greatest impact on the subjects and the caregivers. The participant’s verbal reactions such as “...Wow... look at that...”, “... are these my results....”, “... I am always over the line....” and “.... can I print that off?” were common.

Further feedback was that participants wished to be able to access the e-mail option from all pages, and were not interested to enter their Insulin regimen. Participants also pointed out that upgrades to be kept to a minimum and would prefer to e-mail questions to a help desk from the site.

Most surprising were the results that 85% of the children/adolescents preferred to continue using the Diabetes Assistant programme or alternatively using the diary in combination with the web-based uploading programme, when taking into account the difficulties the participants came across with their personal computers. The majority of parents (75%) answered that they also would prefer to continue using the system (33%) or using the manual diary in combination with “Diabetes Assistant” (42%) than going back to the manual diary only (25%). Parent’s verbal feedback in regard to improvements was based on the speed of the logging to Diabetes Assistant and then uploading of results. Suggestions that would allow uploading results without connecting to the internet and further if the diabetes team needed to receive results to attach the results to their personal e-mail, were offered. However, some parents felt that the study duration was too short to comment, as their involvement at times was minimal to allow the child to develop personal responsibility for their diabetes management.

4.3 Feedback from Clinical Diabetes team and Research Team

The initial impression of “Diabetes Assistant” from the DNE and the research team was very positive as for the age group approached would benefit from any form of intervention that would improve their BG control and offer an opportunity to take on an independent role of SmoBG. Problems encountered during the trial were, low

computer literacy, computer “strength” and the additional time required using the system. The DNE felt that the subjects did not “own it” as most of them still needed frequent encouragement and support by caregivers and research team. The DNE felt that “Diabetes Assistant” wasn’t user friendly, the team found that uploading results took too long compared to the current situation where a quick phone call allows spontaneous adjustments to insulin regimen, essential for this age group. The web based programme required the clinician to check e-mails and respond to those very frequently which is too time consuming and requires more data about the patient than available (e.g. Insulin regimen, food intake, exercise, situational circumstances such as alcohol consumption, illness, infection, stress, and significant hormonal imbalances) The team felt that young adults (18-30 years) would be a more appropriate age group using “Diabetes Assistant”. For adolescents using the cell-phone to upload BG results, providing visual graphs and the option of sending those results with a text message to the Diabetes team could be more appropriate. Using a cell phone would allow the child to “own the responsibility” and the teenager will have control over their cell phone which was not the case when it came to the family computer as for this study. The University of Dundee, Scotland developed a support network with the name “Sweet Talk”, a text messaging service for young people based on social cognitive theory, health believe model and goal setting that does not allow uploading of BG yet. No results were available on the effect of this form of support, however coupling “Sweet Talk” with uploading results or even integrating the BG Monitor into a cell phone would make the support highly transportable, personalised and socially more acceptable in the adolescent population as cell phones are widely used. According to the latest NZ wide broadcasted consumer survey, the most asked for gift for Christmas 2005 for teenage girls were a cell-phone followed by an Ipod* (*Microsoft) and for teenage boy’s, money followed by a cell-phone. On average a teenager spends \$50.00 NZ per month on phone calls and text-messaging using their cell-phone.

5 Conclusion

“Diabetes Assistant” by Roche© Diagnostics has proven to be an innovative web-based programme that could in the future develop in an acceptable tool for children and adolescents offering support in diabetes management in NZ. The rate determining step for this to move forward sooner as identified in this brief feasibility study, the computer literacy of parents and child, affordability of upgraded working home computers with broadband connections.

Results from this feasibility study agree with the literature, experience of local diabetes care teams and anecdotal reports from families, that children and teenager alike wish for more convenient, personalised, socially acceptable and innovative methods of SmoBG.

We need to keep in mind that consultation with children/adolescents, parents and clinical teams are paramount in order to ensure that services and resources are relevant, meaningful and acceptable.

“Diabetes Assistant” to date and in Dunedin, NZ has not managed to establish an effective role supporting our young population with Type 1 DM. More research is needed to establish if a slightly older population that has more control over their personal home computer and higher computer literacy would benefit from this innovative programme.

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Appendices

Appendix 1 Roche Diabetes Assistant Questionnaire – Participants section

Appendix 2 Roche Diabetes Assistant Questionnaire - Caregivers section

Appendix 3 Roche Diabetes Assistant Questionnaire – Team section

Appendix 4-6 Raw Data – see CD Rom attached

Appendix 7 Table 4.1 Questionnaire results from female participants

Appendix 8 Table 4.1 Questionnaire results from male participants

Appendix 9 Opinions and verbal feedback gathered during the interview