31st Annual International Conference of the IEEE EMBS
Minneapolis, Minnesota, USA, September 2-6, 2009

UK and Canadian Perspectives of the Effectiveness of Mobile Diabetes Management Systems

Emily Seto, Robert S. H. Istepanian, Joseph A. Cafazzo, Alexander Logan, Ala Sungoor

Abstract— **The use of mobile technologies for self-monitoring of blood glucose and blood pressure for diabetes patients is becoming increasingly popular worldwide. This is propelled by the proliferation of the wider usage of mobile phones and other wireless technologies and computing platforms in the healthcare sector. Such technologies can play a pivotal role in chronic disease management and patient self-care. There have been several clinical trials in recent years on mobile diabetes management in UK and Canada. However, no studies to date have addressed and correlated the technological and clinical outcomes concerning the use of mobile chronic disease management systems for diabetes from the UK and Canadian perspectives. In this paper we address some of these correlative issues based on similar clinical trials on mobile type-2 diabetes management systems deployed in these two countries. In particular, the outcomes of these trials supported the use of telemonitoring for effective blood pressure control, but telemonitoring was less effective at managing blood glucose control. Some of the clinical results and challenges are presented together with future work and suggestions that aim to validate a generic platform for mobile diabetes management.**

I. Introduction

Mobile healthcare (m-Health) can be defined as 'mobile computing, medical sensor, and communications technologies for healthcare'. The exponential surge of m-health systems in the last few years is due to the massive demand of such systems to alleviate and provide more efficient and effective healthcare delivery mechanisms especially for chronic disease management and self-care. In particular, the global chronic disease population and cost burdens are increasing, especially in the developed world including the UK and Canada. For example, there is an estimated 2.4 million people in the UK currently diagnosed with diabetes [1]. The NHS is currently spending more than £100m each year and the cost is rising [2]. In Canada, over two and a quarter million Canadians are estimated to have diabetes and it is the seventh leading cause of death in Canada [3].

Self-monitoring of blood glucose and blood pressure are an integral part of routine diabetes care, especially for people with type-2 diabetes treated with insulin and/or oral glucose-lowering drugs. Patients with diabetes should monitor their blood glucose and blood pressure closely so that they can modify their lifestyle behaviors (e.g. diet) and have their medications adjusted when necessary. This is an evolving area of mobile healthcare both in the UK and Canada. Similar research has been conduced in both countries on the use of mobile technologies for diabetes self-management [4,5,6]. However, no studies have combined the results of such research and have addressed the correlative outcomes of using these technologies in the UK and Canada.

In this paper we present some of the clinical outcomes of the diabetes and hypertension studies carried out in Toronto and Chapleau, Ontario and London, England using mobile chronic disease systems that share the same wireless and web-based infrastructures. We also discuss the clinical and technical challenges relevant to these m-health technologies and their wider deployment issues from both the UK and Canadian perspectives.

II. Mobile Diabetes Management Systems

In this section we describe the generic modules and the basic architecture of mobile disease management systems used in the diabetes self-management clinical studies in the UK and Canada. These systems share the following functional modules:

(i) The patient module that includes a mobile phone that can receive readings from a glucometer and blood pressure monitor via short-range wireless Bluetooth™. The patient data are then transmitted from the mobile phone to the hospital data servers using commercially available cellular network connectivity. Instructions and alerts can also be sent to the patient's mobile phone from the data servers.

(ii) The secure web interface for patients and their clinicians to access the health information and alerts. The UK system also included a patient journal that enabled the patient to interact with the specialist nurse.

Manuscript received June 19, 2009. The UK authors would like to acknowledge the financial support and funding of the UK clinical trials by Motorola, USA and the IDEN group. R. S. H. Istepanian also received support by the Leverhulme Trust, UK in the form of a study abroad fellowship grant to the University of Toronto. The Canadian authors would like to acknowledge the funding and contributions of the Ministry of Health and Long Term Care of Ontario, Bell Canada, Nortel, and Research in Motion.

E. Seto is with the Centre for Global eHealth Innovation, University Health Network, Toronto, ON, Canada, and the Department of HPME, University of Toronto, Toronto, ON, Canada (phone: 416-340-4800x6409, fax: 416-340-3595, e-mail: emily.seto@uhn.on.ca).

R. S. H. Istepanian is with the Mobile Information and Network Technology Research Centre, Kingston University, London, UK (e-mail: R.Istepanian@kingston.ac.uk).

J. A. Cafazzo is with the Centre for Global eHealth Innovation, University Health Network, Toronto, ON, Canada, and the Departments of HPME and IBBME, University of Toronto, Toronto, ON, Canada (e-mail: joe.cafazzo@uhn.on.ca).

A. Logan is with the Samuel Lunenfeld Research Institute, Mount Sinai Hospital, Toronto, ON, Canada (e-mail: logan@lunenfeld.ca).

A. Sungoor is with the Mobile Information and Network Technology Research Centre, Kingston University, London, UK (e-mail: alaa_sungoor@yahoo.com).

(iii) The system server and central data management system.

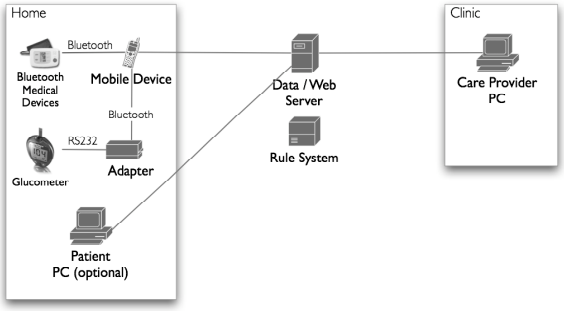

Fig. 1. Generic architecture of the mobile diabetes management systems used in the UK and Canadian trials

The advantages of the mobile diabetes management systems used the UK and Canadian trials compared to other diabetes telemonitoring systems (e.g. store-and-forward systems) include:

- Enabling measurements to be taken at any time and at any place. Patients are able to bring the mobile phone and the portable medical devices (glucometer and/or blood pressure monitor) wherever they go.
- Providing real-time feedback and alerts to patients and their healthcare providers
- Saving patient's time and effort by automatically transferring the data. Patients do not need to enter readings in a logbook, website, interactive voice response system, or download information by connecting the devices to a computer.

In the UK trial, patients in the telemonitoring arm were trained to self-measure capillary blood sugar (One Touch Ultra Glucose Meter, LifeScan, CA, USA). The patients also transmitted weekly blood pressure readings (UA767PBT Blood Pressure Monitor, A&D Medical, Tokyo, Japan). The telemonitoring system used for the UK trial was the MotoHealth™ system (Motorola Inc., Illinois, USA). We allowed a run-in period of 4 weeks for patients to familiarize themselves with the system before transmitting readings according to a personalized monitoring schedule that was agreed upon with the research nurse. The mobile phone alerted the patient when a measurement was due. Data were sent from the patient's mobile phone to a server at St George's Hospital, London. The research clinicians reviewed the recordings via a web-based application on the secure hospital server. Patients in the control group did not use a mobile phone to transmit data. They received their care from the diabetes centre and/or the local practitioners and were free to contact the research team if they wished.

Two Canadian pilot trials were conducted using the diabetes and hypertension telemonitoring system developed at the University Health Network in Toronto. The system development was informed through patient and primary care provider focus groups and usability testing to help ensure that it was as useful and easy to use as possible for both the patients and their clinicians [7,8]. Participants in the first trial, which was conducted in the Greater Toronto Area (GTA), monitored only their blood pressure (UA767PBT Blood Pressure Monitor, A&D Medical, Tokyo, Japan). The second trial was conducted in the Northern Ontario community of Chapleau. Participants in the Chapleau trial were asked to monitor both their blood glucose (One Touch Ultra Glucose Meter, LifeScan, CA, USA) and their blood pressure. Readings were automatically transferred to the data servers at the University Health Network. Alerts were generated and automated voice messages were sent to the patient's home as appropriate. Patients were instructed to call a specified phone number the day before their appointment to see their family physician to generate an automated fax report sent to their physician. Adherence phone reminders were sent to patients in the GTA trial who did not comply with taking their prescribed number of blood pressure measurements, but as discussed below, this feature was turned off for the Chapleau trial because of technical difficulties.

III. Clinical Methods and Results

UK Trial Methods and Results

The UK trial was based at the Thomas Addison Diabetes Centre at St George's Hospital in South London, UK. Patients were invited to take part in the randomized, parallel group study between December 2006 and July 2007. A total of 137 patients were randomized into a telemonitoring group (n=72) and control group (n=65). They were well matched according to their demographic and baseline clinical data. The prevalence of diabetes complications and treatment regimens were similar in each group (see Table 1). Insulin-treated patients had a significantly higher HbA_{1c} than those on oral hypoglycaemic agents only: 8.8% and 7.7%, respectively (p=0.005).

The mean follow-up period was 9 months in each group. The primary outcome measure was HbA_{1c}. We aimed to evaluate 70 patients in each group over 9 months to give the study 80% power to detect a difference of 0.72% in HbA_{1c}. The data were analyzed on an intention-to-treat basis with imputation of carry-over data for patients defaulting or lost to follow-up. Analyses between or within the groups were performed using SPSS 16.0 for Windows (Chicago, USA). Thirty-two patients in the telemonitoring group and 55 patients in the control group completed the study.

The clinical results from these trials indicated that there were no differences in HbA_{1c} between the telemonitoring and the control groups: 7.9% and 8.2%, respectively (p=0.17). However, in the sub-group analysis of the patients who completed the study, the telemonitoring group had a lower HbA_{1c} than those in the control group: 7.76% and 8.40%, respectively (p=0.06). A significant drop in systolic blood pressure was found for patients in the intervention group over the study period (-6.5 [-0.8 to -12.2, 95% confidence interval] mmHg ;p=0.027) but not in the control group (2.1 [9.3 to -5.0] mmHg; p=0.57). No significant changes were found in the diastolic blood pressure for either group.

TABLE I
UK DIABETES COMPLICATIONS AND TREATMENT REGIMENS

	Telemonitoring	Control
Background/maculopathy/ pre-proliferative/laser therapy,n	18/9/0/2	16/6/4/3
Nephropathy, n	31	35
Cardiovascular disease history positive, n	14	10
Diet therapy alone, %	5	5
Insulin alone, %	26	25
Oral hypoglycaemic agents (OHA), %	47	56
Combination of OHA and insulin, %	22	11

Canadian Trials Methods and Results

The Canadian trials used a before-and-after design to assess the effectiveness of telemonitoring on blood pressure and blood glucose control and its acceptability to the users.

For the GTA study, 33 patients with type-II diabetes and uncontrolled ambulatory hypertension (24-hr ambulatory BP, over 130/80 mmHg) used the telemonitoring system for 4 months. See Table 2 for the demographics and clinical data for both Canadian trials. The participants were recruited from the practices of 25 family physicians in the GTA. Participants were asked to take two consecutive BP readings in the morning and evening at a minimum of 2 days per week. The 2-week average blood pressure dropped an average of 9 mmHg in systolic blood pressuring and 3 mmHg in diastolic blood pressure over the 4 months ($p<0.001/0.005$ systolic/diastolic). Patient adherence to the protocol was above expectation. The average number of readings per week was 12.3. Two patients dropped out of the study for unrelated reasons. In the interviews, 17 of 20 patients indicated that they would like to continue using the system or use it in the future.

For the Chapleau study, 26 patients with type-II diabetes and uncontrolled ambulatory hypertension were recruited and followed by a diabetes clinic. Patients were asked to take the same number of blood pressure readings as the GTA trial, but were also asked to take two glucose readings a minimum of three days per week. There was no significant decrease in blood pressure (pre-study 142/79, post-study 142/78; $p = 0.7$) or blood glucose (pre-study 7.9 +/- 1.6 mmol/L, post-study 6.8 +/-1.7 mmol/L) over the study period. Only 18 of the 26 patients completed the 4-month trial. The average number of blood pressure readings per week was 8.9. During the interviews, some patients expressed a desire to continue using the system, but most believed they couldn't afford to pay or were unwilling to do so.

TABLE 2
PATIENT DEMOGRAPHIC AND CLINICAL DATA FOR CANADIAN TRIALS

	GTA Trial	Chapleau Trial
Number of participants	33	26
Number dropped out of study	2	8
Age (SD)	58.1 (9.9)	63.7 (8.7)
Male (% of total)	20	14
Caucasian (% of total)	21	18
Body mass index in kg/m2 (SD)	32.2 (6.2)	31.9 (5.2)
Office blood pressure in mmHg (SD)	140/80 (15/11)	141.3/80.7 (11/8)
Dyslipidemia (% of total)	18	13
Current smoker (% of total)	3	2
HbA1C (SD)	7.2 (1.2)	Not available
Creatinine (SD)	94.9 (36.3)	Not available
Average number of blood pressure medications per patient (SD)	2.4 (1.8)	3.3 (1.5)

IV. DISCUSSION

From these results we can deduce the following issues:

1. Telemonitoring is an effective strategy for blood pressure control of type-II diabetes, but may be less effective for blood glucose control. A decrease in average blood pressure was found for both the UK and GTA trials, but there were no significant changes observed in the blood glucose levels in the UK and Chapleau trials.
2. Consistent communication between patients and their providers is necessary for effective telemonitoring, especially with respect to keeping the patients complying with acquiring measurements regularly. During the UK trial, providers were overwhelmed with the number of emails being sent to them from the patients and the monitoring system (each reading was sent as an email to the providers), and were unable to respond to the patients' messages. For the Canadian trials, providers were only alerted when their patient's measurements were out of the target range. A recent qualitative analysis of the UK patients' thoughts on using telemedicine concluded that its potential depends on consistent, supportive interactions with healthcare providers. During the Chapleau trial, the diabetes clinic's physician and nurse practitioner resigned from their positions for reasons unrelated to the trial. This could help explain the higher dropout rate and fewer blood pressure readings compared to the GTA trial.
3. Technical difficulties with the telemonitoring system can lead to high dropout rates. The dropout rate from the intervention arm in the UK study was higher than the predicted 10-15%. Patients cited technical issues related to operating the equipment, such as losing Bluetooth™ connectivity, as the main reason behind the protocol violations. During the Chapleau trial, cellular coverage was unavailable for very long periods of time, which resulted in the patients' data not being transmitted. This was a source of frustration for the patients because they were being sent adherence reminders even though they

were following the protocol. Therefore, the adherence reminder feature had to be turned off for this study.

4. Adherence reminders help patients to comply with the telemonitoring protocol. The GTA trial included adherence reminders. However, the adherence reminders feature was not used in the Chapleau trial. The average number of readings per week was substantially higher for the GTA trial (12.3 vs 8.9). It is possible that fewer patients in the UK trial might have dropped out and would have been more compliant if the monitoring system included more 'patient friendly' adherence reminders.
5. Patients may find taking measurements for multiple parameters to be overwhelming, which could lead to decreased adherence. For the GTA trial, patients were very compliant when asked to take only blood pressure measurements. However, for the UK and Chapleau trials, patients were asked to take both blood glucose and blood pressure measurements. Adherence was poor for both of these trials.
6. Cost effectiveness and quality of life analyses of the studies are currently in progress to help evaluate the potential of m-health diabetes telemonitoring in both countries. However, the preliminary cost analysis in the UK trials indicate a correlated cost saving of around $1M/ 1000 patient population compared to usual NHS costing of the diabetes population in the trials.

From these issues, we can deduce the following items that need to be addressed in any future design of generic diabetes management systems that can be operated seamlessly in multiple urban and rural settings.

- Patient adherence reminders appear to a necessary component of any effective telemonitoring system and will reduce dropouts and improve patient adherence.
- Asking patients with diabetes to monitor multiple parameters compared to a single parameter appears to decrease adherence. The benefit of monitoring additional parameters needs to be weighed against its potential negative effects on adherence.
- The efficacy of mobile diabetes management systems on blood glucose control remains unproven using the UK or Canadian telemonitoring systems. This finding has been supported in other randomized controlled trials of conventional approaches to self-monitoring [9].
- Telemonitoring technologies need to be standardized and interoperable. These issues are currently being addressed within the Continua Health Alliance for the relevant IEEE standards for medical devices. However, more work needs to be done on these issues for various disease management systems and requirements. These issues are important yet pending challenges that need to be addressed in any future design and further technical refinement of these systems for successful and reliable large deployment healthcare services.

V. CONCLUSION

We have shown that mobile telemonitoring can be an effective method for blood pressure control, provided that patients comply with their clinical protocol and that the mobile telemonitoring system has a patient-centered design. These results are consistent in both the UK and Canadian trials. Blood glucose control continues to show little effect with such interventions. However, further joint studies are required to provide further evidence on these issues, especially with systems with adherence reminders and other methods of engaging patients in self-care. The adherence reminders and consistent clinical engagement were significant factors in the improved blood pressure control, high compliance, and low dropout rate found in the GTA trial, which were not present in the two other trials. There is also some concern that the combined use of blood pressure and blood sugar monitoring may overwhelm the patient and affect adherence. Greater success may be achieved through focusing on targeted priorities with specific, achievable goals.

ACKNOWLEDGMENT

The UK authors would like to thank Dr. Ken Earle from St. George's medical school and NHS Trust in London and his team for the provision of clinical data of this study.

REFERENCES

[1] Diabetes in the NHS: Commissioning and providing specialist services, http://www.diabetes.nhs.uk/diabetesinthenhs.pdf (Accessed June 2009).
[2] Diabetes UK, www.diabetes.org.uk (Accessed May 2009).
[3] Public Health Agency of Canada (www.phac-aspc.gc.ca), 2007.
[4] R. S. H. Istepanian, E. Jovanov, and Y. T. Zhang, "Guest Editorial Introduction to the Special Section on M-Health: Beyond Seamless Mobility and Global Wireless Health-Care Connectivity," *IEEE Transactions on Information Technology in Biomedicine*, vol. 8, no. 4, pp. 405-414, Dec 2004.
[5] R. S. H. Istepanian, S. Laxminarayan, and C. Pattichis (Eds.), *M-Health: Emerging Mobile Health Systems*, Springer-Verlag, London, 2006.
[6] Y. Zou, R. S. H. Istepanian, X. Wang, and T. Geake, "Design and Implementation of Universal Mobile Diabetes Management System," *Journal of Mobile Multimedia*, vol. 1, no. 4, pp. 273-284, Jan 2006.
[7] R. Lopez, A. Chagpar, R. White, M. McLean, M. Trudel, J. Cafazzo, et al., "Usability of a diabetes telemanagement system," *30th Annual Canadian Medical and Biological Engineering Conference Proceedings,* June 2007.
[8] A. G. Logan, W. J. McIsaac, A. Tisler, M. J. Irvine, A. Saunders, A. Dunai A, et al., "Mobile Phone-Based Remote Patient Monitoring System for Management of Hypertension in Diabetic Patients," *American Journal of Hypertension,* vol. 20, no. 9, pp. 942-948, 2007.
[9] A. Farmer, A. Wade, E. Goyder, P. Yudkin, D. French, A. Craven, R. Holman, A. L. Kinmonth, and A. Neil, "Impact of self monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial," *BMJ*, vol. 335, no. 132, Jul 2007.