EXPLORING THE POSSIBILITY FOR A PERVASIVE TECHNOLOGY SOLUTION TO FACILITATE EFFECTIVE DIABETES SELF-CARE FOR PATIENTS WITH GDM

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EXPLORING THE POSSIBILITY FOR A PERVASIVE TECHNOLOGY SOLUTION TO FACILITATE EFFECTIVE DIABETES SELF-CARE FOR PATIENTS WITH GESTATIONAL DIABETES

Research in Progress

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Abstract

Gestational diabetes(GDM) is increasing exponentially. To address this, we contend that a pervasive mobile solution that can facilitate self-care is a prudent strategy. To demonstrate proof of concept, user fidelity, usability and acceptability of such a solution a small pilot study of 10 patients was designed. A quasi-experimental approach employing a randomized control trial with a two period cross-over clinical trial strategy over 10 week duration at a private hospital in Melbourne, Australia was adopted. The main outcomes of interest were to establish proof of concept and the fidelity of the technology solution. Directional data gathered including patient and clinical interview data serve to demonstrate both proof of concept and fidelity. Without exception both patients and clinicians have preferred the pervasive mobile solution to the standard care approach. The study serves to highlight that pervasive mobile solutions can provide a useful adjunct in the effective monitoring and management of GDM.

Keywords: gestational diabetes, chronic disease, public health informatics, health informatics, mobile health

1   Background

Two key trends are apparent: 1) diabetes is increasing exponentially (Help4Diabetes, 2012) and 2) the adoption and embracement of mobile solutions is increasing rapidly (Degusta, 2012). Globally, diabetes mellitus [diabetes] is one of the leading chronic diseases (Geisler & Wickramasinghe, 2005). The total number of diabetes patients worldwide is estimated to rise to 366 million in 2030 from 171 million in 2000 (Wild, Roglic, Green, Sicree, & King, 2000).

In Australia alone, an estimated 275 individuals develop diabetes daily (Dixon & Webbie, 2006) making Australia a significant contributor to this projected trend. Further, an estimated 700,000 Australians, representing approximately 3.6% of the population, were diagnosed with diabetes in 2004-05 while between 1989-90 and 2004-05 the proportion of Australians diagnosed with this disease more than doubled from 1.3% to 3.3% (Dixon & Webbie, 2006). Additionally, between 2000-01 and 2004-05, Australian diabetes hospitalisations increased by 35% from 1,932 to 2,608 hospitalisations per 100,000 people (AIHW, 2008). Hence, most are agreed that diabetes is one of the fastest growing chronic diseases in Australia (AIHW, 2007, 2008; Chittleborough, Grant, Phillips, & Taylor, 2007).

In addition to the unpleasantness of this disease to its sufferers, it must also be kept in mind that diabetes and its complications incur significant costs for carers, governments, and the entire health system (Chittleborough et al., 2007; Geisler & Wickramasinghe, 2005). In the US, between 2010-2011, costs associated with diabetes were US$174 billion ($116 billion direct medical costs and at least $58 billion indirect costs) (Help4Diabetes, 2012) while in 2004-05 direct healthcare expenditure on diabetes in Australia was AU$907 million, which constituted approximately 2% of the allocatable recurrent health expenditure in that year (AIHW, 2008; Wickramasinghe, Troshani, Hill, Hague, & Goldberg, 2011). Further costs include societal costs that represent productivity losses for both patients and their careers (Chittleborough et al., 2007).

Recognizing the growing problem of this chronic disease as well as noting that during this same time there has been an exponential rise in the penetration, use and up take of mobile phone solutions and applications it seemed logical to investigate the possibility of developing a mobile pervasive technology solution to support and facilitate better monitoring and management of individuals with diabetes; ie, a diabetes monitoring app (software application). We choose to focus on the case of GDM (gestational diabetes) since women suffering with GDM tend to also be in the population range that has high mobile phone usage as well as being highly motivated to address issues with their blood glucose levels so as to try to avoid any complications to their baby and/or themselves. To understand the use of this monitoring app then, it is first necessary to understand the key aspects of chronic disease management and diabetes self-care as well as the case of GDM.

1.1   Diabetes Care and the Importance of Self-management

Currently, there is no cure for diabetes. Recommended treatment protocols require effective and ongoing lifestyle management, together with particular attention and monitoring by healthcare professionals and patients (Britt et al., 2007). In order to be effective, it is essential that patients are both informed and active participants in their treatment regimen (AIHW, 2007, 2008). Thereby, making self-management an essential part of prudent diabetes care (Colagiuri, Colagiuri, & Ward, 1998; ICIC, 2008). Nevertheless, self-management is both time-consuming and requires significant self-discipline (Russell, Suh, & Safford, 2005). Current support strategies include regular assessment, goal-setting, action-planning, problem-solving and follow-up (ICIC, 2008). However, since effective self-management often requires patient interaction with their healthcare professionals (Knuiman, Welborn, & Bartholomew, 1996), difficulties often arise when diabetes sufferers encounter problems

ranging from making appointments to needing to travel to many locations (Van Eyk & Baum, 2002; Wellard, Rennie, & King, 2008; Zgibor & Songer, 2001).

Solutions for supporting self-management to date (Chau & Turner, 2007; Rudi & Celler, 2006) have not always been effective, as they have been complex and awkward for patients to embrace easily (Reach, Zerrouki, Leclercq, & d'Ivernois, 2005). It has been noted that computer-assisted telemedicine can help diabetes sufferers improve both their self-management (Balas et al., 2004) and their relationship with healthcare professionals (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Downer, Meara, Da Costa, & Sethuraman, 2006) and thus the use of a pervasive mobile solution would appear to have merit.

1.2 Gestational diabetes

Gestational diabetes (GDM) is a form of diabetes and presents in pregnancy, usually detected by routine screening in asymptomatic women (Wickramasinghe et al., 2011). Typically, incidence: 4.6% of pregnancies i.e., greater than 12,400 women per year in Australia (Templeton & Pieris-Caldwell, 2008). Some women, especially those in whom the diagnosis of GDM was made early in pregnancy, may have pre-existing undiagnosed diabetes. In Australia and New Zealand, universal screening for GDM is recommended by the Australasian Diabetes in Pregnancy Society (ADIPS) (Hoffman, Nolan, Wilson, Oats, & Simmons, 1998), however the uptake of the recommendation is rather variable (Rumbold & Crowther, 2001). Most commonly the diagnosis of gestational diabetes is made following routine screening at 24-28 weeks gestation, with smaller numbers of women diagnosed earlier or later in pregnancy. Maternal complications of GDM include polyhydramnios and premature labour, pre-eclampsia and perineal trauma (Hoffman et al., 1998). Prenatal complications include macrosomia, shoulder dystocia, bone fractures and nerve palsy (Crowther et al., 2005). It recurs in subsequent pregnancy in 30-80% of women, the incidence varying with ethnicity, being lower in Caucasian women (Kim, Berger, & Chamany, 2007).

Treatment of women with GDM aims to control maternal, and therefore fetal, hyperglycaemia and the associated tendency to fetal hyperinsulinaemia, which is at the root of the fetal complications (Metzger et al., 2008). Critical to the treatment of women with GDM then is careful and systematic monitoring of maternal glycaemia and appropriate adjustment of lifestyle, dietary and pharmacological therapy (Crowther et al., 2005; Metzger et al., 2008; Moss, Crowther, Hiller, Willson, & Robinson, 2008).

1.3 The development of a pervasive mobile technology solution

In order to develop the solution, it was first necessary to understand the key elements of chronic disease management as set out by Rachlis (Rachlis, 2006). Integral to this model is the interaction between an informed patient and a pro-active care team both of which is possible only with solutions that can facilitate better management and monitoring (Goldberg, 2002a, 2002b, 2002c, 2002d; Wickramasinghe & Goldberg, 2003; Wickramasinghe & Goldberg, 2004).

Recognising that many, too many ICT(information communication technology) solutions in healthcare are not successful (Wickramasinghe and Schaffer, 2010), a user centred design (UCD) approach was adopted to address this. As noted by LeRouge and Wickramasinghe(2013), who performed an extensive literature review looking at the design and development of various technology solutions to support the management and monitoring of chronic diseases as UCD approach is prudent to ensure that the design and development of the technology solution meets the requirements and expectations of both clinical and patient users. This point is also supported in the medical literature (Crocco et al, 2002; Kollmann et al., 2007; Tang et al 2013) as well as well established in the management and IS literature (Ives and Olson, 1984). UCD can be considered in general terms as a type of user interface design (Vredenburg, Isense, & Righi, 2002). In addition, it is a process where attention is given to the needs, wants and desires of end users of a product or solution and is characterised by a multi-stage

problem solving process including: planning and feasibility, requirements, design, implementation, test and measure, post release and analysis (Vredenburg et al., 2002). In the case of the design and development pervasive mobile solution this includes a 30-day e-business acceleration project in collaboration with many key players in hospitals, such as clinicians, medical units, administration, and IT departments. At completion, this e-business acceleration project a scope document to develop a proof-of-concept specific to the unique needs of a particular environment is delivered.

The web-based model (figure 1) provides the necessary components to enable the delivery framework to be positioned in the best possible manner so it can indeed facilitate enacting the key components of the chronic disease model successfully. In addition, the web-based model is designed to be flexible and dynamic; thereby, enabling it to suit the complex nature of healthcare environments by iteratively, systematically, and rigorously incorporating lessons learnt data to healthcare processes for ensuring superior healthcare delivery. This manner not only maximizes the value of past data and learning, but it also makes processes amendable as complex needs and requirements evolve. These are considered essential critical success factors in the design and development of ICT solutions for healthcare (Eysenbach, 2000; Wickramasinghe and Schaffer, 2010).

What makes this model unique and most beneficial is its focus on enabling and supporting all areas necessary for the actualization of ICT (information and communication technology) initiatives in healthcare. By design, the model identifies the inputs necessary to bring an innovative chronic disease management solution to market (Goldberg, 2002a, 2002b, 2002c, 2002d; Wickramasinghe & Goldberg, 2003; Wickramasinghe & Goldberg, 2004). These solutions are developed and implemented through a physician-led mobile e-health project. This project is the heart of the model that bridges the needs and requirements of many different players into a final (output) deliverable, a "Wireless Healthcare Program".
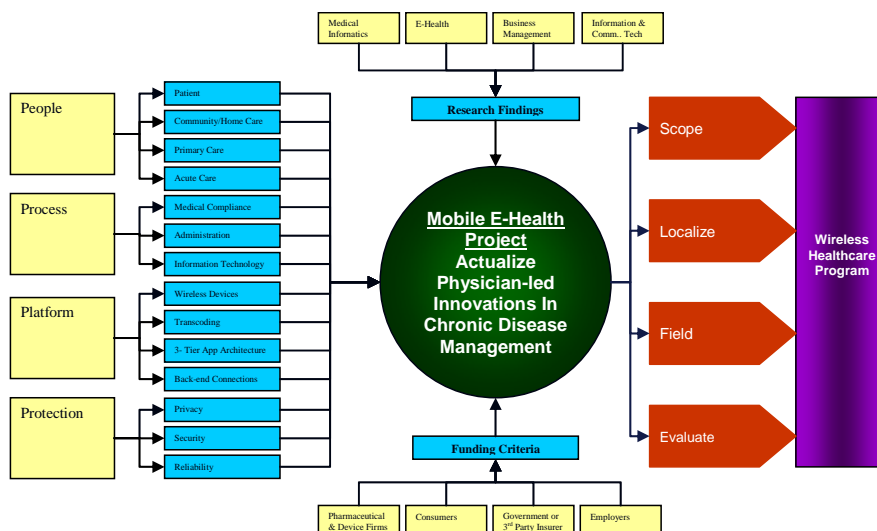
Figure 1: Depiction of the underlying conceptual model and delivery framework. As can be seen the emphasis is on four key inputs of people, processes, platform and technology. The project is always clinician led. Moreover, it also captures the dynamic nature of healthcare by continually enabling latest research findings to be incorporated. The sustainability of the solution is ensured through the multiple sources of funding. These all support the four key aspects of the delivery framework; namely, scope, localize, field and evaluate.

Figure 1. The Model

Succinctly, the final solution works as follows (figure 2), the individual takes their blood glucose readings. These are then either directly transferred to the mobile device or manually entered and then

sent to the designated member of the clinical care team who on reading the information can send a message back to the patient.
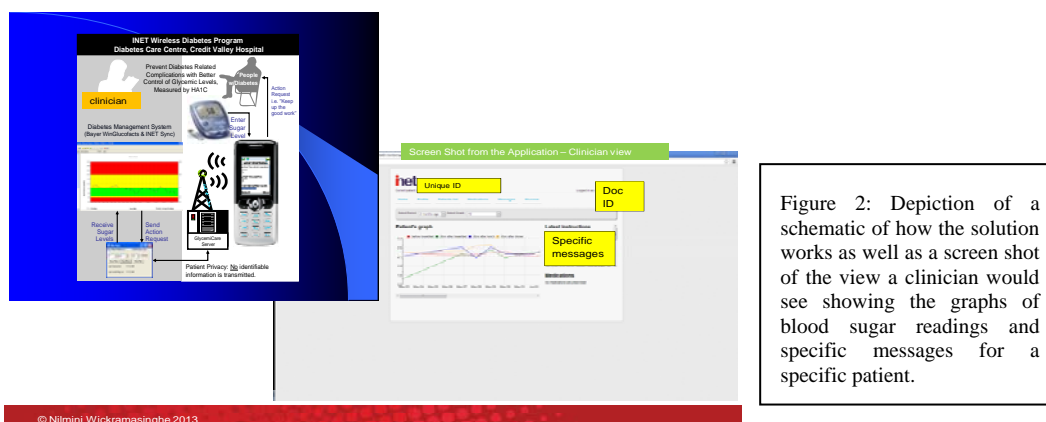

Figure 2: Depiction of a schematic of how the solution works as well as a screen shot of the view a clinician would see showing the graphs of blood sugar readings and specific messages for a specific patient.

Figure 2. The Solution in a Nutshell

2   Methods

Given the proceeding, we set out to investigate the possibility of applying the pervasive mobile solution in an Australian context. Specifically, we wanted to investigate the benefits of a pervasive technology to facilitate and enable superior self-care for patients suffering from GDM (gestational diabetes).

2.1   Research design

The DiaMonD (Diabetes monitoring device) study subscribed to the established techniques adopted by Wickramasinghe and Goldberg (Goldberg, 2002a, 2002b, 2002c, 2002d; Wickramasinghe & Goldberg, 2003; Wickramasinghe & Goldberg, 2004, 2007) to date; i.e. the AMR (adaptive mapping to realization) methodology. In addition, a two arm cross over style unblended RCT (randomised control trial) was utilised which means that the control group at a predetermined time converts to using the technology solution while the intervention group at this same point in time then reverts to the traditional solution. This strategy is deemed appropriate in studies of this nature so that it is possible for patients to compare with /without technology scenarios[1]. Specifically, patients diagnosed with GDM were randomly selected, after clinical assessment of their appropriateness to participate and patient consent was received, into either the standard care arm or technology arm (i.e., standard care plus the mobile solution) of the trial. Each arm of the trial was briefed regarding standard care procedures and educated regarding good management of GDM. The technology arm was also educated on how to use the technology solution. As GDM is usually diagnosed at about week 28 we ran the trial for 10 weeks to ensure that all patients were less likely to deliver their baby during the trial. Thus, at 5 weeks after initial allocation into standard care arm and technology arm respectively cross over took place and the standard care arm was then introduced to the technology solution and the technology arm was given standard care. Just before cross over patients were all interviewed and asked to complete a brief questionnaire. Again at the completion of 10 weeks of the trial a questionnaire was administered, all patients were interviewed and de-briefed (figure 3).

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[1] www.implementationscience.com/content/4/1/69

Step 1

Patient advised by OBGYN to get test for GDM.

Step 2

Patient tested for GDM & found + ve. OBGYN decides if patient appropriate for study and if so briefs the patient about the study and patient signs consent. Then patient makes appt to see diab edu. Odd no. Patients ie. 1,3,5,7, 9 start with tech soln while even no. start with std care. All patients briefed about GDM and those in tech arm also learn how to use the appln. All patients complete questionnaire 1.

Step 3: Between week 1-5(incl)

Data is checked as per normal with std care and with tech soln on-line data is viewed by clinicians. Any unexpected issues are resolved as they occur.

Step 4: Week 5 cross over time

All patients complete questionnaire. Std care now go to tech soln and are briefed on the tech soln. Tech soln go to std care and are treated as per normal std care procedures.

Step 5: Between weeks 6-10(incl)

Data is checked as per normal with std care and with tech soln on-line data is viewed by clinicians. Any unexpected issues are resolved as they occur.

Step 6: Week 10 last week of trial

All patients complete questionnaire. De-brief takes place. Clinicians complete questionnaire and de-brief takes place.
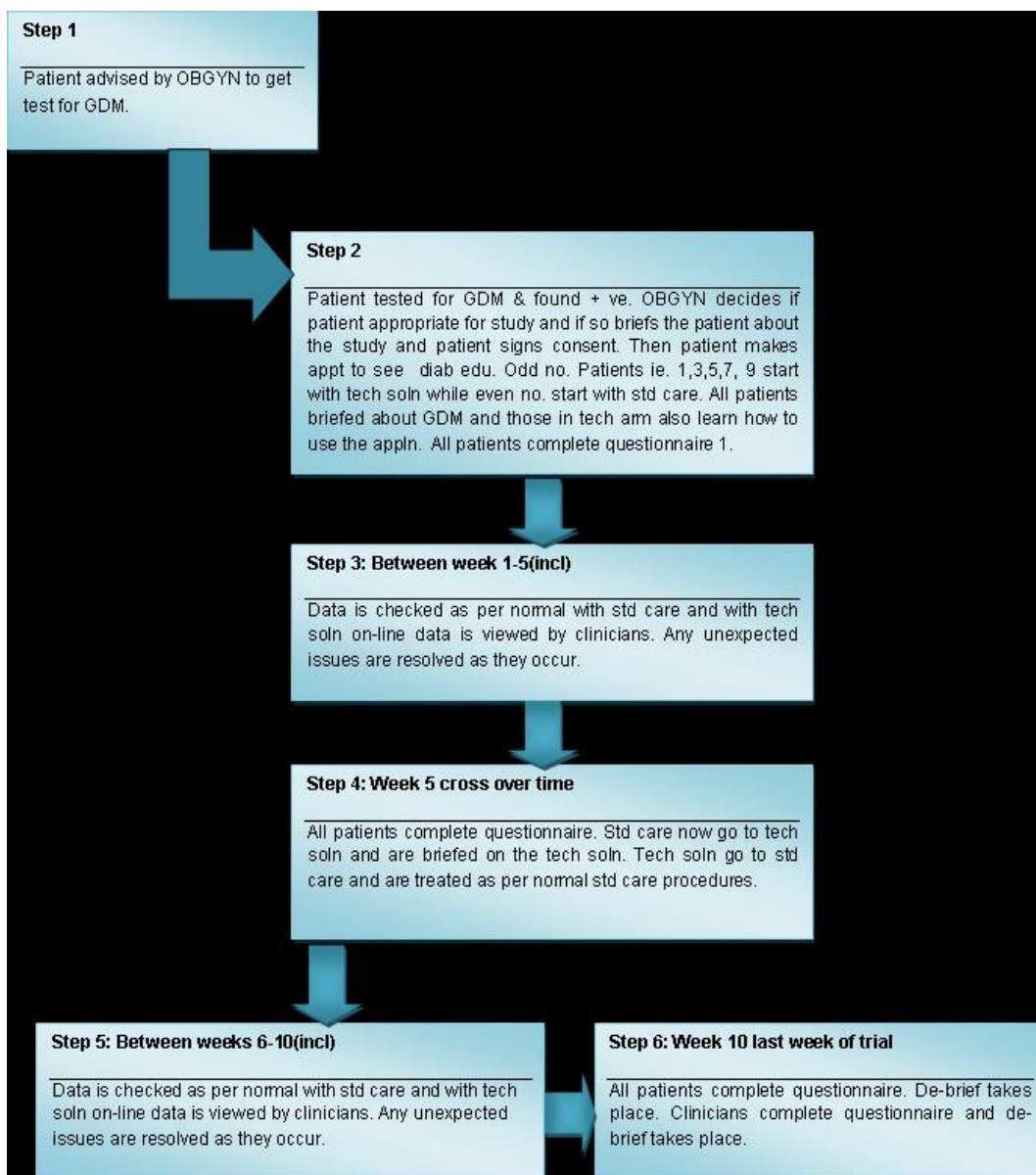
Figure 3 Research design

Established qualitative and quantitative techniques have been employed to analyse the collected data. Specifically, from the qualitative data, thematic analysis was performed in accordance with standard approaches described by Boyatzis (Boyatzis, 1998) and Kvale (Kvale, 1996), while simple regression techniques and exploratory data mining techniques will form the major focus for the quantitative part.

2.2 Data collection

Data was collected at the start, at the cross over point and at the end of each respective patient's participation in the trial via an interview and the administration of open ended questionnaires. Specifically, patients were asked to assess their familiarity and competence generally suing their own mobile device and then how comfortable they felt using the specific application for monitoring and

managing their GDM. They were also asked if they preferred the standard care approach or the technology solution and what specifically they liked about each. Patients were also asked to provide any enhancements or other features they would like to have in the application. In addition, clinician data was captured at the start and conclusion of the project via interview and the administration of open ended questionnaires. Clinician's were asked to compare the standard care versus the technology solution and how each impacted their ability to treat the patient. Teehee were also asked from a medical stand point did the technology solution enable the delivery of better healthcare pertaining specifically to GDM and to describe exactly how and why this was so.

3   Results

The results to date of this research in progress include the establishment of an appropriate delivery framework and web-based conceptual model that are tailored to the private healthcare context in Australia. This is an essential first step in order to successfully apply the pervasive mobile solution. From this, it was possible to then program the solution to the required local processes and requirements. Once the solution was approved by the clinicians and ethics clearance received it was then used in the technology arm of the trial.

Whether patients started with standard care and then migrated to the technology arm or vice versa, all patients interviewed have preferred the technology solution over the standard care approach. It is noted that the standard care approach essentially consisted of keeping logs of blood sugar readings and food intake and when required insulin usage. One patient noted (and all patients to date have expressed similar sentiments):

"…as a busy working person I have no time to note things down but with the mobile solution I can record things as I go so easily. I cannot believe this solution has not been used yet…"

At this time we have 9 patients in the trial and 5 have already delivered healthy babies, one with twins. All patients to date as well as all the clinicians (obstetricians, diabetic educator and endocrinologist) have stated that the technology solution is superior to existing standard care. In addition, they have provided feedback on enhancements including easier ways to display key information and other features that patients and clinicians respectively would like to have at the same time in addition to blood sugar readings.

4   Discussion

The DiaMonD study supports a pervasive mobile technology solution, which, while not exorbitantly expensive, has the potential to facilitate the superior monitoring and management of diabetes suffers. The proposed solution enables patient empowerment by way of enhancing self-management. This is not only a noted desirable objective because it allows patients to become more like partners with their clinicians in the management of their own healthcare (Lacroix, 1999; Opie, 1998; Radin, 2006) but also to date yet to be achieved in an optimal or satisfactory fashion (Colagiuri et al., 1998). Further, by enhancing the traditional clinical-patient interactions (Gururajan & Murugesan, 2005; Mirza, Norris, & Stockdale, 2008), the solution should provide better data management and effective and efficient clinical care focus.

This research in progress has implications for both practice and theory. Clearly, a small pilot trial cannot provide statistically significant results but the goal of the study was to establish proof of concept and fidelity of the solution. Our directional data to date has enabled us to do this as well as answer the posed research question: Can a pervasive mobile solution be used as an adjunct to support better blood sugar control of GDM patients. In particular, the benefits of such a technology are in the

enablement of heightened self-care by patients and providing clinicians with germane data and relevant information to assist in their patients' control of blood sugars. Further, key barriers include clinician support while key facilitators include patient preference. The major limitation of this study is the small patient cohort; however this was necessary to first establish proof of concept.

Armed with proof of concept, fidelity and usability and consistent with the principles of UCD we shall now begin the next phase of the study which includes a larger trial that revises the solution to take into account both clinical and patient user feedback. This feedback included various suggestions for monitoring other vital metrics apart from glucose as well as including other features that can provide useful information that in turn will support the necessary behaviour modification required for patients with GDM.

From the stand point of theory, our research to date provides support for the adoption of a UCD approach for successfully developing an ICT solution for a healthcare context. Moreover, we believe that the findings also suggest important insights for ICT innovation. Given that more recently in health care we are witnessing a plethora of ICT innovations developed at significant expense, we believe that it now becomes prudent to understand key issues regarding these innovations such as institutional issues, the combination of a multiplicity of actors as well as changing regulations. From our current study we believe that a critical success factor is the development of an appropriate delivery framework and business model as was discussed earlier. Our future, research will explore this aspect in more details.

5. Conclusion

It has been generally accepted for a few years now that diabetes is increasing exponentially (WHO, 2002); however, less well known is that GDM is also increasing significantly (Diabetes Australia, 2014). This is even more problematic, since like all pregnancy related issues two people's lives are affected; mother and baby. Further, the far reaching implications of gestational diabetes, if untreated are significant as this leads to increased likelihood of contracting diabetes for the child and the mother, and then also having a higher risk factor for any other healthcare issue. In addition, for the community and the healthcare delivery system, a system that is already challenged with escalating costs, as well as workforce shortages not only will there be then an on-going patient population to treat, since as a chronic disease there is no immediate cure for diabetes, but also these sufferers will have much more likelihood of further complications with other healthcare issues. This makes trying to address the increase in GDM a priority. We contend that, given the general age of patients with GDM, they are a natural group to opt for a pervasive mobile technology solution to assist them in their management and monitoring of their blood sugars. Thus, we believe that such solutions hold the key to addressing this significant problem. In closing we also note that an added advantage of such pervasive solutions is that they do not add significant financial burdens to the healthcare system by way of their pervasive nature; and thus they offer a superior solution for patients and clinicians as well as support a healthcare value proposition of better access, quality and value.

Acknowledgements

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