Achieving Value-Based Care in Chronic Disease Management: The DiaMonD (diabetes monitoring device) Solution

ABSTRACT

Background: The World Health Organization (WHO) notes that diabetes, a chronic disease, is a silent epidemic, and by 2020 there will be a 54% rise in the total number of individuals diagnosed with this disease (WHO 2017). These are alarming figures, which have significant repercussions for the quality of life of individuals and their families as well as for the financial stress of healthcare systems globally. Early detection and proactive management of diabetes is essential.

Objective: The aim of the study was to assess the usability, acceptability and fidelity of Diabetes Monitoring Device (DiaMonD) for patients with gestational diabetes mellitus (GDM). Specifically assessed were: 1) Patient compliance, 2) Patient satisfaction, 3) Level of Glycaemic control achieved, and 4) Health professional satisfaction.

Methods: Using a design science research perspective, the Diabetes Monitoring Device (DiaMonD) solutions was adapted to the Australian healthcare environment. Once the solution was deemed fit for purpose by the director of the OBGYN clinical institute and on securing all relevant ethics approvals, a two-period two-arm non-blinded cross over clinical trial was conducted for 8 weeks total time with cross over at 4 weeks to establish proof of concept, usability and fidelity. The patient perspective was assessed by using structured questionnaires at four specific stages of the project while the clinician perspective was captured via semi-structured interviews and unstructured questionnaires.

Results: The ten patients studied reported preferring standard care with the technology solution to standard care alone. Further, all the clinicians involved concurred that the technology solution greatly assisted their ability to provide higher value patient centred care. They also noted that it was extremely helpful for assisting in systematically monitoring glucose levels and any/all changes and trends.

Conclusions: Based on these initial findings, we proffer a holistic pervasive approach to enable the achievement of value-based, patient-centred care in chronic disease management. Key lessons include the importance when designing such solutions to focus on the two primary user groups (patients and clinicians).

Key words: diabetes, gestational diabetes, chronic disease management, value-based care, mobile health, power-knowledge, Australian healthcare system, two period two arm cross-over, clinical trial
Introduction

Currently, chronic diseases -- such as diabetes, obesity and cancer, rather than infectious diseases -- are not only increasing but also account for the largest part of most healthcare budgets, thereby placing a significant burden on healthcare systems (WHO, 2017). By definition, chronic diseases are incurable and hence, once an individual contracts a specific chronic disease, he/she must live with it for the rest of his/her life. This translates into a life-long interaction with the healthcare system and on-going monitoring and management of an individual’s lifestyle particularly, various health and wellness aspects including; diet, exercise and medication intake. To do this effectively and efficiently is especially desired by the two key stakeholders in chronic disease care, the patient/individual and their clinical care team.

Arguably, the most prevailing chronic disease is diabetes. Today, the World Health Organization (WHO) notes that diabetes is a silent epidemic, and by 2020, there will be a 54% rise in the total number of individuals diagnosed with this disease (WHO 2017; 2016; Lancet 2016). These are alarming figures and have significant repercussions for the quality of life of individuals and their families as well as for the financial stress of healthcare systems globally.

Early detection and proactive management of diabetes is essential (Templeton & Pieris-Caldwell 2008). A critical treatment imperative is to provide patients with diabetes appropriate monitoring to enable better assessment and control of blood glucose and thus also prevent further complications (Wickramasinghe et al. 2011). It is also essential that a cost effective solution that is convenient to both patients and clinicians, and least disruptive to patient lifestyle, be adopted (Wickramasinghe et al. 2014). Hence, Inet Intl. Inc. developed a pervasive technology solution to facilitate patient empowerment with their diabetic care (Goldberg 2002a-d). Succinctly, the solution utilizes pervasive mobile technology to transfer critical information between patient and providers so that superior monitoring may ensue. This solution has proved successful in assisting to lower HbA1C (the universally recognised marker for diabetes) in trials in Canada and the US (Wickramasinghe et al., 2011).

We contend that such a pervasive technology solution that can enable ubiquitous (anytime, anywhere, anyplace) monitoring of diabetic patients while simultaneously and continuously educating them should be a prudent part of any diabetes management program. Further, we wanted to understand the impacts of such a solution and unpack, more systematically, critical user issues, key barriers and facilitators, as well as the potential for using generated data for developing a better understanding of individuals’ diabetic issues. This in turn could lead to better population health protocols and strategies to prevent or stem the escalating increase and prevalence of diabetes. The result would enable a deeper understanding of diabetes in general, which could perhaps assist at a public health level with regard to better containment and management of this and other chronic diseases as well as the individuals’ own ongoing care. Hence, we conducted a clinical study to establish proof of concept of the technology solution, particularly focussing on the solution’s usability, acceptability and fidelity for the key user groups: patients and their care team. The chosen setting was a private, not-for-profit, tertiary healthcare facility in Australia. We adopted a design science research methodology (DSRM) to tailor the design and develop the Diabetes Monitoring Device (DiaMonD) Solution developed
initially by Inet Intl. Inc., so that it would be appropriate for supporting specific clinical needs, which is referred to in healthcare as being “fit for purpose” in the chosen healthcare setting. This includes being compliant with all medical, security and privacy requirements as required by law.

We report on the findings of our clinical study, based on our holistic pervasive approach, to enable the achievement of value-based care in chronic disease management that is patient centric and focusses on the two primary user groups (patients and clinicians). Given that healthcare costs are an important aspect of all healthcare agendas today, we frame our recommendations against a value-based paradigm, as we believe this a responsible approach to take. Moreover, a key emergent aspect of the study was the power-knowledge dynamic that exists between patients and their clinical care team. We expand on this finding, noting how it might influence adoption and use of the technology solution. In particular, we note that when developing technology solutions, it is important to engage both user groups, and without clinician support and engagement, it is unlikely that patients will be as willing to adopt or use a technology solution. In the following sections, we first position the study by providing a background, which highlights the key issues around value-based healthcare, chronic disease and diabetes, the Australian healthcare context, power-knowledge and data analytics before presenting the research method, key findings, discussion and conclusions.

BACKGROUND

Value-based care
Healthcare delivery especially in OECD countries today is facing many challenges, most notably aging populations, rise in chronic diseases and escalating healthcare costs (Wickramasinghe and Schaffer, 2010). The US is facing the steepest increases with predictions for healthcare costs being 20% of GDP by 2020 (Porter and Teisberg 2009; Bracy 2016). To address this, many experts are recommending a shift to a value-based healthcare focus rather than current systems such as fee for service or managed care (Porter and Teisberg 2009; Bracy 2016). At the centre of a value-based approach, the focus is on ensuring for all patients’ superior access and quality while also minimising costs. To address escalating healthcare costs in the US (and many other OECD countries), many are advocating incorporating a value-based system for healthcare delivery including bundled payments for services.

Existing health status, or pre-existing conditions (eg. Diabetes or other chronic disease), appears to constrain patient access to important, but expensive treatments, based on measures of quality and inclusion criteria for treatment (Porter and Teisberg 2009). While on the surface these decisions appear scientifically sound, the practical solutions available to the obese, diabetic or elderly with multiple chronic comorbidities or socio-economic barriers and limitations who attempt to achieve better health are limited. Hence, solutions that assist to support individuals with chronic disease would enable them to have better access to healthcare treatments for specific issues such as a knee replacement in a value-based, bundled care healthcare context.

In 2016, CMS has begun a shift in payment from volume to value, aligning 85% of all payments it makes linked to quality or value by the end of this calendar year, with 30% of payments tied to quality or value through Alternate Payment Models (APM). In 2016, the US began shifting to
“value-based reimbursement” in the MACRA\textsuperscript{1} and MIPS\textsuperscript{2} programs with the goals to overcome waste, benchmark all providers’ Medicare payments and adjust them based on comparison with peers’ clinical outcomes for the same procedures. In addition, the US government is shifting to fixed-price “bundling” for many known treatments, e.g. knee and hip replacements (18,19). These reimbursement changes are intended to guide providers towards evidence-based medical decisions and procedures. Such evidence-based processes are supposed to be unbiased and scientifically optimized formulations that describe the best way to treat patients for the best overall outcomes.

To date the US healthcare environment has made substantial investments into examining how to create and deliver value-based care. These strategies are now being carefully examined in Australia which is likely to adopt similar principles and thus all technology solutions are now being viewed in this light.

We believe responsible development of any healthcare solution should at the very least examine the possible impact of the proposed solution on access, quality and cost, as this can have significant and far reaching consequences to an already challenged healthcare system, and thus, we also examine our proffered solution in this light.

**Diabetes mellitus**

Diabetes mellitus is one of the leading chronic diseases, and its prevalence continues to rise exponentially. The total number of diabetes patients worldwide is estimated to rise to 366 million in 2030 from 171 million in 2000 (Wild et al 2004).

Australia is expected to be a significant contributor to this projected trend. An estimated 1,211,251 Australians were diagnosed with diabetes and registered with the National Diabetes Services Scheme (NDSS) in June 2016 (Diabetes Australia 2016). This represents those who have been diagnosed with any type of diabetes and including type 1 diabetes, type 2 diabetes and gestational diabetes.

An estimated 280 Australians develop diabetes daily (Diabetes Australia 2016; Diabetes Australia 2002). Moreover, for every person diagnosed with diabetes, it is estimated that there is another who has yet to be diagnosed, which doubles the number of diabetes sufferers (Diabetes Australia 2016). If uncontrolled or poorly managed, diabetes can lead to chronic vascular and kidney diseases, strokes, heart attacks, eye diseases and neuropathy and for some individuals amputations of extremities and limbs (AIHW 2007; 2008). Further, diabetes and its complications incur significant costs for the health system in Australia, including costs incurred by carers, government, and the entire health system (DiabCost Australia 2016). Currently, costs for diabetes in Australia are estimated to be around $14.6 billion (Australian dollars) per annum (ibid). This figure excludes additional costs; namely, societal costs that represent productivity losses for both patients and their careers (DiabCost Australia 2002). Taken together, this makes identifying a suitable solution to support cost effective on-going management of diabetes a strategic necessity both in Australia and globally.

\textsuperscript{1} Medicare Access and CHIP Reauthorization Bct of 2015

\textsuperscript{2} Merit-based Incentive Payment System
As noted above, diabetes has several forms (Type 1, Type 2 and GDM) which require nuances in treatment, although all are concerned with blood glucose levels and the body’s inability to process the glucose in the blood. Type 1 diabetes is essentially an autoimmune condition that causes the immune system to destroy cells in the pancreas that produce insulin (Diabetes Australia 2016). It usually presents in childhood or early adulthood but can occur at any age (ibid). Type 2 diabetes is the most common form of diabetes (ibid). It is often preventable, as it is often associated with lifestyle factors (ibid). Essentially in type 2 diabetes, insulin production by the pancreas becomes progressively slower and key organs in the body become resistant to the effects of insulin (ibid). The least well researched type of diabetes is the third type, gestational diabetes mellitus (GDM).

Gestational diabetes mellitus (GDM) is a common form of diabetes that presents in pregnancy, sometimes with symptoms but often diagnosed in otherwise normal women on routine screening tests. GDM is more common in older women, in those with a family history of diabetes, in those who are overweight, and in those of non-Caucasian heritage (Carolan et al 2010a,b). Maternal complications of GDM can be serious and include polyhydramnios and premature labour, maternal hypertension, low birth weights and stillbirth (Fan et al, 2006). 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, hyperglycemia and the associated tendency of fetal hyperinsulinemia, which is at the root of the fetal complications (Metzger et al. 2008). After many years of uncertainty as to the value of such treatment in GDM, two key trials have now shown benefit for both mother and offspring for antenatal initiation of lifestyle modification and glucose monitoring, coupled with insulin therapy as necessary (Crowther et al. 2005; Landon et al. 2009). Antenatal treatment of detected mild GDM was also associated with improved health status for women during the antenatal period and at 3 months after birth, with less postnatal depression (Crowther et al. 2005). Specifically, there is agreement in the literature that specific self-management activities including glucose monitoring, dietary restrictions, and exercise regimes can result in good outcomes for mothers and babies, suggesting that self-management behaviors can be critical (Crowther et al. 2005; Fan et al. 2006). More recently, in Australia, there has been a lowering of the threshold level for when a pregnant woman is now classified as having GDM, which has immediately led to a significant increase in the number of women now diagnosed with GDM over and above the growing trend that has been occurring (Namkervis et. al. 2012). This change in classification makes it even more pressing to find a suitable solution.

**Power-knowledge**

Integral in the use of many technology solutions in healthcare is the adoption and embracement of the solution by both clinician and patient. This also holds for the DiaMonD solution we want to investigate. However, we also note that there is, in the clinical-patient relationship, a critical power-knowledge dynamic in which the clinician has more power and domain knowledge than the patient.
Lamb and Kling (2003) distinguishes between power-based and influence-based agency, but others such as Wickramasinghe and Lamb (2009) have taken a Foucauldian power-knowledge perspective to unravel the underlying dynamics of agency, especially in healthcare contexts, noting the special role of physicians as knowledge worker agents. That is, while physicians are agents and hired to perform certain tasks, they also have unique expertise and thus can influence decision making and outcomes. Other scholars (e.g., Agarwal 2009 and Goh et al. 2016) have turned to Petty and Cacioppo’s (1986) Elaboration Likelihood Model (ELM) to assist to understand the essence of persuasion, be it central (appeals to logic or reason) or peripheral. In this sense, advice from physicians can be appreciated as powerful central input (especially when data driven) given their position, expertise and respect. Central route induced changes are generally considered more stable (and, thus, more predictive of sustained behavioural change) since they demand more deliberate and reasoned consideration. Patient motivation (as a moderator in the ELM) would be considered especially high given the overt attention of pregnant women to physician advice. Peripheral persuasion in the form of encouragement by family and friends would also be expected to be generally supportive.

**METHODOLOGY**

The aim of this study was to assess the usability, acceptability and fidelity of the pervasive technology solution (DiaMonD) for patients with GDM and thereby establish proof of concept. Specifically, the study was designed to assess: 1) Patient compliance, 2) Patient satisfaction, 3) Level of Glycaemic control achieved, and 4) Health professional satisfaction. From this, we expected it would be possible to develop a deeper understanding of the benefits, barriers and facilitators as well as any possible negative impacts of such pervasive mobile solutions in supporting and enabling superior chronic disease management. In addition, the study served to answer the following research questions:

a) How does a mobile solution enable and support the value-based care paradigm in the context of chronic disease management?

b) What are the benefits and suitability of such a pervasive technology solution to self-care?

c) What are the key barriers and facilitators for the application of a pervasive technology solution to support GDM patient care?

d) What are the possibilities of applying the tools and techniques of data science to enable precision healthcare delivery and/or inform public health care initiatives regarding better chronic disease management practices and protocols?

e) Are patients influenced and persuaded by their clinician to adopt the solution and is this important in choosing the solution?

We decided to conduct our clinical study focusing on GDM patients. We believed this was a prudent choice for several reasons including: 1) given the recent regulatory change in Australia, finding solutions to better manage the increased number of GDM patients became a national priority for healthcare organisations, 2) GDM patients are typically of child bearing age, and thus, this age group is relatively tech savvy, and 3) GDM presents in a defined time frame; i.e., during pregnancy, so it is possible to run a study with defined time frames. Specifically, we set about to conduct a clinical study to establish proof of concept, acceptability, usability and fidelity of the DiaMonD solution at a private not-for-profit, tertiary healthcare system in Australia focusing on GDM.
The chosen data site to conduct our study, a large tertiary, not-for-profit healthcare system, is situated in Melbourne, Australia. The Australian healthcare system is essentially a two-tier complementary system (Muhammed and Wickramasinghe 2017). This means that all citizens and permanent residents have basic healthcare provided by a national government scheme called Medicare and then can choose to take on additional cover via private healthcare insurance. In Australia, the healthcare system has historically been centered on the practitioners and service providers (ibid). It is a highly fragmented system with both State and Federal government jurisdiction (ibid). Hence, there exist many types of healthcare providers from solo practice, to public hospitals (government hospitals) to various types of private hospitals. The chosen data site is in the private system; hence, patients receiving treatment at this hospital must have private insurance. In addition, the hospitals in this system are tertiary which means they conduct leading research to strive to discover better ways to treat medical issues, and its not-for-profit status means that any surplus is reinvested into the system.

DiaMonD (Diabetes Monitoring Device)
The DiaMonD solution was developed by Inet Intl. Inc, a Canadian company to provide diabetes self-management and monitoring to all patients suffering from diabetes. Succinctly figure A2 shows the basic solution as developed by Inet. Key aspects of the solution include it is fully HIPAA compliant, totally pervasive which means it works on any mobile platform (Android, IOS etc) and it requires co-use or co-adoption of patient and their clinical care team.

Please Insert Figure 1 The basic DiaMonD Solution (figure provided by Inet Intl Inc.) here

To tailor the chosen pervasive technology solution, DiaMonD, to the specific healthcare context of the data site as well as comply with legal and ethical requirements for use of a technology solution in a study with pregnant women, it was necessary to make several tweaks to the technology solution so that it was both fit-for purpose and compliant. We note that in Australia any study that involves pregnant women, no matter how minimally invasive, requires the highest levels of ethical clearances at a national government level. Naturally, we complied with all requirements and secured all necessary ethics clearances; however, to do this in a systematic fashion, we employed a design science research methodology (DSR) approach.

Design Science Research Methodology (DSR)
Design science is an important and legitimate research paradigm in information systems (Gregor & Hevne, 2013). Design science research involves constructing a wide range of socio-technical artefacts, such as new software, processes, algorithms or systems intended to improve or solve an identified problem (Myers & Venable, 2014). The design science guidelines originated from information-systems design theory originally proposed by Walls et al. (1992) as “a prescriptive theory which integrates normative and descriptive theories into design paths intended to produce more effective information systems.” Eventually, Peffers et al. (2007) expanded design theory into a design science research methodology by incorporating the principles, practices and procedures required to carry out research by applying design science theory. They suggested that design science theory as a methodology, needs to be consistent with prior literature, provide a
nominal process model for doing design science research, and provide a mental model for presenting and evaluating design science research (Peffers et al. 2007). Moreover, Hevner and Wickramasinghe (2017) note that in healthcare contexts use of design science research methodology is especially prudent when fine tuning innovative solutions.

Hevner et al. (2004) presented seven guidelines for understanding, executing, and evaluating design science research. Various studies (Nguyen and Wickramasinghe 2017; John et al 2016; Arnott & Pervan 2012; Xu, Wang, Li, & Chau 2007) have used these guidelines for building algorithms and systems. The three-cycle view captures the design science research idea to refine the artefact design iteratively through several interconnected design, relevance, and rigor cycles as illustrated by Hevner (2007). The improved four-cycle model of IS design science research for capturing the dynamic nature of IS artefact design is illustrated in Figure 2 (Drechsler & Hevner 2016). This refinement is intended to increase both the artefact’s effectiveness to address the real-world problem as well as its knowledge contributions over several iterations. The fourth cycle in the DSR model, termed as change and impact cycle, is to better capture the dynamic nature of artefact design for dynamic real-world contexts. Applying the change and impact cycle to a mobile healthcare application like DiaMonD, the app itself, the mobile device(s), and the patients and/or clinicians that use the app we believed would be prudent and would greatly assist to ensure that the solution was fit for purpose in the Australian healthcare context. The design of DiaMonD using design science research is further discussed in Table 1, while Figure 2 depicts the design science research methodology.

Table 1 Design Science Research guidelines for DiaMonD

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<tr>
<th>Design Science Research guidelines</th>
<th>DiaMonD</th>
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<tr>
<td>Guideline 1: Design as an Artefact</td>
<td>DiaMonD – a convenient and innovative mobile solution to support patient and clinical users and enable diabetes self-management and monitoring to ensure. It also has the potential to support a value-based care agenda as it can increase access, has the potential to increase quality of care and more especially timeliness of feedback and does not appear to impact costs of care delivery. If anything it has the potential to reduce them by preventing more serious problems form occurring.</td>
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<td>Guideline 2: Problem Relevance</td>
<td>To address the need for continuous and superior monitoring and management of GDM patients. To provide in a timely fashion anywhere, anytime key data to facilitate better decision making. To provide an appropriate technology solution that can support self-management of diabetes for both patients and clinicians.</td>
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<td>Guideline 3: Design Evaluation</td>
<td>Clinicians and potential patient users were included at various points in the design and testing of the solution. In addition, hospital legal representatives were consulted to ensure the solution complied with all government requirements for technology solutions interacting with pregnant women in medical research. This was an iterative process and concluded when legal, clinical and representative patient users were satisfied that the solution was fit for purpose. In particular patient and clinician feedback enabled the solution to be suited to the Australian context. Key examples include ensuing the scale to measure blood glucose levels was correct, since different scales are used in different countries, the correct names of the medications were enabled, appropriate legal requirements met and message included such as “if you have any</td>
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<td>Design Science Research guidelines</td>
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<td>concern please contact your health professional [number provided] immediately” while patient-users provide insights onto the look and feel from their perspective on how they would like data displayed. All these aspects were addressed before the solution was used in the study.</td>
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<td>Guideline 4: Research Contributions</td>
<td>In this study, users’ perspectives of the mediating role of the solution are explored.</td>
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<td>Guideline 5: Research Rigor</td>
<td>Theoretical foundations and conceptual models drawn from information systems, chronic disease management protocols, healthcare quality and safety were used to inform the development cycles to evaluate DiaMonD in clinical contexts.</td>
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<td>Guideline 6: Design as a Search Process</td>
<td>In this project, the design was essential to be correct to meet with ethics requirements in pregnancy type studies and ensure full and complete risk mitigation in such a context.</td>
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<td>Guideline 7: Communication of Research</td>
<td>Internal communication: Presented the technology and clinically-oriented users through focus groups, simulations exercises, brainstorming meetings, as well as technical and managerial meetings. External communication: Progress and findings are reported in a book chapter and peer review papers submitted to international conferences and professional peer-reviewed journals in relevant disciplines.</td>
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Please insert Figure 2 Four-cycle model of IS design science research (Drechsler & Hevner 2016) here

**Research Design**

As noted above, our goal was to investigate the usability, fidelity and proof of concept of the designed and developed mobile solution in the selected case site; namely, at a private not-for-profit tertiary healthcare environment in Victoria, Australia. Hence, our study was suited to a single case study methodology, and in designing the study, we subscribed to the recommendations of Yin (2015).

As Gestational diabetes mellitus (GDM) was selected, and as previously identified occurs during pregnancy, the study constituted a clinical intervention on pregnant women. In Australia, the Australian research code of ethics classifies any clinical intervention on pregnant women at the highest risk and hence, the ethics process is at a national approval level and very strict. Ethics approval was received, but the ethics committee limited the sample to 10 patients, given that it was a first type of clinical study of its kind to be administered on pregnant women, and thus, fell into a high risk category; if a patient dropped out, for whatever reason, we were able to add another patient.

A two period, two arm cross-over clinical trial strategy (Rigby, 2003) over an 8 weeks duration per patient was adopted, with two equal periods of four weeks each. As we wanted to understand
the benefits, if any, of using a technology solution in addition to standard care protocols, it was necessary to have two arms to the cross-over study design so that all patients experienced both with and without the technology. One arm was the control (i.e., standard treatment of GDM by the hospital), and the other arm was the intervention (i.e., standard care plus technology). In compliance with ethics and laws in Australia, no patient is allowed to be denied standard care, and hence the intervention arm was designed as standard care plus the technology solution.

On the advice of the OB/GYN professionals, the duration was set at eight weeks. This was deemed a suitable time, as it was unlikely a baby would be delivered during this time frame, and we would have time for the patient to experience both arms of the study. Hence, cross-over was set at four weeks. As noted by Rigby (2003), it is ideal to have a cross-over time so that all participants can experience treatment with and without the technology, and then they can comment on the differences. It is also recommended to have participants start with the technology solution and cross to without and vice versa so that it is possible to identify any biases more easily with technology use (ibid).

Specifically, two groups were used. Figure 3 depicts the study design adopted. The first group experienced “Standard care” protocols and treatments, and the second group was introduced to the “Standard care & Technology solution.” Patients were offered the opportunity to participate in the trial once a diagnosis of gestational diabetes had been made, based on a glucose tolerance test administered between 26-28 weeks in pregnancy. All appropriate ethical clearances were secured before the trial began. Enrolment in the study was done by the endocrinologist under the supervision of the consultant obstetricians and was totally optional. At the time of enrolment, all pertinent information regarding the study was shared with patients including the cross-over strategy employed. Following enrolment in the study, patients were randomly allocated to either the “Technology solution” or “Standard care” arms of the study. All patients were then educated in the technique of blood glucose monitoring (BSL’s) by a diabetic educator, as per standard clinical practice. They were also then educated in the use of “technology based” or “traditional” recording techniques for BSL’s.

Decisions regarding need for insulin or other medical therapy were always made at the discretion of the clinician, and based on current treatment guidelines and standard care. At the time of enrolment into the study, patients were asked to complete a short questionnaire, exploring demographic details, their familiarity with technology in general, and their understanding of gestational diabetes. Four weeks into the study, cross-over occurred; thus patients initially in the “Technology solution” or “Standard care” arm now entered the “Technology solution” arm and vice versa. Once again, the diabetic educator provided education regarding the use of “technology based” or “traditional” recording techniques for BSL’s. Also, at this time, a short questionnaire was administered to patients regarding their experiences during the first four weeks.

The patient perspective was assessed at four specific stages of the project (Appendix 1a):
1) A structured questionnaire at the start of the project (PQS) – the objective here was to assess patients’ familiarity with technology and in particular mobile devices as well as ascertain their health literacy especially as it relates to diabetes management;

2) A structured questionnaire at the end of using the standard care (PQES) - the objective here was to assess patients’ overall satisfaction with managing their diabetes and how beneficial they felt the standard care approach was in enabling them to do so as well as identify any issues they may have with the standard care approach;

3) A structured questionnaire at the end of using the technology solution in conjunction with standard care (PQEST) – the objective here was to assess the patients overall satisfaction with the technology solution to assist them in managing their diabetes as well as any issues and general comments or suggestions they may have regarding the technology solution;

4) A structured questionnaire at the end of the project (PQE) – the objective here was to assess patients’ overall satisfaction and compare their views between the standard care versus the standard care with the technology solution.

We note that to comply with ethics, we did not interview patients at the completion of the study as it was considered too much stress and imposition for a new mother.

As there were two key user groups, patients and clinicians, it was necessary to also understand findings from the clinical team. The clinical care perspective included a focus on three key groups, namely; the obstetrician, the endocrinologist, and the diabetic educator, as these are the key members of the patients’ care team. These individuals were presented unstructured questionnaires to complete at the start (CQS) and the end of the study (CQE) and were also invited to an interview where they were asked unstructured and semi structured questions about the study and their opinions on the role and benefit of the technology solution (Appendix 1b and 1c). Given that the clinicians were at all times participating in both arms of the study, they were not given questionnaires at the point of cross-over but rather were asked about the cross-over aspects during their interview at the end of the study. It was our desire to have questionnaires for the clinicians at the point of cross-over but ethics noted that this was superfluous and that clinicians should not be given more questionnaires than necessary, so it was removed to comply with ethics requirements. Once again, the questionnaire at the start of the study had the objective to assess ease of use with technology in day-to-day life, determined by mobile solution used and the frequency of use. The questionnaire at the conclusion of the study was designed to ascertain overall satisfaction with the technology solution, and allow for any recommendations moving forward.

RESULTS
To address the stated aims and answer the posed research questions, this study analyses the data from two key perspectives, namely; i) patient perspective and ii) clinical perspective. Findings from these two categories will be presented in turn. Subscribing to the directives of Boyazis (1998), the gathered qualitative data was then analysed by examining the occurrence and frequency of the a priori themes and then the occurrence and frequency of any emergent themes.
From the patient perspective, the five key a priori themes include: i) Health literacy and understanding regarding diabetes management, ii) General familiarity and use of mobile solutions, iii) Standard care, iv) Technology solution, and v) Suggestions to enhance the technology solution. All patients reported preferring standard care with the technology solution over just standard care. Further, thematic analysis served to uncover other results from the patient data collected including: their supportive care team played a big role in their being comfortable with the technology solution because they trusted their doctor and were confident in his/her decision; they were committed to doing whatever was best for their unborn baby’s health, so having timely advice made them feel they were doing the best for their baby.

Some comments included:

“Overall, a wonderful initiative. This app makes it easier for patients with GDM as its quick to enter readings, easy to track trends using graph on website and an effective and efficient way to communicate with doctors/nutritionist. For busy mums to be especially this is a fantastic tool, easier than remembering to call with readings each week. Excellent concept!” [patient 02]

“[patient 07]”

In addition, all patients preferred to have the mobile solution together with standard care rather than just the standard care approach. All patients used mobile phones daily and felt very comfortable entering the required data. They all had a good understanding of the protocols they should follow for GDM, once it was explained to them by their healthcare professional, and they complied as best as they could. This is not uncommon, given most mothers-to-be try to do what is in their unborn baby’s best interests. At the conclusion of the study, many ideas for further enhancement were provided by the patients, including having a recommended food diary, assistance on where to get the needed food, recommendations for alternate exercise and voice recognition to avoid data entry. All patients completed the four questionnaires.

For consistency, the same a priori themes were used to examine the data collected from the clinicians. Overall, all the clinicians preferred the technology solution over the standard care only scenario. Sixty percent of clinicians were totally happy with using the application, and it was acceptable “as is” for them, while 40% were happy with the solution but thought it could be further enhanced and was only useful for “typical” GDM patients. They had reservations about using the solution in the case of “complicated” GDM patients. We note that, given ethics clearances obtained, we could not include high risk patients in the study, so we cannot show any results for high risk patients. Enhancements included also keeping track of weight and blood pressure on an on-going basis and graphing these together with the blood glucose levels.

Further, the clinicians all concurred that the technology solution greatly assisted their ability to save time and made the monitoring of gestational diabetes more efficient, effective and was extremely helpful to assist in systematically monitoring glucose levels and any changes and trends any time regularly. This enabled them to provide better/optimal care for their patients; as they noted, having the key data at the right time greatly assisted them to make prudent decisions. Moreover, they noted that, especially in pregnancy, a small change in blood glucose can have a severe impact on the tiny foetus (baby) as it develops, given that for an adult a 1-2 point
difference is a very large difference. For a tiny foetus however, every extra second of a higher concentration of blood glucose can lead to major issues for the baby on birth and even throughout life as this represents an extremely higher concentration given the significant size difference.

In terms of usability, there were suggestions to change the format of patient’s entry so that it was clear when patients were seriously out of range versus slightly out of range. The only concern from the diabetes educators was pertaining to communicating with patients through the application rather than face-to-face appointments, when dealing with a large sample size and the likely time requirements this would involve. It is anticipated that with appropriate staffing and workflow process in place, this should not be an added burden, and it will also lend itself to capturing large amounts of data in a systematic fashion. These data can then be analysed, so potential benefits at a more population health level might ensue, which in turn might lead to new insights into diabetes management, treatment and even prevention.

The clinicians in the study were particularly interested to further investigate the potential of the data and how data analytics might be used to identify key trends. They noted that GDM is the least well understood form of diabetes and having cohorts of data on GDM patients would provide immense value in assisting to better understand this disease. They believe that the data collected could be helpful to examine what diets and exercise and when this occurred was best with GDM management as well as other factors including ethnicity and age. To get such a rich picture and understanding would assist them to develop better protocols for their patients and even contribute to public health protocols.

The clinicians also identified as a major barrier hospital regulations and legal and government aspects.

OBGYN 1: In obstetrics there is always much focus if things go wrong - it is not good for the hospital and the government and legal issues are complex and it tends to get quite emotional too. Thus it tends to be quite conservative. Without hospital executive support it is not possible to move forward with technology solutions this is key especially in our area.

In addition, emergent themes developed that focused on the need for coaching and/or education, the need to redesign existing operations to make the best use of the efficiency and effectiveness potential the technology solution affords, and concerns about time commitments required, and managing expectations regarding response rates by a member of the clinical care team. Finally, clinicians identified that it would be good to further enhance the solution to provide monitoring and management post-delivery to ensure that the mother still controls her blood glucose levels.

DISCUSSION

On analysis of the collected data, we contend that acceptability, usability, and fidelity were established as was initial proof of concept of the solution. Specifically, all patients using the technology solution with standard care had better management of blood glucose levels and were able to monitor and manage their GDM together with their clinician more effectively and efficiently when compared with just being on standard care. This was based on daily readings,
examination of medical records/report and patient and clinician feedback. We note that the sample size was small (and this was due to ethics restrictions as already mentioned); however, we believe that by running further confirmatory studies we can develop a larger evidence base to further demonstrate the benefits of the DiaMonD solution for supporting and enabling superior care for patients with GDM. Moreover, the study does establish the benefits of such mobile solutions to both patients and their clinical care team to be used as an adjunct with standard care protocols.

In addition, the above findings and results enable us to begin to answer the posed research questions:

a) How does a mobile solution enable and support the value-based care paradigm in the context of chronic disease management?
b) What are the benefits and suitability of such a pervasive technology solution to self-care?
c) What are the key barriers and facilitators for the application of a pervasive technology solution to support GDM patient care?
d) What are the possibilities of applying the tools and techniques of data science to enable precision healthcare delivery and/or inform public health care initiatives regarding better chronic disease management practices and protocols?
e) Are patients influenced and persuaded by their clinician to adopt the solution and is this important in choosing the solution?

Table 2 provides the detailed answers. We believe that the study does highlight the huge potential and benefit for embracing pervasive mobile solutions to facilitate superior care and management in the context of diabetes and other chronic diseases. We also believe that such an approach represents a paradigm shift “a clinician-patient partnership” in the treatment of diabetes which could be helpful to stem current escalating costs and effect better blood glucose control on going.

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<th>Question</th>
<th>Answer</th>
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any significant impact to current costs. In fact they noted that their primary duty is to
treat the pregnancy not the GDM per se; and thus anything that assists them to treat
GDM more effectively and efficiently is always going to lead to a higher value of care
delivery. Moreover, they noted the potential for cost savings by ensuring better
glycaemic control, which in turn leads to less complicated births and healthier babies
when born. The clinicians also strongly felt that with the technology solution they
could provide better care which was their key goal.

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<tr>
<th>What are the benefits and suitability of such a pervasive technology solution to self-care?</th>
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<td>The benefits are many including: i) peace of mind for the mother-to-be, ii) convenience for the mother-to-be, especially if she is a working mother, iii) minimisation of travel and waiting times for the mother-to-be which is especially beneficial for more remotely located patients, iv) ability to receive immediate feedback and thus intervene faster if there is a risk or problem. Similarly, benefits for the clinicians include: i) ability to stream line workflow, ii) provide better tailored care to patients, and iii) more effectively manage mother and baby’s health.</td>
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<th>What are the key barriers and facilitators for the application of a pervasive technology solution to support GDM patient care?</th>
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<td>One of the biggest barriers identified is government regulations and policies around pregnancy care which would be needed if the solution were to be embraced on an ongoing basis. To offer it as an optional solution is not a problem as long as it complies with all regulations. Key facilitators included clinician and hospital executive support. Patients also intimated that if their clinician did not support the solution they would be reluctant to adopt it while clinicians’ clearly stated they would not be so comfortable for their patients to use a technology solution they did not recommend and support because at the end of the day they bear the risk and responsibility. This would also mean that a key facilitator is clinician support and endorsement as well as hospital executive support.</td>
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<th>What are the possibilities of applying the tools and techniques of data science to enable precision healthcare delivery and/or inform public health care initiatives regarding better chronic disease management practices and protocols?</th>
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<td>On discussion with clinicians, they believed that collecting the data from all patients would provide deeper insights into GDM – a still less well understood type of diabetes which would in turn help to inform practice protocols and population health initiatives. Significant to clinicians was the ability, from analysed data, to give them a clear(er) picture of the current state likely trends and possible impacts to both mother an unborn baby. In this regard, graphical representation was highly welcomed and in fact the graphical view provided by the solution currently was a key factor in why clinicians in particular but also patients found the system so useful.</td>
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<th>Are patients influenced and persuaded by their clinician to adopt the solution and is this important in choosing the solution?</th>
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<td>Patients noted that if their clinical care team had not used the technology solution, they would not have used the solution even if they found it better than the standard care. Thus, for them it was important that their clinician was also using the technology solution and was supportive of their using the solution. Clinicians also remarked that if their patients used technology solutions that they did not recommend they would not be as comfortable to treat their patients and advise their patients to stop using such solutions.</td>
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Today chronic diseases have replaced infectious diseases as one of the top global causes of deaths and morbidity [Centre for Diseases Control http://www.cdc.gov/]. Diabetes is one of the five major chronic diseases and has been termed by the WHO as the silent epidemic [WHO, http://www.who.int/topics/diabetes_mellitus/en/]. By definition, for most sufferers of diabetes (or other chronic diseases), there is no likely cure, which makes prudent management of their condition key to living a quality life. Good management is predicated on pertinent information
and germane knowledge (Wickramasinghe et al. 2008), which at times is not always easy for these patients to access and/or acquire.

As the preceding study has served to illustrate, pervasive mobile solutions have the potential to support appropriate self-management. Self-management is not only important as it empowers diabetes patients while acknowledging their central role and responsibility for managing their healthcare, but moreover, active participation of diabetes patients in self-management is a key and recognised strategy for managing their condition and reaching improved treatment outcomes (de Clerq et al. 2001; Kelly et al. 2011).

An important aspect, which was further identified in the preceding study, revolves around the patient and provider, their respective roles and influences with regard to adoption of new technology. As such, clearly the patient plays a very active and empowered role in his/her care and treatment. However, the role of the clinician/provider as the care provider should not be forgotten. In many ways, the physician directly or indirectly plays dual roles as a potential adopter and/or an influencer of the technology. Given the expertise and regard patients generally have for their medical provider, it is reasonable to expect that the provider’s recommendations and advice, not only about a treatment protocol but also about a technology to be used within this care path, will have an influence on it being ultimately tried and even adopted by the patient. Furthermore, as highlighted by the DiaMonD solution, such technologies require the concurrent and mutual adoption by patient and clinician. This then raises several key questions concerning patient adoption and the potential dual roles of the physician as both an adopter and an influencer. Integral to this appears to be an apparent power-knowledge dynamic.

Thus, the mobile solution presented above should be examined from both patient and clinician perspectives about the acceptance of this technology as a tool to facilitate and support on-going treatment. Based on the response to the question on the questionnaire regarding use of the solution if clinicians had not recommended its use, it was evident that clinician support of the solution was important. As we were unable to interview patients, we could not get further information on this, but our study served to highlight that clinicians appear to play a key role in persuading their patients to adopt a technology solution, and this is likely to be partly based on their power-knowledge status. Moreover, we found that clinicians are not so comfortable to treat patients using technology solutions they do not support. Thus, our study provides directional data to highlight that these are important considerations and should be considered in future research. In particular, we assert that the adoption of a technology solution by a patient is highly influenced by their clinician’s endorsement, and thus patients are more likely to use solutions their clinicians endorse than solutions they like that are not endorsed by their clinicians. To investigate this area more closely we believe that Petty and Cacioppo’s (1986) Elaboration Likelihood Model (ELM) could be helpful to assist to understand the essence of persuasion in this context. Specifically, how patients are persuaded and also what persuades clinicians. It would appear from our findings that naturally it is important that both patients and clinicians embrace the technology solutions but when clinicians are on board it is highly likely patients will be too while the converse is not so likely to be true. Hence, our study sheds light on our understanding of the clinician-patient relationship. In particular, it suggests to us to frame
clinician advice as appealing to persuade patients use/non-use while power-knowledge dynamics shows that the professional position that clinicians hold coupled with their expert knowledge can serve to sway patients’ judgements to use/not use a technology solution. This is also an important consideration in designing technology solutions for healthcare contexts.

Value-based care
Given that providing value-based care is on the agenda of most if not all OECD countries’ healthcare agendas, we believe that no study today that proffers a technology solution to facilitate care delivery should ignore value-based care. Some scholars (Wickramasinghe and Schaffer, 2010) have noted that value in healthcare consists of addressing key aspects of access to care, quality of care and cost of care, and thus we examine the DiaMonD solution in the preceding study in this light.

Mobile solutions that are designed to support patients with specific chronic disease -- such as the DiaMonD solution, designed to support patients with diabetes-- will enable such patients to follow appropriate treatment protocols for their chronic disease. When they present for surgery in a value-based bundled healthcare environment, they will not be denied care for being a high risk. Rather, they will provide compelling evidence to show that they are managing their co-morbidities and are an appropriate/acceptable health risk for surgery.

Specifically, we noted in our study that patients received a higher level of access that was anytime, anywhere as they needed assistance, given that they could send, update and receive messages via the mobile solution. Moreover, the quality of care was higher because it was more focussed and precise because the clinicians received timely data and information from which to make key decisions about blood glucose level, insulin dosage, as well as diet and exercise. In terms of cost, for the patients in the pilot study, there was no additional cost. While the clinicians observed that by having better management of GDM, there is a greater likelihood of minimising complications at birth and for the baby and mother post-birth, which in turn would decrease likely healthcare costs at this time. We do note, however, that we did not conduct a formal economic analysis in this study.

Overall, the directional data from the clinical study supports the position that the pervasive DiaMonD solution provides a higher level of access and quality of care and at the same time has the potential to reduce healthcare costs and thus it appears to be consistent with a value-based healthcare paradigm. It also enables us in our future studies to develop hypotheses to test around the central issue of value-based care.

CONCLUSIONS
We presented data from an exploratory clinical study designed to establish proof of concept, in an Australian context, of a specific pervasive mobile solution - Diabetes Monitoring Device (DiaMonD). The aim of the study was to assess the usability, acceptability and fidelity of DiaMonD for patients with GDM. Specifically assessed were: 1) Patient compliance, 2) Patient satisfaction, 3) Level of glycaemic control achieved and 4) Health professional satisfaction. All patients reported preferring standard care with the technology solution over just standard care.
Further, the clinicians all concurred that the technology solution greatly assisted their ability to save time and made the monitoring of gestational diabetes more efficient, effective and was extremely helpful to assist in systematically monitoring glucose levels and any changes and trends at any time more regularly. Based on these findings, we contend that a pervasive technology solution that is consistent with a value-based care paradigm for chronic disease management is important. Moreover, such a solution should be patient centric, focussed on the two primary user groups (patients and clinicians) and be used in conjunction with standard care protocols of care. We believe such a solution has the potential to represent a paradigm shift for diabetes care and more generally chronic disease management. It is likely that the consequent paradigm shift in the approach to treating chronic diseases such as diabetes will provide the needed impetus to address the rising costs and provide better means to manage the current state.

This study describes a pervasive mobile solution designed to support superior diabetes self-care and patient empowerment. By doing so, it enables diabetes patients to control their blood glucose levels and thus enjoy a higher quality of life. However, by analyzing the DiaMonD solution in relation to the principles of value-based care, it is also shown that such pervasive mobile solutions support value-based care delivery by proving greater access and quality of care while simultaneously reducing costs associated with this care. Further, contributions to the power-knowledge dynamic of the clinician-patient relationship were identified.

In closing, we note that it is essential with all technology solutions, but most especially those in healthcare, to examine potential risks or negative aspects, if any; or what may be termed the “dark side”. Based on the study, no significant risks became apparent, and given the extensive rigor applied in the ethics process, we believe any potential risks were identified during this process and addressed. However, we do note that with scale there may be an impact on clinician work load, and this should be investigated in future studies. Thus establishment of usability, acceptability and fidelity is clearly a necessary but not sufficient condition for universal adoption of a technology solution in healthcare contexts.

REFERENCES


Gandomi, A and Haider, M2015 Beyond the hype: Big data concepts, methods, and analytics International Journal of Information and Management 35(2) pp. 137-144.


Wickramasinghe, N. and Schaffer, J. 2010 “Realizing value driven e-health in healthcare” IBM center for the Business of Government


APPENDIX 1a

Questionnaire – Patient (at the Start of the Project)

Please, complete the questions below as best you can by circling the most correct answer:

1. I use my mobile phone
   a. Never
   b. Only in an emergency
   c. Less than 2 times a week
   d. More than 3 times a day

2. When I use my mobile phone I mainly
   a. Text
   b. Call
   c. Text and call in roughly equal amounts
   d. Call more than text
   e. Text more than call
   f. Other----------------------- (please specify)

3. I have/use
   a. 1 mobile phone
   b. 2 mobile phones
   c. A mobile phone and IPad (or tablet) and PC

4. The type of mobile phone I use is (please state)

5. I understand the need to regularly monitor and manage my blood sugar (please circle)

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<td>Not at all</td>
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THANK YOU
Questionnaire – Patient at the end of Stage 1 of the Project
(standard care arm)

Please, complete the questions below as best you can by circling the most correct answer:

1. I understand the need to regularly monitor and manage my blood sugar (please circle)

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<td>4</td>
<td>5</td>
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<tr>
<td>Not at all</td>
<td>Some</td>
<td>unsure</td>
<td>Not</td>
<td>what unsure</td>
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2. I found the standard care easy to understand (please circle)

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<tr>
<td>Not at all</td>
<td>Some</td>
<td>what</td>
<td>difficult</td>
<td>Some</td>
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3. I found the standard care helped me to control my blood sugar (please circle)

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<tr>
<td>Not at all</td>
<td>really</td>
<td>Not</td>
<td>sure</td>
<td>Not</td>
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4. The following would have been helpful to include: (please list)

----------------------------------------------------------------
----------------------------------------------------------------
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THANK YOU
Questionnaire – Patient at the end of Stage 1 of the Project
(standard care arm + mobile solution)

Please, complete the questions below at best you can by circling the most correct answer:

1. I understand the need to regularly monitor and manage my blood sugar (please circle)

   |-----------|-----------|-----------|-----------|
   1  2  3  4  5
   Not at all  Some  Not  Some  Understand
   what unsure  sure  what  understand

2. I found the mobile solution easy to understand (please circle)

   |-----------|-----------|-----------|-----------|
   1  2  3  4  5
   Not at all  Some  Not  Some  Very understandable
   what difficult  sure  what  easy

3. I found the mobile solution easy to use (please circle)

   |-----------|-----------|-----------|-----------|
   1  2  3  4  5
   Not at all  Some  Not  Some  Very easy
   what difficult  sure  what  easy

4. I found the mobile solution helped me to control my blood sugar (please circle)

   |-----------|-----------|-----------|-----------|
   1  2  3  4  5
   Not at all  Not  Not  Some  Most definitely
   really  sure  what  Some

5. The following would have been helpful to include: (please list)

   ---------------------------------------------
   ---------------------------------------------
   ---------------------------------------------
   ---------------------------------------------
Questionnaire – Patient at the end of the Project

Please, complete the questions below at best you can by circling the most correct answer:

1. I understand the need to regularly monitor and manage my blood sugar (please circle)

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<td>3</td>
<td>4</td>
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<tr>
<td>Not at all</td>
<td>Some what unsure</td>
<td>Sure</td>
<td>Not what understand</td>
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2. After experiencing standard care and also standard care + the mobile solution I found the key advantages of the mobile solution to be: (please list)
   -
   -
   -
   -

3. I would recommend the standard care + the mobile solution
   Y/N (please select)
   Why? (please explain)
   -
   -
   -
   -

4. If I could I would prefer to have the option of standard care + the mobile solution
   Y/N (please select)
   Why? (please list)
   -
   -
   -
   -

5. Other features I would like to see included with the mobile solution: (please list)
   -
   -
   -
   -

6. Anything you would like changed with the mobile solution or any other comments: (please list)
   -
   -
   -
   -

Many thanks for participating in our study – have a good day!
APPENDIX 1b

Questionnaire – Clinician (at the Start of the Project)

Please, complete the questions below as best you can by circling the most correct answer:

1. I use my mobile phone
   a. Never
   b. Only in an emergency
   c. Less than 2 times a week
   d. More than 3 times a day

2. When I use my mobile phone I mainly
   a. Text
   b. Call
   c. Text and call in roughly equal amounts
   d. Call more than text
   e. Text more than call
   f. Other----------------------- (please specify)

3. I have/use
   a. 1 mobile phone
   b. 2 mobile phones
   c. A mobile phone and IPad (or tablet) and PC

4. The type of mobile phone I use is (please state)

5. In general I support my patients to use technology that they want to use (y/n) explain

THANK YOU
Questionnaire – Clinician at the end of the Project

Please, complete the questions below as best you can by circling the most correct answer:

1. I found the mobile solution easy to work with (please circle)

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<td>4</td>
</tr>
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</table>
| Not      | Not      | Not      | Some     | Definitely
| at all   | really   | sure     | what     |

2. I would like to see the following additional features included with the mobile solution:(please list)

----------------------------------------------------------------
----------------------------------------------------------------
----------------------------------------------------------------
----------------------------------------------------------------

3. I would suggest the following changes with the mobile solution(please state and explain)

----------------------------------------------------------------
----------------------------------------------------------------
----------------------------------------------------------------
----------------------------------------------------------------

I believe the mobile solution is better than the standard care approach for assisting patients with GDM to manage and monitor their blood sugar levels? Y/N (please circle)

Why?(please explain)

----------------------------------------------------------------
----------------------------------------------------------------
----------------------------------------------------------------
----------------------------------------------------------------

4. I would be happy to recommend using a mobile solution(if available) to monitor and manage blood sugar levels to all my patients who had GDM?

Y/N (please circle)

Why? (please explain)

----------------------------------------------------------------
----------------------------------------------------------------
----------------------------------------------------------------
----------------------------------------------------------------

5. Any other comments:(please list)

----------------------------------------------------------------
----------------------------------------------------------------
----------------------------------------------------------------
----------------------------------------------------------------

Many thanks for participating in our study – have a good day!
APPENDIX 1C

Interview Protocol Clinician

Questions about the trial:

1. Please describe your experience with the technology and standard care arms in the study. What were the key differences, which did you prefer and why? Would you continue to use the solution?

Questions about the technology:

2. Would you recommend this solution to your patients and why?

3. Would you be supportive of your patient using a technology solution you did not recommend why/why not? And if you did not recommend a technology solution do you think your patients would still want to use it why/why not?

4. What are the aspects of a technology solution that must be present vs nice to have vs you don’t care for you to recommend the solution to your patients?

Questions about value-based care

5. When you treat patients do you think about access, quality and value issues – please elaborate on how this comes into your thinking?

6. If a solution supports value based care would you recommend its use to your patients?

Questions about data analytics

7. What types of data would you like to see and how would this help your decision making?

8. Do you think having the data described above would help achieve better treatment results/care and/or would help with population health aspects with regards to GDM? How/Why?