Design and Evaluation of an Ecosystem of Existing Mobile Wellness Apps for Supporting Treatment of Gestational Diabetes Mellitus

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Acronyms

AMIA	American Medical Informatics Association
ANSI	American National Standards Institute
API	Application Programming Interface
BG	Blood Glucose
CCD	Continuity of Care Document
CDA	Clinical Document Architecture
CCR	Continuity of Care Record
CSV	Comma Separated Values
DSRM	Design Science Research Methodology
DSTU	Draft Standard for Trial Use
EHR	Electronic Health Record
FD	Food Diary
FDA	US Food and Drug Administration
FHIR	Fast Health Interoperable Resource
HIS	Health Information System
HL7	Health Level 7
HTML	Hyper Text Markup Language
JMIR	Journal of Medical Internet Research
GDM	Gestational Diabetes Mellitus
GI	Glycaemic Index
GL	Glycaemic Load
LOINC	Logical Observation Identifiers Names and Codes
OSI	Open System Interconnection

PDF	Portable Document Format
PEOU	Perceived Ease of Use
PHR	Personal Health Record
PU	Perceived Usefulness
RIM	Reference Information Model
SNOMED CT	Systematised Nomenclature of Medicine Clinical Terms
SDK	Software Development Kit
STU	Standard for Trial Use
TAM	Technology Acceptance Model
TAP	Think Aloud Protocol
XML	eXtensible Markup Language
UCD	User-centred Design
WHO	World Health Organisation

Glossary

API: A software component that allows data values to be shared between two different systems.

CCD: An electronic document coded in XML to exchange patient health data between EHR systems.

CDA: A standard based on XML and HL7 to define a structure for medical records.

CCR: A standard based on XML to represent patient summary data.

EHR: A system for the electronic storage of patient data that allows access to authorised users in a clinical environment.

HIS: A system used to electronically store patient data and all related functionalities in a medical or hospital setting.

HL7: An ANSI accredited not-for-profit organisation that develops standards for the exchange of patient health data.

FHIR: An emerging new standard to exchange health data.

LOINC: A list of codes to identify different medical tests generally conducted in a laboratory.

PHR: A software application designed for patients to manage and access their health data in a secure way.

SNOMED CT: A list of clinical terminologies used by clinicians and health care systems to identify different diseases.

SDK: A set of software development tools used for the creation of new software applications.

Declaration

"I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning."

Signed by: Sarita Pais

Date: 11/12/2017

Abstract

The increase in Gestational Diabetes Mellitus (GDM) in New Zealand especially in the Auckland region has increased the workload on clinicians. However GDM for a large part can be self-managed. This requires healthy lifestyle interventions like diet and exercise. Mobile wellness apps have potential as a dietary assessment tool. At present, most mobile apps have the potential to share their data. While patients are free to use a mobile app of their choice, data from such heterogeneous sources cannot be stored in one single database system available to clinicians. The aim of the proposed body of work is to develop a wellness data integration prototype to store such data from heterogeneous sources (apps) which can be useful to clinicians.

The main research question is to determine whether a diverse "constellation" of apps can be used together to add value and robustness in a real clinical application area. An ecosystem was built to integrate data from various mobile wellness apps to a developed prototype. Data from various mobile wellness apps was self-collected data that is normally not shared with clinicians. If shared with clinicians through email, the data is isolated and not stored long term for further analysis. Most of this data is non-clinical and has no provision to be stored in existing Health Information Systems. The only possibility is to save these as clinician comments. The text-based comments are not easy for writing any query on them and generating reports.

The current body of work involved investigating the nature of clinical and non-clinical data required for GDM. Standard medical terminologies were of interest to code clinical data. Non-clinical wellness data such as food and exercise, were resolved through data interoperability solutions by mapping data from source to a global schema for all types of data. Blood glucose readings and diet with required nutrition and carbohydrate intake were part of the data captured from wellness apps. The target schema was capable of capturing data from various mobile wellness apps. Design science research methodology shaped the research process of building an artefact for setting up an ecosystem with participating mobile wellness apps data. User-centred design principles guided the design of the wellness data integration prototype built in iterations as part of the ecosystem. Interviews and Think Aloud protocol sessions with clinicians in the early and final stages of the prototype provided necessary feedback to design considerations.

The results demonstrated the perceived usefulness and perceived ease of use of the prototype (artefact) in building an ecosystem of consumer mobile wellness apps. Usability issues were resolved through Think Aloud protocol sessions. The artefact demonstrated the proof of concept and its acceptability in a clinical context. The use of open source software and tools demonstrated the ability of the prototype to store wellness data in clinical systems using health terminologies and health information exchange standards. The criteria for selecting mobile wellness apps for the ecosystem guided the building of a framework for the evaluation of these apps.

1 Introduction

The current body of work investigates the design and evaluation of a data integration prototype as part of an ecosystem of existing mobile wellness apps for the self-management of GDM. Wellness data from various mobile wellness apps was integrated in the prototype. Interoperability was a major issue which was resolved at data and semantic level. Wellness data from the prototype was able to be expressed as a health information exchange standard for further integration into a clinical system if required.

Clinicians working at the Auckland Diabetes Centre participated in the design and evaluation of the prototype. Interviews at various stages of the design paved the way for building a robust system. The selection of mobile wellness apps suitable for the self-management of GDM was undertaken in consultation with the clinicians. Usability issues of presenting the data for clinical consultations were of prime interest to clinicians which lead to acceptance of the ecosystem.

1.1 Rationale and Significance of the Study

Obesity and lifestyle related diseases are a significant problem globally and are of growing concern in New Zealand. According to the National Women's Annual Clinical Report from 2013[1] when this research project was first initiated, data relating to diabetes in women at National Women's showed an increase of 8% over the last two decades between 1991 and 2013. Reports from recent years[2] have shown an increase in GDM cases. In New Zealand, people of Indo-Asian, Maori (Chamberlain et al., 2013) and Pacific ethnicities are at increased risk of developing diabetes when compared with people of European ethnicity. A similar trend is observed in National Women's annual reports. Women of Asian ethnicity (including West, East, Central, South East and South Asia) had a higher risk of GDM when compared to women born in New Zealand or Australia (McDonald, Karahalios, Le, & Said, 2015). Ten percent of women giving birth at National Women's Health (NWH) had GDM, which substantially increased the workload on clinicians involved in their care.

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[1] http://nationalwomenshealth.adhb.govt.nz/Portals/0/Annual%20Reports/ACR_Master_Appendix__1to12_2013_LYNN%20AUGUST%201%20plus%20MP.pdf

[2] http://nationalwomenshealth.adhb.govt.nz/health-professionals/annual-clinical-report/yearly-annual-clinical-reports

Increasingly, there is a focus on personal action to improve one's own health using a partnership model with clinical staff and others to share information and encourage action. The introduction in 2014 of the patient-controlled electronic health record[3] is a reflection of this trend. A shared care plan is proposed where patient's wellness data such as immunisation is shared with the patient. It is also desirable that the patient shares wellness data with their health professionals.

The onset of GDM for women during pregnancy requires healthy lifestyle interventions (diet and exercise) and often treatment with metformin and/or insulin to reduce the risk of adverse pregnancy outcomes. Various organisations have promoted awareness of the disease through websites, telemedicine and of late, through mobile apps to provide appropriate and timely information about diet and exercise.

For women with GDM, there are several mobile wellness apps available to help manage diet and exercise. However, not many have been validated for quality. As of 2011, the US Food and Drug Administration (FDA) has introduced draft guidelines for medical apps. Apps such as WellDoc, Glooko and IBGStar have been given FDA clearance (Eng & Lee, 2013). My Meal Mate (MMM) (Carter, Burley, Nykjaer, & Cade, 2013) developed by Nutritional Epidemiology Group at the University of Leeds, UK has been clinically trialled and proven to have potential as a dietary assessment tool. Apps such as MMM can aid self-management of GDM by monitoring diet and exercise. Årsand, Tatara, Østengen, and Hartvigsen (2010) presented a mobile app to self-manage Type 2 diabetes mellitus. The app was developed to automate most of the process of self-management. It could record blood glucose (BG) readings by using sensor systems, a step counter for physical activities and used less time and effort for recording food and nutrition than manually feeding data. There are many apps which are suitable for self-management of GDM such as SiDiary, onTrack Diabetes, dbees, Happy Pregnancy Ticker. These apps could fall into different categories like health management, education, nutritional references and exercise.

1.2 Research Aim and Objectives

Current devices are not integrated to provide information about BG levels and the diet of women to their 'diabetes in pregnancy' team members. Many apps do not readily export the data or have the ability to export data to multiple stakeholders (J. Shah et al.,

[3] https://www.health.govt.nz/system/files/documents/publications/national-health-it-plan-update-2013-14-nov13.pdf

2010). Therefore when women interact with the team, much of the information has to be re-documented by the clinicians in order to assess whether to modify management plans and decide whether to recommend medication in addition to lifestyle management. It would be of clinical value for women with GDM and their carers, to be able to export these data in a meaningful way.

The approach of this research study was to develop data requirements for data extracted from various wellness apps suitable for the self-management of GDM in partnership with clinicians. Women with GDM are routinely asked to maintain a paper food diary (FD) and record BG readings. They are also asked to keep an eye out for any rapid weight gain. Carbohydrate intake is monitored to manage BG and weight gain. Clinicians and dieticians recommend changes in diet based on these food diaries and BG readings. With the explosion of mobile apps available, people can now choose from a range of mobile apps available on various platforms which are either free or cost only a few dollars to download. Some mobile apps in the US, like WellDoc Diabetes Manager, are now recommended by employers and health providers (Eng & Lee, 2013). If women with GDM choose to use one of these mobile wellness apps then suitable data extracted from these apps should be in a format required by clinicians.

Data collected should be useful for the self-management of GDM and effectively and efficiently help clinicians and dieticians with GDM consultation. Mobile wellness apps are capable of sharing data with clinicians.

GDM can for a large part be self-managed to reduce the risk for a woman and her unborn baby. Chapter 2, Section 2.1, covers the general requirements for managing GDM and the clinical consultations that take place to identify and manage the condition. The various tests and dietary recommendations are partly captured in the Health Information Systems (HIS) of the hospital or clinic. However patient managed health and wellness data has limited options for being stored in the clinical system. Hence, the ecosystem of integrating data from mobile wellness apps has potential for improving communication and consultations between clinicians and patients.

While clinical data from the lab report is maintained in the HIS, data from wellness apps and glucose meters will complement existing data for improved support from clinicians and better self-management. The current body of work focuses on what data needs to be recorded for the self-management of GDM and the data organisation in various formats is explored. Data interoperability is the key criteria when dealing with

data from heterogeneous sources.

Women with GDM will have to diary their food intake alongside monitoring BG. A wellness app which can keep a record of food consumed, could therefore be beneficial to women with GDM. There are also other dietary restrictions on the consumption of raw or smoked meat, as well as certain types of fish which may contain heavy metals, such as mercury or harbour listeria. Mobile apps with easily understood food safety and nutrition information will reduce a dietician's consultation time.

The practice of keeping a FD and recording BG readings is varied among women. Some keep an electronic version of their diet and BG readings, while others keep a manual paper based record. It is of clinical value to share these data electronically.

There are three key research questions:

- How can data from various mobile wellness apps be combined to help and support lifestyle change and clinical decision making in the management of GDM?
- How can this combination be supported and built based on semantic interoperability using lexical database and/or ontologies like health standards, food and nutrition?
- Are clinicians and women with GDM ready to use such approaches?

The wellness data integration prototype developed as part of the ecosystem allowed data from various mobile apps to record FD and exercise as part of the self-management of GDM. Mobile wellness apps were suitably selected in consultation with clinicians. The apps had to have the option to share data from the mobile device with clinicians in a format acceptable to the prototype. Files which were shared as PDF were not acceptable as they were not easily available to save in the prototype database. Files which were shared as Comma Separated Values (CSV), Hyper Text Markup Language (HTML), eXtensible Markup Language (XML) were acceptable.

The design of the prototype was influenced by the research methodology discussed below.

1.3 Research Methodology

Design Science Research Methodology (DSRM) was the main research methodology adopted in this body of work. A User-centred Design (UCD) approach was utilised

within the DSRM to build a prototype as a proof of concept for demonstrating the ecosystem of existing mobile apps. DSRM emphasises the design and evaluation of the artefact (prototype in this case). The design was guided by the principles of UCD. The evaluation was qualitative in nature and various methods, such as interviews and Think Aloud (TA) protocols were utilised. Qualitative analysis of identifying themes in the interview transcripts acknowledged the perceived ease of use (PEOU) and perceived usefulness (PU) of the ecosystem. TA protocols demonstrated the practical issues of the ecosystem and as such, usability issues were highlighted and rectified through the iterative process of developing the prototype as part of the ecosystem.

1.4 Related Publications

The following conference papers and journal articles were published during the course of my research study towards a doctoral degree.

Pais, S. (2015). Preparing Students for Agile Projects and Requirements Engineering Prioritisation Techniques. Proceedings of the CITRENZ Conference.

Requirements prioritisation techniques described theoretically are in practice difficult to implement in agile software development projects when requirements from different stakeholders change during the course of software development. The paper highlights some of the techniques applied through pracical experience. This background knowledge helped to prioritise the user requirements in Chapter 5.

Pais, S., Parry, D., & Huang, Y. (2017). Suitability of Fast Healthcare Interoperability Resources (FHIR) for Wellness Data Symposium conducted at the meeting of the Proceedings of the 50th Hawaii International Conference on System Sciences.

Patient generated wellness data is not stored in clinical systems because of a lack of functionality to do so. An emerging new health exchange standard has potential to extend its resources to maintain such wellness data. Extracts of this paper are discussed in extending the ecosystem in Chapter 9, Section 9.5.

Pais, S., Parry, D., Rowan, J. A., & Petrova, K. (2017). Acceptance of using an Ecosystem of Mobile Apps for use in Diabetes Clinic for Self-Management of GDM. *Proceedings of 16th World Congress on Medical and Health Informatics, MedInfo, China*.

This paper illustrated the prototype design and evaluation of an ecosystem. The ecosystem integrated the data from existing mobile wellness apps and proved its perceived usefulness and perceived ease of use for clinicians and women with GDM at a diabetes clinic. The results of this paper are discussed and analysed in Chapter 7.

Pais, S., Parry, D., & Rowan, J. (2017). A framework of evaluation of mobile wellness apps for use in a clinical setting, IEEE. Symposium conducted at the meeting of the IEEE Region 10 Symposium (TENSYMP).

Consumers have abundant choice of mobile wellness apps to monitor their health and well-being. Clinicians are unable to guide their patients as to the appropriate app. Hence a framework of guidelines would help clinicians in recommending the most appropriate wellness app. The framework presented in this paper is discussed in Chapter 9, Section 9.4.

Pais, S., Parry, D., Rush, E., & Rowan, J. (2016). Data integration for mobile wellness apps to support treatment of GDMACM. Symposium conducted at the meeting of the Proceedings of the Australasian Computer Science Week Multiconference.

Wellness data from mobile apps have potential to integrate in a clinical system useful for the self-mangement of GDM. The wellness data should be semantically represented and also be able to integrate with other clinical systems using appropriate standards. A proof-of-concept prototype was presented in this paper and is discussed in Chapter 6.

Pais, S., Talbot, A., & Connor, A. (2009). Bridging the research-practice gap in requirements engineering. *Journal of Applied Computing and Information Technology, 7*(1).

This paper focused on the perceived research-practice gap related to requirements engineering. The issues and solutions for these gaps were identified and discussed. This background knowledge helped to prioritise the user requirements in Chapter 5.

Pais, S., & Xu, X. (2016). Wellness data sharing from personal health record (PHR) to electronic health record (EHR). Special Issue - SACAIM International Journal of Latest Trends in Engineering and Technology, 106-114.

A proof-of-concept protoype was built to integrate wellness data using an open source EHR system. Wellness data from the PHR system was able to be integrated in the prototype. Existing standards based on XML were applied in the prototype. This concept of extending the ecosystem is discussed in Chapter 9, Section 9.5.

1.5 Thesis Structure

The current body of work is organised in chapters to address the research objectives and questions. The process of designing and evaluating an ecosystem of mobile wellness apps for supporting the self-management of GDM has components from health informatics and information systems domains.

Chapter 1 sets the scene with the research aim and objectives. Research methodology

and the mixed methods used in the design and evaluation of the artefact (ecosystem comprising the prototype developed) are briefly explained.

Chapter 2 discusses the self-management of GDM through food, diet and exercise. The importance of a patient centred approach in clinical consultations is crucial as each individual is different in dealing with their health conditions. Limited patient information about wellness is maintained in different systems such as Electronic Health Record (EHR) and Personal Health Record (PHR). With the advent of patient managed wellness data from mobile apps and other devices, a data driven patient centred approach is of interest in the current body of work.

Chapter 3 discusses the literature on interoperability, as it has been an issue for integrating data from various heterogeneous sources. Semantic schema mapping is discussed in the literature review and various solutions through ontologies and lexical databases are highlighted. Clinical data from EHR systems have similar interoperability issues when integrating with other systems. Various clinical terminologies and data exchange standards have evolved which are of interest when building the prototype as part of the current body of work. The literature on designing systems using UCD principles and evaluating it in the light of the Technology Acceptance Model (TAM) are discussed for related health information systems.

Chapter 4 introduces the research methodology as DSRM, which is used to find innovative solutions to an existing problem in the organisation. The Diabetes Clinic had not been efficient in handling patient managed wellness data related to the self-management of GDM. The sharing of patients' wellness data when saved outside the clinical system was not easily available to other clinicians in the team. The ecosystem built as an artefact (prototype) demonstrated the process of designing and evaluating it. Methods such as interviews and TA used in the iterative design and evaluation are discussed.

Chapter 5 analyses user requirements as part of building the prototype. Each requirement is numbered and prioritised based on the how often it was specified. The stakeholder consultation document and its components for clinician review are elaborated on. User requirements, identification of suitable mobile apps, wellness data and user interfaces of the prototype are discussed.

Chapter 6 presents a detailed version of the prototype design with the inclusion of

relevant mobile apps for FD and exercise logging. The mapping of source data to the prototype database schema is also investigated. The design as a first iteration using UCD principles, is labelled Prototype Version 1.

Chapter 7 considers the evaluation of Prototype Version 1 in terms of perceived usefulness, perceived ease of use and intention to use the prototype. Inductive themes emerged from the set of interviews. The feedback on prototype design was valuable to improve it in the next iteration as Prototype Version 2.

Chapter 8 discusses the TA protocol on Prototype Version 1. Various inductive themes on deductive themes of usability emerged from these sessions. The feedback was useful to improve the design in the Prototype Version 2.

Chapter 9 discusses the design of Prototype Version 2 considering feedback from the evaluation of Prototype Version 1. The prototype is also extended to include additional mobile wellness apps satisfying the various criteria required for the self-management of GDM. The criteria for the selection of mobile wellness apps is formalised which will allow the prototype to include other mobile apps. Integration of wellness data from the prototype to other clinical systems is also investigated. Clinical terminologies are considered to improve semantic meaning of the data. The use of health exchange data standards are also adopted for possible integration with EHR systems.

Chapter 10 discusses the evaluation of Prototype Version 2. With additional functionalities added on to the prototype, clinicians evaluated the perceived usefulness and perceived ease of use of the prototype. Minor new usability issues arose which were remedied. Patient perceptions are also revealed by women with GDM who were participating in the TA protocol sessions.

Chapter 11 discusses the research process undertaken to answer the research questions. The research contributions are discussed which add new knowledge in building an ecosystem of mobile apps. As the prototype is a proof of concept, its limitations are discussed with insights into the future of such ecosystems.

2 Gestational Diabetes Mellitus (GDM) Self-management Background

A literature review was undertaken in order to understand the context of building an ecosystem by integrating data from various mobile wellness apps for the self-management of GDM and to share with clinicians. In order to understand the background of GDM and its self-management, literature around the self-management of GDM with and without the aid of technology was reviewed. It covered clinical literature around management of diet and exercise to manage BG levels and improve pregnancy outcomes as in Section 2.1. Clinical and patient managed wellness data is maintained in various clinical and non-clinical systems and an understanding of this was required to build the proposed ecosystem as detailed in Section 2.4 – 2.5. A patient-centred approach using patient generated wellness data is covered in Section 2.2. Technology has potential to facilitate the consultations. Technology such as mHealth has been used in clinical trials to achieve better health outcomes as highlighted in Section 2.6 and the potential of mobile apps in the consultation process has not yet been realised.

2.1 GDM

The World Health Organisation (WHO) in its review published in 1999[4] defined GDM as "carbohydrate intolerance resulting in hyperglycaemia of variable severity with onset or first recognition during pregnancy". GDM affects between 5% to 10% of pregnant women depending upon the population and ethnic groups studied (Kim et al., 2010). GDM risk is higher in certain ethnic groups. Scholarly information from the American Diabetes Association (2014) and studies (Teh et al., 2011) have shown that GDM risk increases with age, obesity, previous pregnancy/ies and family history.

GDM for a large part can be self-managed to reduce the risk for the woman and her unborn baby. Section 2.1.1 covers the screening test used for GDM, general requirements for self-managing GDM and clinical trials undertaken for various studies related to the self-management of GDM and pregnancy outcomes.

2.1.1 GDM and Associated Tests

Pregnant women are generally screened for GDM between 20 and 28 weeks of gestation by a 50g non-fasting one hour glucose test (Serlin & Lash, 2009). Women with risk

[4] http://apps.who.int/iris/bitstream/10665/66040/1/WHO_NCD_NCS_99.2.pdf

factors for possible unrecognised Type 2 Diabetes Mellitus (T2DM) are screened earlier. Once diagnosed with GDM, fasting and two-hour postprandial glucose levels are required as part of the self-management programme. Maintaining BG levels to the New Zealand standard is associated with better pregnancy outcomes (Rowan, Gao, Hague, & McIntyre, 2010). The average fasting BG level should be < 5.0 mmol/l and the average two hour postprandial levels should be < 6.0 - 6.5 mmol/l. Some of the risks associated with high BG concentrations are macrosomia, caesarean delivery, shoulder dystocia, birth trauma, neonatal metabolic problems, perinatal mortality, hypertension/preeclampsia (Hollander, Paarlberg, & Huisjes, 2007). The Australian Carbohydrate Intolerance Study (ACHOIS) (Crowther et al., 2005) and Maternal Foetal Medicine Unit (MFMU) (Landon, 2010) trials show treatment of even mild GDM improves pregnancy outcomes.

2.1.2 GDM Self-management

The self-management of GDM includes managing diet, BG, nutrition and exercise. It has been clinically trialled in many studies (Crowther et al., 2005; Landon, 2010) to determine whether self-management achieved a better pregnancy outcome. Figure 2.1 describes overall requirements for the proposed GDM self-management programme with inputs from literature as defined in Sections 2.1.3 through 2.1.6. Women with GDM have higher pregnancy risks; diet, nutrition and exercise are important to control foetal weight and manage other pregnancy outcomes. A mobile wellness app can assist in the management of diet, BG, insulin, weight and exercise. Clinical data such as laboratory reports and pregnancy outcomes maintained in the HIS are currently beyond the scope of this research project.

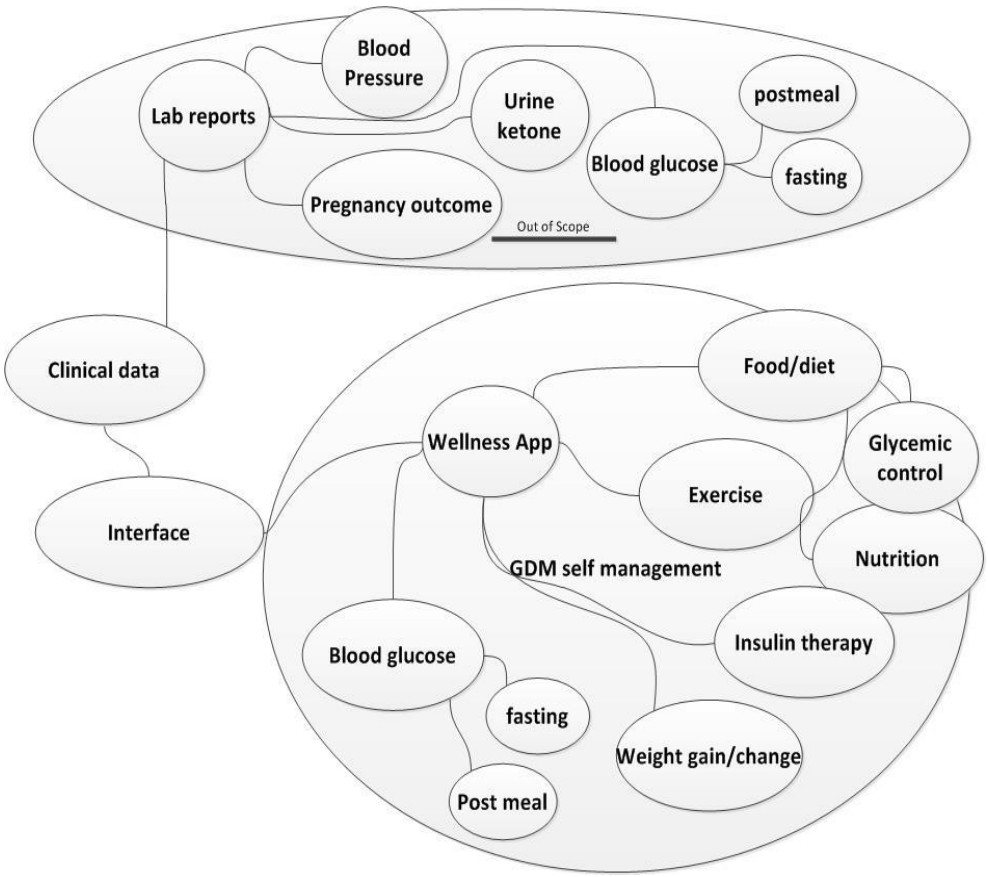

Figure 2.1: GDM Self-management Conceptual Model

2.1.3 Food and Diet

Pregnant women are required to maintain a balanced diet. Nutrition guidelines by the Ministry of Health in New Zealand[5] have a recommended list of nutrient requirements. Food and nutrition guidelines for healthy pregnant and breastfeeding women are also detailed[6,7]. Pregnant women have a higher need for calcium and iron. There are no specific recommendations for carbohydrates (CHO); however the American Diabetes Association guidelines recommend a minimum of 175g CHO/day. There are recommendations about consuming low glycaemic index (GI) carbohydrates, adequate protein and limiting saturated fat intake.

[5] http://www.health.govt.nz/our-work/preventative-health-wellness/nutrition/food-and-nutrition-guidelines

[6] https://www.health.govt.nz/system/files/documents/publications/food-and-nutrition-guidelines-preg-and-bfeed.pdf

[7] http://www.health.govt.nz/publication/food-and-nutrition-guidelines-healthy-pregnant-and-breastfeeding-women-background-paper

2.1.4 Carbohydrate Consumption

Carbohydrates are converted to glucose and enter the blood stream. Different types of carbohydrates affect a post-consumption rise in BG at different times. For example whole grain (brown) bread vs refined (white) bread. Carbohydrate counting has been a dietary control method for Type 1 and Type 2 diabetes and is useful to educate women with GDM to consume appropriate amounts of carbohydrates. It is used to help calculate the insulin dosage in women with Type 1 diabetes. Some women with GDM find carbohydrate counting a useful tool to manage their insulin dosage (Gillespie, D Kulkarni, & Daly, 1998). Sufficient amounts of carbohydrates should be consumed to avoid ketosis. Pregnant women should be able to calculate nutrition count for each food item consumed by referring to the nutrition label or a reference book. Suitable mobile apps such as FoodSwitch[8] which has a New Zealand relevant food database are beneficial to identify healthy food. Such apps are designed to scan the barcode of the food label and display the nutrition value to interpret their acceptability in the form of 'traffic lights' (Whittaker et al., 2013). Currently only limited food nutrients are profiled such as fat, saturated fat, sugar, salt and energy. These nutrients are easy to monitor for the common man (people in general) with limited knowledge about food and nutrients. Carbohydrates are excluded in the app. Carbohydrate counting is not easy and people need to understand how to calculate it. Type 1 diabetes patients are taught this skill to manage their lifetime chronic disease. Details of cooked food need to be manually entered in the app, while a few apps have the nutrients and calories of such food in their food database.

Carbohydrate factor

Carbohydrate factor is the proportion of food by weight that is carbohydrate.

Carbohydrate factor = carbohydrates per 100g / 100

For example in boiled rice total carbohydrates per 100g = 28g

Carbohydrate factor = 28/100 = .28

To calculate how much carbohydrate is consumed in a meal of rice, weigh the boiled rice. Multiply the weight of boiled rice by the carbohydrate factor.

Example: 200g of boiled rice x 0.28 = 56g of carbohydrate.

[8] http://www.foodswitch.co.nz/

Glycaemic Index (GI)

Glycaemic Index (GI) is the rate at which carbohydrates are converted into BG. Food with low GI will convert carbohydrates to glucose more gradually and result in a low postprandial BG concentration.

2.1.5 GDM and Diet Studies

C. Zhang, Liu, Solomon, and Hu (2006) found low cereal fibre and high Glycaemic Load (GL) could increase GDM risk. Further Moses, Barker, Winter, Petocz, and Brand-Miller (2009) recommended a low GI for women managing GDM to reduce the need for insulin. Saldana, Siega-Riz, and Adair (2004) found an association between increased carbohydrates and decreased fat intake to suit the energy levels reduced the risk of GDM. On the other hand increased intake of polyunsaturated fats (Wang et al., 2000) reduced the risk of GDM. Other studies (Radesky et al., 2008) concluded that diet made no significant difference in GDM or Impaired Glucose Tolerance (IGT) risk.

In a study (Grant, Wolever, O'Connor, Nisenbaum, & Josse, 2011) a low GI enabled control of postprandial glucose levels. Although low GI is recommended, there have been no large scale intervention trials done to confirm the benefits of low GI on pregnancy outcomes (Louie et al., 2011). A more recent study by Markovic et al. (2016) had 72 women on low GI and 67 on a healthy diet. It was found that the low GI diet and healthy diet had similar pregnancy outcomes. More trials are required to confirm the importance of low GI. Until such time, low GI will not affect current recommendations from government and health agencies.

There is limited literature available on clinical trials using mobile apps for GDM and diet studies. Although there is literature on the use of technology such as telephone, text messaging, video and internet to support diet and lifestyle for a healthy pregnancy (O'brien, McCarthy, Gibney, & McAuliffe, 2014) the use of smart phone apps is still not known widely. O'brien et al. (2014) reported clinical trials are underway to manage body weight and enhance exercise using mobile apps for pregnant women.

2.1.6 Exercise

Moderate exercise is recommended as part of an active life during pregnancy. There are many studies on the relationship between exercise and GDM.

Tobias, Zhang, Van Dam, Bowers, and Hu (2011) surveyed articles from literature to study the effect of exercise on glucose intolerance. Eight articles were selected and analysed. The meta-analysis indicated a 55% lower risk of GDM for women who

involved themselves in physical exercise before and during pregnancy. Research studies involving clinical trials (Artal, Catanzaro, Gavard, Mostello, & Friganza, 2007; Barakat, Cordero, Coteron, Luaces, & Montejo, 2012) have shown significant improvement in pregnancy outcomes for an intervened group (diet and/or exercise) when compared to a control group.

After reviewing the literature on diet and exercise related to GDM clinical trials, there is evidence of the importance of diet and exercise in the self-management of GDM. Regular communication with clinicians is required to help women with GDM in their self-management programme. A patient-centred approach can improve the overall experience of clinical consultations.

2.2 Patient Centred Consultations

In a 'patient centred' approach clinicians enhance the diagnosis and treatment process with information received from the patient (Levenstein, McCracken, McWhinney, Stewart, & Brown, 1986). The consultation closely works through each patient's problem and involves mutual discussions for treatment rather than focusing on the illness in general (Little et al., 2001). Clinicians caring for women with GDM have a 'patient centred' approach with improved communication and partnership between them.

With technological innovation the 'patient centred' approach can take the next step in enhancing the patient-clinician relationship. In a study of the Swedish quality register for arthritis (Ovretveit et al., 2013), some clinics had allowed patients to enter their self-assessment data through a web interface. The clinic then arranged follow-up specialist or regular appointments depending on the patient's health data. Demiris et al. (2008) has discussed various factors such as design, secured data transmission, evaluation and usability to be considered with the use of technology to aid a 'patient centred' approach.

The increased use of mobile devices is eliminating the need for a user to link to a physically operating network. mHealth applications have been discussed in the management of chronic diseases such as diabetes. There are challenges in ensuring that valid data is entered by patients in order to be accepted in the clinician system. Nevertheless, it empowers patients in understanding their condition and managing it. The benefits of sharing patient data with clinical systems for improved communications and better outcomes has not been fully investigated (Holmen, Wahl, Småstuen, & Ribu,

2017). Patient data privacy and security concerns have been discussed in various articles (Chiauzzi, Rodarte, & DasMahapatra, 2015). Generally consumers are willing to share their data for research (population health) however want it to be anonymised. As the current research is about sharing patient data with their clinicians, the design of the new system, technology and data standards are given importance. Privacy issues are not handled in the current body of work.

Patient centred consultations depend on data sourced by patients about their health and wellness. It is important to understand how clinical data is organised in various systems at primary and secondary care.

2.3 Data Driven Patient Centred Care / Digital Health

Data driven patient centred care has been a topic of interest in the American Medical Informatics Association (AMIA) related meetings (8th Annual AMIA Health Policy Invitational Meeting 2013)[9]. Health informatics solutions and tools are sought to integrate health related data from the clinic to the homes of the patients. EHR systems are not designed to engage patients (Flatley Patti et al., 2014) in a patient centred approach. Patients could contribute to their health data through home-based monitoring devices, sensor technologies and self-reporting. PHR systems such as Microsoft Health and now defunct Google Health platform have not been successful in building an ecosystem. Data interoperability is an underlying issue when mobile apps from different platforms need to communicate. Mobile devices have the potential to access PHRs and other mobile wellness apps and wearable devices to integrate them in an ecosystem.

A framework to develop and implement a patient centred record through a proof-of-concept prototype was proposed by Puentes, Roux, Montagner, and Lecornu (2012). The user requirements for the prototype were realised through field studies conducted at three medical hospitals and two technical units. Clinicians such as specialists, nurses, clerical staff and patients were interviewed. The clinicians provided guidance about the current hospital system workflows to design a potential patient centred prototype which could access inputs on patient health data. Domain specific data models were identified for the prototype. The prototype had data from hospital systems integrated into the data models designed. Patient generated health and wellness data about post-treatment and self-management were part of the data model. The data model also had data entities

[9] https://www.amia.org/meetings-and-events/2013-annual-health-policy-invitational-meeting

from hospital systems such as current treatment, start and end dates and details of the treatment and/or surgical procedure. Similar commercial projects are currently being developed in New Zealand (ManageMyHealth[10], Orion Health Patient Portal[11]) and other countries to extract patient data from hospital systems in a patient portal. However these patient portals still lack the ability to accept data entry from patients about their self-management of chronic diseases.

Ackerman, Filart, Burgess, Lee, and Poropatich (2010) discussed the data perspective of acquiring patient data from various sources into the EHR systems. Major barriers are the lack of technology integration, standardisation and interoperability. Adoption is hampered by cultural and behavioural issues in changing to new technologies. However, more progress has been made in the last couple of years to integrate data in an open platform.

Patient health data has been captured in clinical systems at primary and secondary health care settings. EHR is a terminology used mostly for this purpose which is discussed further in Section 2.4. The characteristics of such systems will give better insights into integrating patient-centred data for clinical consultations.

2.4 Electronic Health Record (EHR)

Electronic health information stored as EHR is defined by ISO/DTR20514 as "A repository of information regarding the health of a subject of care in computer processable form, stored and transmitted securely and accessible by multiple authorised users".

EHR captures patient data such as demographics, past medical history, medications and laboratory test results primarily stored in hospital or medical centres. EHR supports evidence based decision making. EHR contains data which is clinical and administrative in nature. Non-clinical data comprises of demographics and other data for billing and insurance. All clinical data is maintained using standards such as Systematised Nomenclature of Medicine Clinical Terms (SNOMED CT), Logical Observation Identifiers Names and Codes (LOINC) as discussed in Chapter 3 Section 3.4.

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[10] http://www.managemyhealth.co.nz/

[11] https://www.orionhealth.com/nz/options/patient-portal

As hospitals and medical centres have proprietary clinical systems, access to them was not possible as part of the current research study. Hence literature on a range of currently available open source EHRs and PHRs were studied to gain understanding of the type of clinical and related data stored in these systems. The basic functionalities and data schema of these systems helped to build the wellness data integration prototype and the possible exchange of health data from the prototype into EHRs and PHRs.

There are many open source software available for EHR systems. Many vendors and health providers have adopted open source software such as openEHR[12], Tolven[13], openEMR[14], openMRS[15], iTrust[16]. Helms and Williams (2011) evaluated four open source EHR systems based on the statutory criteria prescribed by the Health Insurance Portability and Accountability Act 1996 (USA) (HIPAA) and meaningful use required by National Institute for Standards and Technology (NIST). All four EHR systems namely Tolven, iTrust, opemMRS and openEMR had most of the access controls defined for different users of the EHR system based on HIPAA regulation, Meaningful Use as defined by the NIST[17] and Certification Commission for Health Information Technology (CCHIT) [18]. However all four EHR systems failed in patient emergency handling as there was no access control defined in these systems in case of emergency.

Clinical, health and wellness data is also stored in patient portals. The characteristics of patient portals and the relevant data stored in these portals will be useful in bridging the gap in clinical consultations. Patient portals promote a patient-centred approach which is useful in consultation and treatment of chronic diseases and other health issues which require continued monitoring of vital symptoms.

2.5 Personal Health Record (PHR)

A system for storing and maintaining one's own health data is called PHR. It differs from EHR where data is maintained by medical centres or hospitals. PHR can manage wellness and illness data for a patient. The characteristics and functionalities of PHR were reviewed through the literature.

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[12] http://www.openehr.org/
[13] http://home.tolven.org/
[14] http://www.open-emr.org/
[15] http://openmrs.org/
[16] http://sourceforge.net/projects/itrust/
[17] https://www.nist.gov/
[18] https://www.cchit.org/

The main functionality of PHR (Detmer, Bloomrosen, Raymond, & Tang, 2008) is to store data such as medical history, immunizations, medical and emergency contacts, outpatient and hospital visits, medical alerts, reminders and insurance details.

PHR are referred to by different terms in different countries and organisations. Steele, Min, and Lo (2012) categorised PHRs in various ways like standalone, web, hybrid, cloud based, mobile based, USB or smart card PHR. Web, cloud based and hybrid store data in a central location with the ability to share data with other stakeholders. This could also safeguard against loss of data in the event of system failure.

A tethered PHR is a personally controlled portal connecting to the EHR system. Some examples of such tethered PHRs are Dossia, My Health Vet and MyGroupHealth. A PHR could also be a standalone system. However some health providers in the USA have integrated PHR systems such as Microsoft Heath Vault with the HIS. PHR is sometimes called Personally Controlled Electronic Health Record (PCEHR) as in Australia which deployed this system nationally in 2012. The Clinical Document Architecture (CDA) standard was used in the development of PCEHR with the local extension using health information exchange standards such as Health Level 7 (HL7).

The PHR recommended by primary health providers allows patients to view their medical records as most of them are tethered to EHR systems. PHR systems can allow patients to maintain their wellness data however a tethered PHR may not allow this as the patient may not be accurate when feeding in their health data and ignorant of the correct medical terminology. PHR developed by independent vendors may not be linked to the medical centre. PHR systems such as Microsoft HealthVault have partnered with other mobile wellness apps and devices to extract data from BG meters and weight scales. This allows individuals to track and manage their health and fitness goals.

2.5.1 Adoptions of PHRs

The adoption of PHRs is still limited and depends on various factors. Archer, Fevrier-Thomas, Lokker, McKibbon, and Straus (2011) reviewed various research articles considering factors such as usability, functionality, support and their integration with a patient's HIS or EHR. Patients with chronic diseases are more motivated to use PHRs.

One of the drawbacks of patient controlled PHR is the manual data entry which may not be accurate or complete. Non web-based PHRs are prone to data loss similar to paper-based PHR.

Kerai, Wood, and Martin (2014) conducted a pilot survey (n=80) on the acceptance of PCEHR by elderly people. Most responses were in favour of the PCEHR with some concerns about privacy / security. Another study of PCEHR (Andrews, Gajanayake, & Sahama, 2014) at the same time concluded that the value proposition such as usefulness was not highly regarded. Yet another survey of PCEHR - which is now called MyHealth Record (Muhammed & Wickramasinghe, 2017) - has provided positive feedback from clinicians and the general public although issues such as security and privacy were identified. Cebul, Love, Jain, and Hebert (2011) conducted a study collecting data for a year from PHR-based and paper-based practices which were achieving composite standards of outcomes for diabetes care. The study concluded that practices using PHR achieved a higher level of care and better patient outcomes. My HealtheVet Pilot, a PHR for US Department of Veterans Affairs had positive feedback from patients (Woods et al., 2013) on three main themes about perceived improved communication with clinicians, perceived improved knowledge about self-care, perceived improved patient participation. However, patients felt the disclosure of complete clinical notes increased stress and anxiety about their disease which was earlier not known to them. A study undertaken in New Zealand (Gu & Day, 2013) found that patients were content with the improved communication with their health professionals using the PHR system implemented by the medical centres although usability issues in using the tool were raised.

Various countries have adopted different models to roll out a similar patient controlled HIS (Kerai et al., 2014). In the UK the Summary of Care Record is a report on essential health data about a person from the National Health Service. People are automatically registered and need to opt-out if they do not wish to have access. In Australia people have to register to access their health data on PCEHR. The 2012 rollout was well under the target of 500,000 users within the first year. There is no such national promotion in case of the USA. PHRs are initiated by healthcare providers and hence usage is low. Canada and New Zealand are in the initial stages of introducing a national PHR.

Given the popularity of mobile apps and wearable devices to track health and wellness data, the integration of such data into PHR is envisioned by researchers (Roehrs, da Costa, da Rosa Righi, & de Oliveira, 2017). Ford, Hesse, and Huerta (2016) applied technology diffusion theory and bass modelling on secondary data from health related surveys of US citizens and predicted that PHR adoption will exceed meaningful use (MU) targets in the US. MU Stage 2 recommends that a patient should be able to access

their health data from their health provider for better clinical engagement and MU Stage 3 recommends an electronic exchange of health and wellness data between patient and health provider.

Patients now own a huge amount of health and wellness data captured in mobile apps and wearable devices. Such patients who are dissatisfied with the current patient-clinician consultations and health care will create a new revolution by contributing their health data for research and feed it into EHR systems (Mandl & Kohane, 2016).

2.5.2 Standards in PHR

PHR systems do not have any certification requirements at present. The Certification Commission for Health Information Technology (CCHIT) has a PHR Work Group and a PHR Advisory Task Force to advise on privacy, security, functionality and interoperability (Jones, Shipman, Plaut, & Selden, 2010). The same certification body for EHR is recommended for PHR.

As mentioned previously the standardisation of coding health data for exchange is not well defined. The Continuity of Care Record (CCR) and Continuity of Care Document (CCD) are the two main standards used in PHR systems. As such the data from PHR in CCR/CCD data format was able to be integrated in an EHR system by using HL7/CDA data format (Plastiras, O'Sullivan, & Weller, 2014). Using the ontology information model a middle layer was applied to map the data. Lahteenmaki, Leppanen, and Kaijanranta (2009) demonstrated the exchange of PHR content using external vocabularies and ontologies to attain semantic interoperability. The PHR message structure was generated as XML to feed into the reasoning engine which then matches with the PHR database schema using the set of ontology collection. The ontologies were built based on existing ontologies such as compendium of physical activities (Ainsworth et al., 2000) and nutrition (Cantais, Dominguez, Gigante, Laera, & Tamma, 2005). More recent and relevant ontologies (Ainsworth et al., 2011) will need to be considered for similar future projects.

K. Zeng, Bodenreider, and Nelson (2008) used CCD format in the design and implementation of a PHR to keep track of medications. Java Architecture for XML Binding (JAXB) package was used to automatically generate object classes from XML schemas. The medication terminology mapping was derived from RxNorm and was accessible through an application programming interface (API). Since there are different names and codes for the clinical drug domain a mapping was required to match

the semantically equivalent but lexically different codes.

There are many open source PHR systems available and a review of a few of them is undertaken.

2.5.3 Open Source PHR Systems

Indivo X

Indivo X[19] is an open source PHR system (Mandl, Simons, Crawford, & Abbett, 2007) with the capability to add more features. Initially developed at the Children's Hospital Boston it has the ability to store data in CCR or CCD format. Lessons learned from three hospitals (Halamka, Mandl, & Tang, 2008) gave insight into the security and access of PHR systems. Sensitive information such as mental health and HIV was made available to the patient if legislation allowed and the website was on a secured encrypted connection. Indivo X is a personally controlled health record system which was first deployed in 2001 (Simons, Mandl, & Kohane, 2005) with an LGPL license. It uses CCR derived data types. However IT companies have introduced their own PHR platforms such as Google Health, Microsoft HealthVault. Hence there is not one open platform available to create an ecosystem of connected devices.

A survey of PHR technologies (Robison, Bai, Mastrogiannis, Tan, & Wu, 2012) revealed that Indivo X features are available in most PHRs and are a foundation for building new PHR systems such as MyOSCAR and Dossia. Most of the PHRs use CCR and/or CCD format to exchange data and other coding standards such as SNOMED CT and LOINC.

Microsoft HealthVault

Microsoft HealthVault is a cloud based platform to manage health records. It can integrate with various devices, services and third party applications and communicate with health providers. Data in CCD or CCR formats are accepted from health providers into Microsoft HealthVault. The source code as Software Development Kit (SDK) for various development environments such as .NET, Android, PHP, iOS and Windows Phone is available.

There are also other applications integrated with Microsoft HealthVault such as HealthJibe[20], Heart360[21] and Live Healthier[22]. Wellness devices from glucose meters

[19] indivohealth.org

[20] https://www.healthjibe.net/

can be integrated with PHRs such as Microsoft HealthVault. Most applications and devices are based on US standards and may not suit the rest of the world.

Microsoft HealthVault has been used in research studies. In one such intervention study of 450 patients (B. R. Shah et al., 2011), 150 patients were given home based blood pressure (BP) monitors, nurse assistance and enrolled in Microsoft HealthVault. Another group of 150 patients were given BP monitors and enrolled in Heart Vault. A third group was the control group receiving standard care. Heart360 was integrated with Microsoft HealthVault system to provide self-care assistance. Tools such as Microsoft HealthVault proved to have the potential to improve coronary disease management.

Microsoft HealthVault has the capability to export data in CCR, CCD format. At present only data such as demographics, BG (except FD) are exported. However users can share with others their FD data at different levels of access such as read, update, delete and create. Users can also choose to share different types of data including food and exercise.

Dossia

Dossia[23] was established in 2006 as a consortium to allow employees of many major companies in the USA such as Walmart and Intel to manage their health data. Commonly used data schema and APIs were published online. Glucose measurement readings were stored in health standards such as LOINC are of interest in the proposed body of work.

2.5.4 PHR – A New Zealand Perspective

MedTech's ManageMyHealth (MMH) is a clinical system which can receive a patient's medical information such as laboratory reports directly from the medical centre and is accessible by the patient and clinicians. A patient can also book appointments online and order repeat prescriptions. MMH has the limited functionalities of a PHR system. MMH is a tool to provide primary and secondary care information to the clinician as it is integrated with many clinical systems. Currently patients cannot record their wellness data in MMH.

Mobile technologies have been used in research for health interventions. With higher

[21] https://www.heart360.org/
[22] http://www.livehealthier.com/
[23] http://www.dossia.org/

penetration of smart phones and consumer downloadable mobile apps there is evidence of its use in clinical trials related to GDM and is discussed in Section 2.8.2 Mobile Wellness Apps for GDM.

2.6 mHealth

Technology has been utilised as part of intervention in clinical trials to achieve successful outcomes. Websites have been created to educate patients about their conditions and to collect their test results for consultations with clinicians. Video conferencing has facilitated remote patient consultations. These technologies facilitated telemedicine. The popularity of mobile phones facilitated sending SMS' as a common intervention to remind patients to test their BG, blood pressure or to send encouraging messages to quit smoking. Thus the word 'mHealth' was coined to associate with health interventions using mobile phones. Fjeldsoe, Marshall, and Miller (2009) reviewed 14 studies on preventive health behaviours with positive outcomes observed in 13 of these. Telemedicine using ICT enabled remote monitoring proved successful in some clinical trials (Ekeland, Bowes, & Flottorp, 2010) to manage health conditions such as diabetes, cardio vascular and smoking cessation. However evidence for health outcomes is patchy and has not been measured adequately. With the advancement in technology newer devices and technological tools are utilised as health interventions.

Systematic literature reviews of various mobile phone interventions (Free et al., 2013; Holtz & Lauckner, 2012) have shown some positive outcomes for smoking cessation, behavioural programmes for diabetes such as weight management and self-management of chronic diseases. Short Message Service (SMS) has been used to send reminders for clinical appointments, to provide health information such as messages encouraging people to lose weight or stop smoking. As mobile phones are portable and ubiquitous they are intuitively attractive for applications engaging in behavioural change programmes. Studies have also included patients using a mobile phone to self-monitor BG, keeping a FD, nutrition and exercise details. Various outcomes were studied (Krishna, Boren, & Balas, 2009) such as haemoglobin A1c and body mass index (BMI). The outcomes from various studies showed improved self-efficacy and BG levels.

Different systems at primary and secondary care such as EHR and PHR have captured the essential health data. However there have been issues transferring health data from one system to another because of interoperability, policy and privacy considerations. The current body of work will investigate issues related to data interoperability. With

the introduction of mobile apps patients have useful data about their health and wellness to share with their clinicians. The data shared is viewed at consultation times but not necessarily captured in clinical systems. The concept of building an ecosystem involving EHR, PHR, mobile and other medical devices is ideal and will contribute to better clinical experience for patients through a patient-centred approach.

2.7 EHR PHR mHealth Ecosystem

According to ISO definition (ISO/TR 20514:2005) Integrated Care EHR is a "repository of information regarding the health of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorized users. It has a commonly agreed logical information model which is independent of EHR systems. Its primary purpose is the support of continuing, efficient and quality integrated health care and contains information which is retrospective, concurrent and prospective".

The core functionalities in building an EHR PHR mHealth ecosystem is to integrate clinical data from various sources and to support decision making. It is important to note that PHR systems and mobile apps are patient controlled and data entered by the patient or caregivers may not be accurate and needs to be considered while making medical decisions.

A tethered PHR system is linked to EHR and allows for data values to get automatically populated. This could be useful to integrate clinical laboratory reports into the PHR systems and is a more accurate source of data. Untethered systems are not linked to the EHR system and are managed by patients themselves. However these systems should still be able to send data to clinicians and preferably to the clinician's system. With the introduction of mHealth, wearable and IoT technologies, there is a greater value if patient managed health and wellness data can be integrated into the clinical system. In most cases the wearable and IoT devices integrate in their own platform or system such as a mobile app to synchronise the data from devices into the app or a cloud based server. The issues of data interoperability come in the way when devices on different platforms want to communicate.

To build a successful EHR PHR mHealth ecosystem usability with data interoperability are major concerns at present. Patient education is another concern as patients are active participants who share their data in the ecosystem (Marceglia, Fontelo, Rossi, & Ackerman, 2015).

After reviewing the different terminologies in clinical data and the different systems used in health settings by clinicians and patients, concerns around the issue of data interoperability remain. In clinical systems health informatics terminologies such as SNOMED CT, LOINC and health exchange standards such as HL7 and emerging Fast Health Interoperable Resource (FHIR) are utilised to retain the semantic meaning of data when transferring patient data from one system to another. The research in this body of work involves health and wellness data from patient managed devices such as apps from mobile phones and glucose meters. Clinical standards are not maintained in mobile apps and as such the data extracted from it into clinical systems will only be useful in the clinical environment if it retains the semantic meaning of the data.

The literature around data interoperability in web technologies and databases is sought to seek solutions outside the clinical systems. These solutions have evolved since the internet and web applications as open platforms were built with the notion of sharing heterogeneous data.

2.7.1 Ecosystem Related Research Studies

An ecosystem was proposed by (Reilent, Lõõbas, Kuusik, & Ross, 2011) where PHR systems need to synchronise data received from other sources such as wellness apps and medical devices to maintain the currency of personal health data. An HL7 V3 messaging system was used to allow data interoperability between the data repository and all systems interacting with it. The major challenge in PHR is that much of the patient data varies in format and standard clinical coding systems and terminologies do not support it. However the authors have proposed similar research on integrating sensor data for assisted living. Sensor data was saved as Resource Description Framework (RDF) format which could be processed using existing reasoners and SPARQL tools (Kuusik, Reilent, Lõõbas, & Parve, 2010).

Plastiras et al. (2014) proposed an ontology-driven middle layer to enable data export from PHR to EHR systems using HL7 format. This ontology can solve semantic issues by mapping words with similar meaning.

A group of researchers developed data mappings from 10 participating hospitals in Taiwan to integrate with the PHR system (Jian et al., 2011). Most legacy hospital systems did not follow a standard medical terminology such as CDA. Hence an XML template was designed which could correspond to a wide range of data across different hospitals. The limitation of this project was that it was manually coded and may not be

suitable to other hospital systems in other parts of the world.

Puustjärvi and Puustjärvi (2011) developed an active PHR system where data could alert the patient's physician. Complex XML schema from PHR was transformed to ontology. XML schema was transformed to OWL classes and related elements of XML schema transformed as OWL data properties. Ontology based PHRs were semantically more interoperable than XML schema based PHRs.

Marceglia et al. (2015) built a proof of concept prototype involving an EHR system called OpenMRS and connecting it with an app developed in the iOS platform. There was a bi-directional exchange of patient data in the CDA standard. The mobile app was activated through an EHR message to start the monitoring. Once the data was collected in the app it generated a CDA compliant data message to send to the EHR system.

An ontology was developed in Australia to help aboriginals with Type 2 diabetes communicate with their doctors. The vocabulary of these patients and the diabetes self-care was integrated in the ontology. In another example of diabetes diet care (H.-C. Li & Ko, 2007) an ontology was built with food nutrition values from their national food nutrition composition database and alternate foods in the same food group with desired nutrients were recommended.

EHRs use different medical terminologies and as such for these systems to exist in an ecosystem with patient controlled PHRs there should be a better approach to mapping the data from one system to another.

Most mHealth related research studies are using apps developed for the purpose of the research study. There have been few recent studies involving downloadable apps.

2.8 Mobile Wellness Apps

With the pervasiveness of smart phones, there have been a number of wellness apps available for different mobile devices on different platforms such as iPhone, Android, Blackberry and Windows Phones. However each app is different and has not been assessed for quality and standardisation.

A survey study in the United Sates revealed 58% of mobile users had downloaded a mobile app related to health (Krebs & Duncan, 2015). Participants did not want to pay for the apps. Nearly half of the participants had stopped using the app after a while because of a loss of interest and the high data entry requirements. In the case of GDM,

the diabetes condition is temporary and women are asked to keep FD and BG readings for a short period of time. Relevant mobile apps which help in maintaining a FD are useful in the current body of research. They may continue to use them after they have delivered the baby for a healthy lifestyle and managing GDM in subsequent pregnancies.

Most of these wellness apps can take inputs such as body weight, gender, calories to be consumed in a day, calories actually consumed in a day and input of various meals eaten during the day. For a number of applications the user needs to enter the data about the meal consumed. A few apps have a link to a food database which calculates the calories for a given portion size. Some apps have features of food and exercise in them. There are apps for exercise which calculate the net calories by calories gained through food consumption and calories burnt through exercise. The information thus collated is useful to the user to manage their diet, weight (loss/gain/maintain) (Carter et al., 2013) and medical condition.

The US FDA has regulated mobile wellness apps which connect to medical devices such as glucose meters which track the user glucose levels and advise insulin dosage. In Europe the equivalent Conformite` Europe`enne (CE) mark sets the standard with regards to the safe use of such devices (Censi, Mattei, Triventi, & Calcagnini, 2015). Other mobile apps which allow the user to input data about their wellness and communicate it with others are not regulated under the US FDA.

There are around 23,490 and 17,756 health and fitness apps available on the iOS and Android app platforms (Higgins, 2016). The number of mobile apps on wellness have increased over the last three years to around 40,000 apps (Aitken, 2013). Clinicians have difficulty in identifying good mobile wellness apps for their patients (Powell, Landman, & Bates, 2014). In some cases medical centres have specific requirements and have developed their own app. Patients are aware of the commercial downloadable apps and adopt them to make lifestyle changes. The clinician prescribed app may not necessarily suit the patient if they are accustomed to their own apps.

There are discussions of new emerging data from the collaborative efforts of patients and clinicians in a shared care plan from devices such as smart phones and home monitoring devices (Mori, Mazzeo, Mercurio, & Verbicaro, 2013). The data, process and governance around these newly created health and wellness data has not been explored. As such the clinical standards and terminologies are still not defined for these types of data. The re-use of such data in clinical systems is visualised through various

research and proof of concept prototypes (Jung, Kim, Chung, & Park, 2014).

2.8.1 Developing Mobile Wellness Apps

There were very few references in academic literature about mobile wellness apps when this research study was first initiated in 2013. However such apps are gaining importance in research studies with recent published research.

My Meal Mate (MMM) (Carter et al., 2013) is one such example mentioned previously. MMM can keep a FD and aid in weight management through diet and exercise. It can then export the entire database with all user entries for further analysis of food consumed. The limiting aspect of MMM is that the food database is UK based and not suitable for New Zealand. Food databases are diverse and need to be built to suit each country. A branded food found in the supermarket has a nutrition profile which could be different to a similar branded food in the same or different country. Cooked food can vary a lot and as such is difficult to profile the wide range. A similar issue is faced with ethnic food. New Zealand has multi-ethnic communities and designing a food database is a challenge. The food composition has limited food descriptions and needs continuous updates.

A mobile app for managing diabetes was developed which was able to synchronise data from mobile apps to PHR and also receive data from EMR (Jung et al., 2014). The PHR system was built on the United States integration model based service where the PHR system was able to link to different participating medical providers. Data from EMR was only displayed on the PHR system because of the required legality that hospital data is not stored in a patient's portal database.

2.8.2 Mobile Wellness Apps for GDM

Very few studies have been published relating to technology aided interventions for diet and lifestyle in pregnancy. Only two studies in progress relating to mobile apps for pregnant women were recorded by O'brien et al. (2014). One of them was about increasing physical activity during pregnancy (Choi, hyeon Lee, Vittinghoff, & Fukuoka, 2016) by using a step counter device and reporting it in an interface connecting to clinicians. The daily mean step count between the intervention and the control group was not statistically significant for the small sample. It was difficult to increase the physical activity goal for women who had an inactive lifestyle before pregnancy. The intervention group participants had the opportunity to discuss about their fatigue and ways to overcome this which promoted a positive outlook for physical

activity. In another weight watch programme associated with pregnancy (Clifton et al., 2016), a mobile app and step counting device was utilised to prevent excessive weight gain as a primary outcome. The secondary outcomes were related to the health of the mother and baby. In yet another research related to healthy weight gain in pregnancy the study used a custom built mobile app to recommend nutrition and physical activity to women (Knight-Agarwal et al., 2015).

A new mobile app was designed and trialled in Norway for women with GDM (Garnweidner-Holme, Borgen, Garitano, Noll, & Lukasse, 2015). The current practice prior to the app was to log blood sugar readings in a booklet. With the new app, women were able to use Bluetooth wireless technology in their smart phone to download glucose meter readings into the mobile app. The app was also capable of storing FD and exercise. Cloud technology was not used in the design of the app as patient data privacy was a concern to the national data protection authority. Expert groups and patients were involved in the design and testing of the app through interviews, surveys and observations.

In another study by Mackillop et al. (2014), an Android phone app was developed to connect to a glucose meter via Bluetooth and upload the meter readings to a website accessible by clinicians. Women were also able to include a short message to indicate if the reading was pre-prandial or postprandial and also include their food details. 48 patients took part in the research study; 85% sent their meter readings and 98% of those readings had a meal tag. Women were remotely managed and if the pre-prandial readings were >= 5.9 mmol/L or postprandial >=7.8 mmol/L or one reading per day was >= 9.0 mmol/L then a clinic midwife would call the women to give advice on diet and medication (Mackillop et al., 2016). 49 women took part in the survey questionnaire and rated high levels of satisfaction in using the technology (Hirst et al., 2014). Another mobile app has been designed in a hospital in Australia to aid in the self-management of GDM (Kaplan, 2014). However no further details are available.

A review of mobile apps for GDM was conducted between 2012 and 2013 (Rand, Hirschhorn, & Mungovan, 2014). The apps considered had a range of functionalities related to GDM and nutrition information. They allowed the recording of BG levels, food intake and exercise. Most apps were developed in the USA and no New Zealand or Australian apps were found. The apps also failed to meet Australasian Diabetes in Pregnancy Society guidelines for GDM in Australia. Although there are not many

mobile wellness apps in academic research, similar research projects for the self-management of chronic diseases such as diabetes are of interest in this body of work.

Mobile apps have the potential to contribute to a data-driven ecosystem provided the data interoperability and useful systems are built.

2.9 Summary

A general understanding of GDM gave a good foundation for determining the clinical requirements to be fulfilled in a technological intervention. The important consideration was around the self-management of GDM and hence studies related to food, nutrition and exercise were researched. Communication with clinicians was vital and literature around patient centred consultation was researched. Consultations were data driven capturing patients' symptoms, FD, BG readings and exercise by discussing these issues verbally.

There is no provision in the current EHR systems to capture this data electronically and hence patient wellness data is captured as clinician comments in the system. Patients are required to recall their GDM self-management activities from their own notes.

Smart phones have high penetration in New Zealand. As of 2013 (Sullivan, 2013), 64% of the population aged between 15 and 65 owned a smartphone. This number is expected to increase to 90% in 2018. Suitable mobile apps can aid in electronic sharing of data from patients to clinicians and capture them in a clinical system. There are limited studies related to the self-management of GDM and the integration of data from mobile wellness apps to clinician systems. The review of mobile wellness apps for diabetes, GDM and fitness is undertaken and demonstrated in Chapter 6 Design of Ecosystem and Prototype Version 1.

PHRs have similar potential for patients to log their wellness data and share it with clinicians. However past studies have highlighted the low adoptions of PHRs due to various issues such as usability, perceived usefulness, privacy and integration with EHR systems. Similar concerns are envisioned in the case of integrating mobile apps. Patient managed health and wellness data maintained in PHRs and mobile apps are unable to be stored in clinical systems. Hence in building a data integration prototype, existing EHR, PHR systems and mobile apps are investigated. Solutions around data interoperability issues are sought from literature to determine whether a combination of different techniques would aid in building the prototype in this body of work.

3 Literature Review

In the continuous effort to build an ecosystem by integrating data from various mobile wellness apps for the self-management of GDM and to share with clinicians, literature in health informatics and other domains of data integration are sought as outlined in Sections 3.1 -3.7. The ecosystem is built in consultation with clinicians and the principles of involving users in the design of the ecosystem is considered as described in Section 3.8. In order to build a useful and easy to use ecosystem theories of technology acceptance are considered and discussed in Section 3.10. Other evaluation methods are discussed in Section 3.9 and 3.11.

In order to build an ecosystem that accepts data from various devices and mobile apps, the format, structure and meaning of the data is of prime importance. Interoperability is a term used to describe this manipulation of data and is discussed in the section below.

3.1 Interoperability

Interoperability is the ability of an IT system to work with other IT systems with minimal effort from users. It enables systems to communicate, exchange data and utilise the data in these systems.

Different organisational bodies have given definition to the term '*interoperability*'.

According to the IEEE Standard Computer Glossaries (Geraci et al., 1991), "Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged."

In healthcare, HIMSS (2013) defined interoperability as "the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged". HIMSS defined three types of health information technology interoperability: foundational, structural and semantic.

Foundational interoperability allows data exchange from one system to another without the need for interpretation of data in the receiving system.

Structural interoperability allows health data exchange from one system to another preserving the clinical meaning of the data. It defines the structure and format of the data exchange at the data field level.

Semantic interoperability includes the structuring of health data and standard clinical codes to interpret the data in the receiving systems. This level of data exchange is required in systems connecting EHR, PHR, mobile technologies and medical devices.

HL7 a leading clinical data exchange standard has adopted the definition of interoperability from IEEE. In addition it defines technical, semantic and process interoperability.

Technical interoperability is the ability to transmit data without error. The receiving system will not analyse the data semantically to understand it. Technical interoperability is attained through interoperability at data level. Since the advent of the internet, data exchange through web applications was challenging with the heterogeneous nature of data in the source and target applications. Semantic web (Berners-Lee, Hendler, & Lassila, 2001) had solutions for such data exchange through web services (McIlraith, Son, & Zeng, 2001). Data exchange through web services was through XML using Simple Object Access Protocol (SOAP) in the early 2000s. Web Services Description Language (WSDL) has the description to locate these web services. Representational State Transfer (REST) or RESTful is another way of exchanging data over the internet using stateless protocols such as HTTP. The underlying data formats XML and JSON are the same in the traditional REST and the current stateless REST API. JSON is a light data format used in mobile apps. Most mobile apps are able to export the user input data such as CSV, XML or JSON format. The simplest data format used to export data is still CSV format. However the schema is not known and it will be difficult to automatically map this type of data to a target database. XML uses HTML-like tags to structure data. Data schema is stored along with data values and is readable by both humans and machines. XML data files can be parsed and made more meaningful to the user in a web browser. Database middleware tool for managing data from heterogeneous data sources was developed using XML (Reynaud, Sirot, & Vodislav, 2001).

Semantic interoperability is the ability to interpret the data and make effective use of the information thus exchanged. Semantic interoperability through ontologies (Noy, 2004) and linked data (Bizer, Heath, & Berners-Lee, 2009) have been achieved in the semantic web. Ontology is used to represent knowledge in a particular domain. It is “specification of a conceptualisation” (Gruber, 1995) for building and sharing knowledge.

Ontology is the description of a concept called *'class'* (Noy et al., 2001). Each class has properties describing its attributes. A class can have sub-classes. Instances of classes contribute to the knowledge base. A richer set of relations are built through the hierarchical structure. Data and information stored in the semantic web can be shared with other applications through ontology matching techniques expressed as Web Ontology Language (OWL) (Shvaiko & Euzenat, 2013). However existing quality ontologies and linked data are required to fulfil its true potential.

Process interoperability involves the integrity of workflow processes between different systems. The Institute of Medicine (IOM) report of 2005 described user role specifications and data flow to support work settings and building a user friendly interface. IOM (2011) further emphasised the safety of patients in these systems.

Solutions to interoperability have often been a topic of discussion in forum meetings (Hufnagel, 2009). It was concluded that acceptable architectural models, standards and information content would allow interoperability. In the USA, Healthcare Information Technology Standards Panel (HITSP) is a partnership organisation to connect the public and private sector in exchanging health data between different software applications. In a federated architecture, an EHR can connect to a PHR and share required patient data. The connected system will grow eventually by agreeing on the data content and formats. Cross-standard translation of clinical standards such as SNOMED CT, RxNorm is expensive. If industry and clinical users agree on a minimum set of clinical data through HITSP, it reduces the development cost of EHR systems.

Schema definition languages such as XML, SQL-DDL, RDF and ontologies are different ways to achieve successful interoperability (Haslhofer & Klas, 2010). However this is not easily achieved due to operational issues. XML standards applied in Business to Business (B2B) interoperability were discussed by Lampathaki, Mouzakitis, Gionis, Charalabidis, and Askounis (2009). The Clio project (Fagin et al., 2009) provided algorithms to map data from source schema to the target schema. Such declarative schema mappings have previously been used in related research (Fagin, Kolaitis, Miller, & Popa, 2005; Lenzerini, 2002).

Kataria and Juric (2010) researched semantic technology to retrieve data from heterogeneous sources. Theirs was an ontology developed solution to manage semantic heterogeneities. Local ontologies were mapped to get a derived ontology for reasoning.

ISO/TS 18308 standard defines data representation, interoperability services, ethical and privacy issues in relation to data stored and access levels to different users on the EHR systems. Clinical data interoperability has been developed through health information exchange standards such as HL7 and other clinical terminologies such as SNOMED CT, LOINC.

In 2003, the HL7 EHR Special Interest Group (HL7EHRSIG) put together a functional guidelines document for an EHR system. It covers standards such as HL7 V2 and V3, CDA, CCR and CCD. There are three ways to achieve interoperability: technical, semantic and process levels. Technical interoperability should preserve the structure of information while sending and receiving data; semantic should consider the data semantics and validations; while process interoperability should be able to process the data received.

Wynden et al. (2010) defined an integrated data repository for clinical data using technologies such as XML, HL7 standards and ontologies. Lahteenmaki et al. (2009) proposed using ontologies and vocabularies to achieve semantic interoperability. The synonym information from ontologies was used to match the data schema from various vendor applications into one target PHR. Data interoperability was set up using the ontology concept to share clinical and non-clinical data from a PHR (Sachinopoulou, Leppanen, Kaijanranta, & Lahteenmaki, 2007). Nutrition data in food and diet was taken from food ontology (Cantais et al., 2005).

Some successful deployments in recent times in New Zealand are GP2GP (Jordan, 2012) which allowed patient's records to be electronically transferred between health providers. The CDA data format is used for electronic exchange. Other examples are eReferrals and eMedication.

Data from PHR and mobile wellness applications is crucial in managing chronic diseases like diabetes. Most of the data in these applications are stored in different data schema. To some extent PHR have the capability of storing data in clinical data formats such as CCR, CCD. However wellness apps do not have any particular standard and use the normal data formats available such as CSV, XML, JSON and HTML.

3.2 Semantic Schema Mapping and Lexical Database

Data integration from different application systems has been an issue as data have different schema in their original system. Schema matching from source to target data

is usually done manually in data warehousing or e-business (Doan & Halevy, 2005). Once a schema match is established it is saved for future data extraction. However it does not work on an ad hoc basis.

Schema matching is based on heuristics through practical and domain knowledge experience. Rahm and Bernstein (2001) presented various schema matching approaches. The first approach is to match by schema or instance. At schema level linguistic or constraint based matching is done at the element or structure. Examples shown in Table 3.1. Matching cardinality is the number of matches from source schema element to target schema element. This could be 1:1, 1:n, n:1 or n:m.

Table 3.1: Examples of Match Cardinalities (Adapted from (Rahm & Bernstein, 2001))

	Matching cardinality	Source elements	Target elements	Matching expression
1	1:1, element level	Price	Amount	Amount = Price
2	n:1, element level	Price, Tax	Cost	Cost=Price*(1+Tax/100)
3	1:n, element level	Name	FirstName, LastName	FirstName, LastName=Extract(Name,…)
4	n:1, structure level (n:m element level)	B.Title, B. PuNo, P.PuNo, P.Name	A.Book, A.Publisher	A.Book, A.Publisher=Select B.Title, P.Name from B, P where B.PuNo=P.PuNo

At the atomic level it is an attribute in XML or a column in a relational schema. An example of atomic level match is patient.patientName ~= client.name.

Element level matching is implemented through algorithms similar to relational join queries.

Linguistic approaches are used to map semantically similar schema elements. Synonyms are referred from dictionaries and thesaurus to find a match. Similarities of names are extracted from substrings, soundex as demonstrated as in a patient index (Bell & Sethi, 2001). Hybrid matching was used to get the best results when a combination of structure and element level mapping algorithms were used.

Ten years on, the same authors (Bernstein, Madhavan, & Rahm, 2011) along with another reported on the state of schema matching including techniques used in commercial applications. Most commercial systems have GUI-based editor for manual

mapping which later generates code for the schema matches. Microsoft BizTalk Server, IBM Infosphere, Stylus Studio and SAP Netweaver are some examples.

Schema or semantic matching techniques are semi-automatic (Doan & Halevy, 2005). Rule-based technique has been employed to find mappings which are created through schema information like data type, attribute name and integrity constraint. However rule based technique in schema mapping does not check data instances.

Semantic integration through ontologies has been used previously (Cruz & Xiao, 2005; Noy, 2004). Data integration through semantic mapping using WordNet is demonstrated through projects such as Mediator Environment for Mutliple Information Sources (MOMIS) (Bergamaschi, Castano, & Vincini, 1999) and has recently been made available as an open source project (Bergamaschi et al., 2011). Another project called Xyleme (Reynaud et al., 2001) used synsets in WordNet to find semantic mappings of XML data. In the MOMIS project, integration is completed in two steps; common thesaurus generation and global virtual schema. Currently most schema and ontology matching systems include instance level matching with semantics (Bernstein et al., 2011).

Another prototype called Spicy[24] developed in the University of Basilicata, Italy is available with source code. Spicy can handle all types of data such as relational, XML and ontology which was a limitation in the earlier prototypes. Spicy can generate automated SQL and XQuery code upon the intuitive graphical mapping of source schema to target schema.

The architecture of Spicy (Bonifati, Mecca, Pappalardo, Raunich, & Summa, 2008) has schema matchers and a mapping generation module. Mappings are based on Clio's algorithms (Popa, Velegrakis, Hernández, Miller, & Fagin, 2002). A range of matches are generated by these schema matchers with each corresponding match given a similarity measure called the level of confidence. Each target attribute could match to a number of possible source attributes. However only one source attribute mapped to the target is desired. Correspondences whose similarity is above the threshold are considered. The mapping verification module compares the transformed source to the target. Transformations are ranked and if no satisfactory mappings are obtained, the threshold is lowered and the process repeated. Experimental results show a high

[24] http://www.db.unibas.it/projects/spicy/

precision and good scalability for the mapping process.

Research is still active in schema mapping (Sutanta, Wardoyo, Mustofa, & Winarko, 2016). It has evolved from manual models and methods to semi-automatic models and methods. User intervention is still required to check for any discrepancies. There is still scope for further improvement. Although there are solutions available for clinical terminologies, non-clinical data which are not maintained in the clinical system will require technical interoperability solutions. Most mobile apps developed for consumers are not designed for integration with clinical systems.

3.3 Clinical Data Interoperability

Clinical data is maintained at different levels in the health system. Primary healthcare data is maintained by the General Practitioner (GP), practice nurse and midwives. Secondary health data is maintained by specialists and hospitals. Pregnancy consultations are transferred to secondary care when the conditions of the women requires a hospital setting. Women with GDM are treated in a diabetes clinic as part of secondary care in a hospital setting. In practice, clinical data is maintained in various systems in different standards and when required to be exchanged between different clinical systems need to follow standard data transfer protocols, discussed in the following sections.

Electronic data interchange standards were used in admission, discharge and laboratory reports from two participating hospital systems in the Netherlands to 27 GPs (Branger et al., 1992). The research study demonstrated increased speed and efficiency of transferring health data from hospitals to GPs for continued support of their patients. These electronic data interchange standards need to be universal if they are to be used across different countries. In a survey study in Europe (de Lusignan et al., 2001) different clinical codes were reviewed which aided in identifying and transferring patient information from one system to another which supports data interoperability. These clinical standards are of interest in the current body of work if there is reference for a particular medical terminology. It could also help in building on existing standards. An understanding of clinical standards and clinical data interoperability is required to learn how health and wellness data maintained by patients can be integrated in a clinical system.

3.4 Standards in Clinical Data

Clinical data stored in various information systems such as medical centre, inpatient and outpatient hospitals, laboratory tests and pharmacies are not linked, as different organisations / business partners capture and process them separately. There is no one particular standard within or across different countries. If data is stored in a particular standard or format it is easy to link all related historical data about patient diseases and treatments. There have been various standards development organisations in the US and European context.

American National Standards Institute (ANSI) founded in 1918 assists standards developers such as private organisations or government to reach consensus in approving a standard. ANSI does not create its own standards. HL7 is an example of the ANSI accredited organisation.

As part of the standardisation, health data needs to be encoded in a particular fashion to aid the use of such data in an information system by software developers as well as to facilitate the exchange of such data among various systems. Unfortunately no one standard can address the issues of all medical terminologies. Medical terminologies are updated on a regular basis. Considering all the issues it is important to understand some of the relevant controlled medical terminologies and how clinical data is structured and stored in various formats. Clinical standards used in HIS for various objectives such as LOINC have terminologies relating to laboratory results. ICD-10 relates to diseases, SNOMED CT has concepts relating to clinical data, HL7 is used as a messaging service between systems. The underlying data structure/schema is XML. Some of the key standards to exchange health related data between information systems are discussed in the Sections 3.4.1 – 3.4.5 and some of the key health terminologies are discussed in the Sections 3.4.6 – 3.4.7.

3.4.1 Health Level 7 (HL7)

Health Level 7 (HL7) is based on an existing standard called ASTM (Hammond, Jaffe, Cimino, & Huff, 2014) and was initially established in 1987 by a group of volunteers in the USA. The name reflects the 7th layer of Open System Interconnection (OSI). The principal concept of HL7 is the exchange of data between two systems. This is achieved through data communication sent through a structured message with defined encoding rules. HL7 messages carry patient administration details such as admission, discharge and transfer (ADT). A message consists of many segments; and each of these segments

consists of fields. A message begins with a Message Header Segment (MSH) and has the triggering event defined. Example ADT^A01. A field has a pre-defined data type such as string, numeric, date. The main feature of the current version of HL7 (v3) is an object oriented model called Reference Information Model (RIM)[25]. The message structure is constructed in XML. Most medical systems still use HL7 V2 which is not compatible with current technologies. HL7 V3 is technically compatible; however it is too complicated to be developed. New Zealand uses HL7 V2. A few countries such as Holland have adopted HL7 V3.

3.4.2 Continuity of Care Record (CCR)

The Continuity of Care Record (CCR) is developed by a Standards Development Organisation (SDO) called ASTM. ASTM defines CCR as "a core data set of the most relevant administrative, demographic and clinical information facts about a patient's health care, covering one or more health care encounters". CCR uses XML to facilitate the exchange of structured medical data. CCR Version 1 was in simple, human and machine readable form and overlapped with the HL7 CDA. CCR Version 1a evolved to become more complex with an object oriented data model and overlapped with CDA in general.

3.4.3 Clinical Document Architecture (CDA)

The Clinical Document Architecture (CDA) is derived from the HL7 RIM and uses all the standards from HL7 such as datatypes and information models. It uses XML to exchange structured data and is more complex than CCR Version 1a. One possible solution for managing different technologies in health informatics is to adhere to one standard like mapping CCR to CDA using XSLT transformations.

3.4.4 Continuity of Care Document (CCD)

The Continuity of Care Document (CCD) is a newer format and is adopted from CCR and other past standards from HL7 CDA and ASTM (D'Amore, Sittig, & Ness, 2012). It is adopted by many EHR vendors in the US. It allows the exchange of patient health data from proprietary EHR systems. Although it supports individual patient health data exchange it can be extended for use in medical research and population health. The standard supports administrative and clinical data.

[25] https://www.hl7.org/implement/standards/rim.cfm

3.4.5 Fast Health Interoperable Resource (FHIR)

The Fast Health Interoperable Resource (FHIR) is the next generation framework developed by HL7 with the best features of the HL7 Versions 2 and 3 and CDA 26. It is a free license accepted by the HL7 leadership and community. The need for FHIR has come as HL7 V3 is complex and takes a long time for development; HL7 V2 is old style and not compatible with new technologies such as mobile applications and cloud computing (Bender & Sartipi, 2013). FHIR published a Draft Standard for Trial Use (DSTU) at the end of 2013 and has progressively developed various versions since then. The current FHIR Release 3 Standard for Trial Use (STU) was published in April 2017.

The building block of FHIR is 'resource' to exchange data in the form of existing web technologies such as XML and JSON. Mobile applications can use JSON which is light. FHIR supports RESTful web service architecture which is a state of the art technology.

3.4.6 Systematised Nomenclature of Medicine Clinical Terms (SNOMED CT)

Systematised Nomenclature of Medicine Clinical Terms (SNOMED CT) is the most common clinical health terminology to feed in primary health data which is beneficial to clinicians as it has a common language to most health terms. SNOMED CT allows national licenses and New Zealand has one.

SNOMED CT terminology file consists of three main components: concepts, descriptions and relationships as shown in the logical model (Figure 3.1).

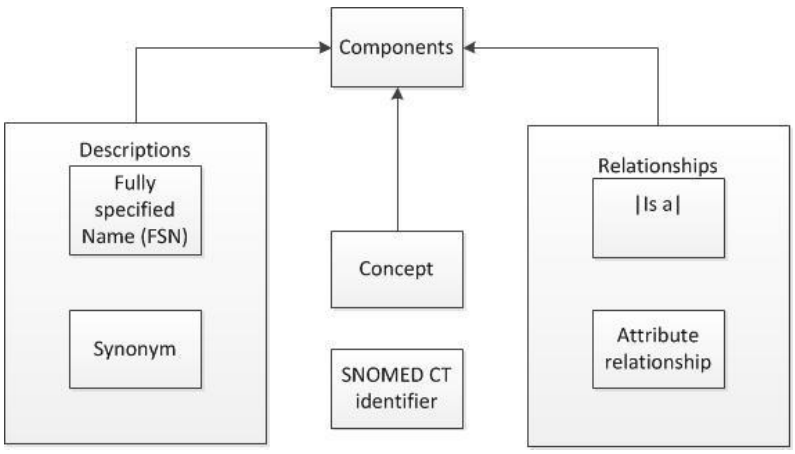

Figure 3.1: Logical Model of SNOMED CT (Adapted from SNOMED CT Starter Guide 2017)

'Concept' has a unique number assigned in SNOMED CT. *'Descriptions'* is a textual information assigned to a concept in human readable form. There are two types of descriptions used – Fully Specified Name (FSN) and Synonym. FSN is a unique

[26] http://hl7.org/fhir/

description of a Concept. On the other hand concept can have several synonyms; only one synonym is considered *'Preferred'* in each language while the other synonyms are *'Acceptable'*.

An example of concept descriptions in English language is illustrated below (Figure 3.2):

Concept id = 22298006

Descriptions for concept id 22298006 are myocardial infarction (disorder), myocardial infarction, infarction of heart, cardiac infarction, heart attack, myocardial infarct, MI-Myocardial infarction. Of these descriptions myocardial infarction (disorder) is the FSN and other descriptions are synonyms. Myocardial infarction (disorder) and myocardial infarction are preferred synonyms while the rest are acceptable.

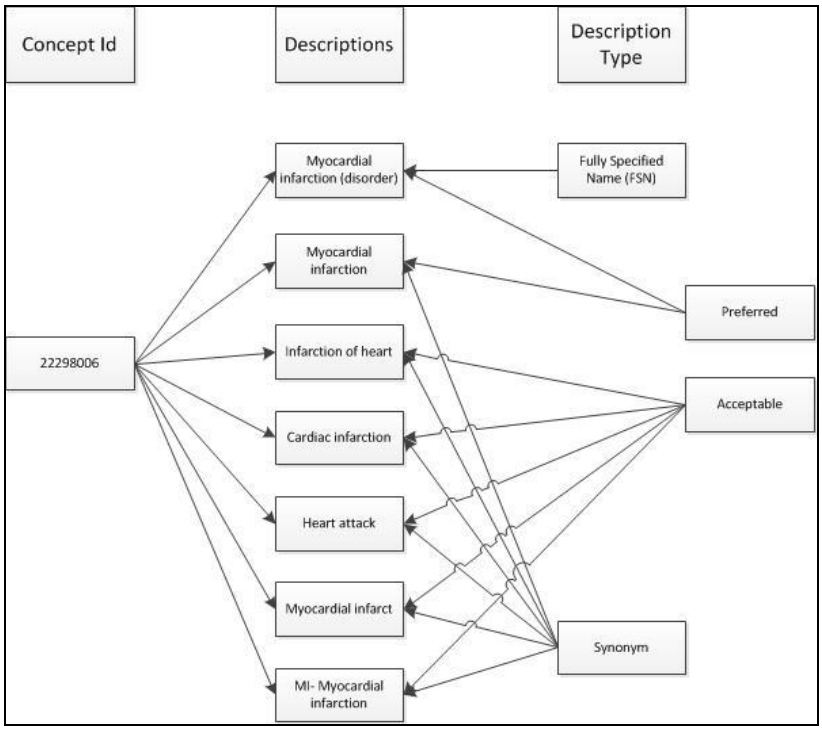

Figure 3.2: Example of SNOMED CT descriptions for a concept (Adapted from SNOMED CT Starter Guide 2017)

Similar to coding diseases to a concept id which means the same in various systems allowing semantic interoperability of health data, there are terminologies for coding the various clinical observations and tests a patient undergoes. One such is LOINC discussed in Section 3.4.7.

3.4.7 Logical Observation Identifiers Names and Codes (LOINC)

LOINC has unique codes for various laboratory tests and clinical observations which

improve the semantic meaning of the data in different systems. There are various types of tests and sub categories which are clearly identified through these codes.

Non-clinical data such as food databases do not have standard clinical terminologies. A food database can be diverse considering all ethnic food.

3.5 Non-clinical Data Interoperability

PHR data can be keyed in manually or received by seamless connections to external devices such as a BG meter. Data from PHR and mobile wellness apps are crucial in managing diseases such as diabetes. A patient can manage their diet and exercise through wellness mobile apps. Data interoperability is an issue when managing data in or from other systems. Although clinical data through EHR uses standard messaging systems to a limited extent to exchange data, support for PHR is minimal.

Domain specific ontologies are hard to find and their suitability for the proposed prototype needs to be verified. Food ontologies have been used in various academic research (Alhazbi, Alkhateeb, Abdi, Janahi, & Daradkeh, 2012; C.-S. Lee, Wang, & Hagras, 2010; Snae & Bruckner, 2008) to get data semantics. Very few food ontologies are known such as the Wine and Food Ontology, Eurocode2, ITACA (Cantais et al., 2005) and the food category available on bioportal[27]. Only ITACA has nutritional information on food. In the New Zealand context there is a reasonably comprehensive food and nutrition database viz. New Zealand Food Composition Database[28]. The data therein is formatted in CSV, XML which is easily exported to another database.

Cantais et al. (2005) developed a Personalised Information Platform for Health and Life Sciences (PIPS) based on existing ITACA ontology with nutritional information on different foods. Snae and Bruckner (2008) developed a food recommendation system called Food-Oriented Ontology-Driven System (FOODS) based on three factors namely economical constraint, available ingredients and nutritional value. Food ontology specific to the cultural needs of people was developed and implemented in a project to combat diabetes (Alhazbi et al., 2012). C.-S. Lee et al. (2010) designed a diet recommendation system based on fuzzy ontologies on personal profile, food profile and the third linking personal and food profile.

[27] http://bioportal.bioontology.org/
[28] http://www.foodcomposition.co.nz/concise-tables

An ontology based mapping solution was proposed to achieve data interoperability of heterogeneous data formats from various HIS (Khan et al., 2014). Health standards in HL7 CDA were mapped to Virtual Medical Record (vMR) at the concept and property level. The attributes of the class Observation defined in HL7 CDA were of interest to obtain patient's health data such as blood pressure, BG readings and pulse.

Data interoperability is not just the issue in clinical systems, it is prevalent in data warehousing and e-business where data from heterogeneous sources needs to be brought together in one system. The literature from non-clinical systems is useful in the current body of work to consider data integration from mobile wellness apps.

3.6 Developing New Data Schema

Nahm et al. (2010) presented a methodology to standardise the smallest unit of data called '*data element*' in a clinical environment. Building such data elements allows data exchange and knowledge representation and can have secondary use of such data for analytics. The data elements were built based on (Rector, Rogers, & Taweel, 2004) framework: stakeholder engagement from primary and secondary data uses, identification of data in patient care and natural language definition of data. Data elements are built based on the ISO 11179 standard and UML diagrams such as class diagram and activity diagram. The methodology approach is now used in HL7 to define data elements in different clinical areas.

Emerging new wellness data from devices such as smartphones and home devices were discussed (Mori et al., 2013). The re-use of such data needs to be in such a format that the semantic interoperability is achieved.

Processing data as unstructured text is not suitable for further processing. Classifications such as ICD are for statistical calculation on population data and lack details; SNOMED CT has multiple representation for the same concept; Archetype and Domain Clinical Models (DCM) are organisation specific; representation of data as ontology for semantic web is still in its infancy. Stakeholders from different countries need to arrive at a consensus to accept current Health Informatics Standards such as HL7 CDA, HL7 RIM, FHIR to extend to new emerging wellness data.

3.7 Open Platform

Software systems developed on open standards will have better acceptance from third party vendors and other systems. Data interoperability has been an issue in clinical

systems and will be relevant in a patient-centred health and wellness management system. Hence a standard for such shared health data needs to be adopted in the open architecture systems with software programs called API written to support most medical devices and mobile apps. Collaboration with different industry partners is essential for long term sustainability.

Publicly available application programming interfaces (APIs) have the potential to share patient generated health data from participating mobile apps and sensor devices to build a software ecosystem. Data interoperability can be achieved through this approach. Individuals have access to their health and wellness data and can share it with clinicians. Such practices are recommended by researchers (Hull, 2015; Mandl, Mandel, & Kohane, 2015).

Gay and Leijdekkers (2015) developed an Android app to connect to third party devices and back end servers to integrate data from these devices into the app. The open standards used in wireless technology and acquiring APIs from third party partner devices and apps have helped progress in creating an app. The researchers have even connected the app to EHR systems such as Microsoft HealthVault and Google Health.

Technology enabled health ecosystems are emerging where systems are integrated with mobile apps and personal wellness monitoring devices such as glucose meter, blood pressure monitors and weighing scales. PHR system such as Microsoft HealthVault has integrated over 200 devices with over 100 apps.

IBM introduced Greenolive, an open platform for wellness management (L. Zeng, Hsueh, Chang, Chung, & Huang, 2010). The intention was to connect and integrate different apps and devices for a single user to monitor wellness. The platform is not supported anymore and IBM has introduced Bluemix; an open platform based on PaaS for developing and deploying mobile apps (Hsueh, Chang, & Ramakrishnan, 2016). The APIs available should make it easy for developers to easily build applications on this platform and store the mobile data in a cloud based system. The app can share data with other systems.

Open mHealth (Estrin & Sim, 2010) has the architecture of an hourglass with a narrow waist similar to internet protocol for data transfer. The narrow waist allows health specific data standards which have semantic meaning in different systems. The architecture allows for patient managed health and wellness data in mobile apps and

other interacting devices. Schema for health data such as BG readings, blood pressure are defined in open mHealth. The schema are linked to health standards such as SNOMED CT, LOINX and RxNORM. This makes it easy for developers without a health background to develop apps using Open mHealth to connect to one ecosystem.

Although there are efforts from different organisations to offer an ecosystem to develop new mobile apps and share on a cloud based system, there is limited evidence of such adoptions and practices. App developers need to build apps using open standards which aid in sharing a patient's health and wellness data with clinicians.

There is limited published research on how data from various suitable mobile wellness apps and glucose meters can be integrated in a clinical setting. The research to be undertaken asks the question: how should wellness data such as food, diet and BG readings from heterogeneous sources be mapped in order to generate standardised reports to clinicians to aid in the self-management of GDM.

The outcome of the research will enable the integration of mobile wellness data and support clinicians in managing lifestyle change and clinical decision making. It will help in health interventions for treatment and the self-management of GDM.

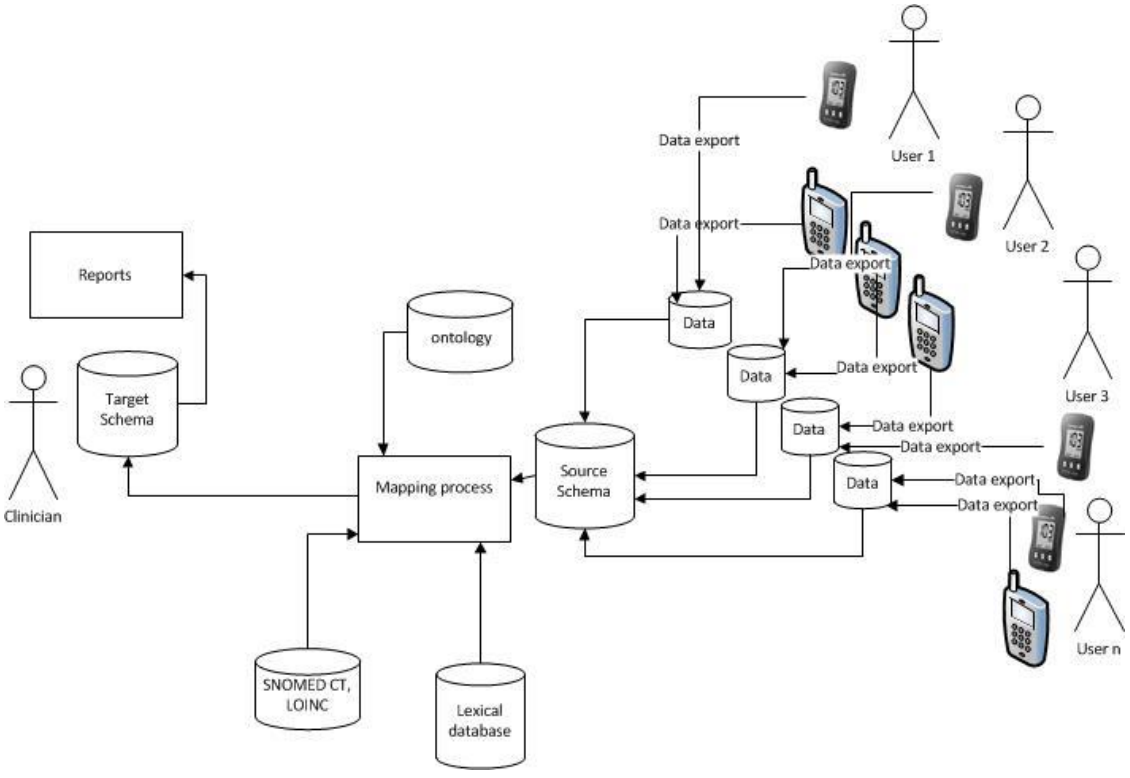

Figure 3.3: Data Integration of Mobile Wellness Apps and Wellness Devices

In order to realise the potential in building a data integration prototype as depicted in Figure 3.3, the literature about clinical data, personal health record system and data interoperability is researched in depth under different sections.

After reviewing the literature on data integration techniques to allow data interoperability and considering the clinical standards, terminologies and health exchange standards, the approach for designing systems which are useful and easy to use for end users is explored. It would be interesting to know if end-users are involved in the design of health related systems and what methods would suit them best.

Research in the area of Human Computer Interaction has contributed to designing useful and usable systems. One such approach is a user-centred design which is discussed in depth in the following Section 3.8.

3.8 User-centred Design (UCD)

UCD is a term used when users and different stakeholders are involved in the design process from the initial stages to the final product. Norman (1986) stated that for the user the interface is the system. Thus the design of the interface must start from the user requirements. The interface design determines the technology required to build the system.

3.8.1 UCD Definition

"User-centred design emphasizes that the purpose of the system is to serve the user, not to use a specific technology and not to be an elegant piece of programming. The needs of the users should dominate the design of the interface, and the needs of the interface should dominate the design of the rest of the system." (Norman, 1986)

There is no clear definition of UCD (Karat, 1996) and as such the techniques and methods used to involve users in the design varies. Users have the domain knowledge in their particular profession and lack technological expertise to design useful systems. Communication is a major hurdle in getting consensus from different users and it is recommended to be improved through prototypes, mock-ups and videos (Gulliksen & Lantz, 2003).

3.8.2 UCD Principles

Gould and Lewis (1985) introduced three principles in designing a computer system.

1. Early focus on users and tasks: Identifying the different users for a system is crucial in the beginning to understand their cognitive, behavioural, anthropomorphic and attitudinal characteristics.
2. Empirical measurement: The design and evaluation of the system from early stages as mock-ups, prototypes to the final system are recorded, measured and analysed.
3. Iterative design: User testing helps in identifying problems in the design of the system which are fixed in the next iteration. Thus the design of the system is iterative repeated in multiple cycles of design, test, measure and redesign.

Later a fourth principle was added (Gould, 2000) as stated below.

4. Integrated design: All usability aspects are managed by one group with a single focus and usability activities run in parallel. This will have greater control on the design. Designing the user interface and writing the user manual simultaneously and reviewing and editing the process has a tighter control on the design.

Norman (1988) used the UCD terminology to define principles for good design based on usability issues:

1. Use the knowledge in the world and in the head. Three different conceptual models were defined: the design model, the user's model and the system image. The conceptualisation of the design in the designer's mind needs to be equivalent to the user's model. They both communicate this through the system image (interface). Hence all three aspects are important to design a model that is functional, learnable and usable. The user manual must be planned together with the design and updated with the changes in design. This links the ideas from designer to user and feeds back to the designer.
2. Simplify the structure of tasks. The designer should use technology to simplify the tasks making it visible to receive feedback.
3. Design for error. Design should help user to come out of an error and have another opportunity to complete the task.
4. Standardise. When all design concepts fail, then standardise how the task can be accomplished. The user will learn to do it correctly the next time.

These principles are difficult to follow unless there are clear guidelines. The designer is working as a team with other designers, users and stakeholders and hence the aspect of working as a team is important.

Gulliksen et al. (2003) defined 12 sets of principles about UCD after lessons learnt through the development of a software project. They added additional principles to those previously stated (Gould, 2000; Gould, Boies, & Ukelson, 1997; Gould & Lewis, 1985). The design process should be simple and easy to understand by all users. Documentation using Unified Modelling Language (UML) is difficult to read for users. Small incremental changes in continuous prototyping can involve users actively and be user focused. Usability goals should be under control while achieving the design criteria. Although the design team expects people from multiple disciplines, their experience witnessed that usability experts' opinions were ignored towards the end of the project as goals and deliverables were important to be met. A professional attitude is required among users so that it is not an individual's goals which dictate the design.

3.8.3 UCD Practice in Industry

A survey of UCD practice in industry (Vredenburg, Mao, Smith, & Carey, 2002) yielded in-field analysis and iterative prototyping. Informal methods were more popular than formal methods such as focus groups. Task analysis was achieved through indirect sources rather than using real users. The industry projects were pressured for time and as such informal methods were utilised. Heuristic evaluation methods were used as they were cost effective (Mao, Vredenburg, Smith, & Carey, 2005).

UCD principles have been utilised in health related systems involving stakeholders at different levels. Examples of such system design is useful in the current body of work to lead the research process in the right way. Hence prototypes and systems built using the UCD process from literature, are a good starting point to shape the current body of research.

3.8.4 Health Related Systems using UCD Principles

Fonda, Kedziora, Vigersky, and Bursell (2010) developed a prototype to aid in diabetes self-management adopting UCD principles. The researchers met focus groups and developed the prototype in stages with feedback from users at every revision. The prototype received data from a PHR for decision support. Microsoft HealthVault was the chosen PHR as it had built-in authentication and security features.

The prototype built had the following functionalities for diabetes self-management.

a) Healthy eating – keeping track of food consumed with portion size and nutrition.
b) Being active – keeping track of physical activities and calories burned, using a monitoring device integrated with the PHR.
c) Monitoring – All clinical laboratory tests were recorded in the PHR and glucose meter readings were integrated with the PHR.

Martin, Clark, Morgan, Crowe, and Murphy (2012) embraced UCD and used open ended semi-structured interviews early on in the design of the medical device to obtain user requirements from clinical users. Their experience using this approach had enough details for the developers to design a potential device which was safe, clinically effective and easy to use.

A prototype on breast cancer information (Burstein, Fisher, McKemmish, Manaszewicz, & Malhotra, 2005) was built using metadata repository collected through a user-centred approach. The search engine strategies were built on a user profile which had rich insights from cancer patients helping to design the prototype for other users. Initially the prototype was built using focus groups and interviews with various cancer patients. The repository had reliable information suitable for a user.

A review of mobile apps design using UCD (Hermawati & Lawson, 2014) highlighted that the end users were involved in designing and evaluating the app prototype and some of the qualitative methods involved were interviews and focus groups. However although the group of users were multidisciplinary the design lacked theories about behavioural change.

Recommendations were made for the use of EHR systems to improve the quality of care of patients which was realised by a group of academics and EHR vendors initiated by the AMIA Board of Directors (Middleton et al., 2013). Among the recommendations the foremost was on improving usability for effective UCD systems. Although some EHR vendors adopted UCD principles the practice was not universal. Standardised use cases depict the required functionalities and these can be shown through common user interfaces. The user will have less cognitive load while learning new EHR systems. The EHR systems should also adhere to the Meaningful Use guidelines initiated by Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health IT (ONC).

3.9 Evaluation Methods in UCD

Evaluation methods were explored with reference to UCD. Van Velsen, Van Der Geest, Klaassen, and Steehouder (2008) reviewed 63 studies related to user-centred evaluations and found most were on three variables: usability, perceived usefulness and appropriateness of adaptation. In 37 cases formative evaluation was done in the design phase, 18 studies had summative evaluation at implementation and the remaining eight could not be identified as either summative or formative. In 47 cases questionnaires were used to evaluate usability, perceived usefulness and intention to use, followed by 27 cases where interviews were used. Data logs, focus groups, think-aloud protocol and expert reviews (Ghulam Sarwar Shah & Robinson, 2006) were other forms of user-centred evaluation. Qualitative analysis of interview transcripts was also used more commonly in user-centred evaluations.

Although a conceptual framework of UCD involves users in the iterative development of the prototype with continuous feedback, not much is known about how a patient-centred decision support system is built using UCD (Witteman et al., 2015).

Schnall et al. (2016) adopted the Information System Research framework comprising three cycles of Relevance, Rigour and Design (Hevner, 2007) in designing a mobile app for health intervention. UCD methods such as focus groups were employed in the Relevance Cycle to realise the needs and requirements of the end-users. Similarly usability studies helped in the Design Cycle by improving the design in each iteration. The rigour cycle comprised of the review of technology related interventions to meet the purpose of building a new mobile app.

The three cycles of Relevance, Rigour and Design are part of the DSRM followed in the current body of work as the overarching research methodology as outlined in Chapter 4 Research Methodology. The main emphasis is to build and evaluate an artefact. Hevner, March, Park, and Ram (2004) suggested seven guidelines in building and evaluating an artefact. Evaluation of the artefact and adoption factors are borrowed from information systems evaluation methods and technology adoptions theories.

3.10 Evaluation Methods in Design Science Research Methodology

DSRM emphasises the build and evaluation of an artefact. Various types of artefacts can be built. Artefacts need not necessarily be an instantiation of the IS system, it could also include the construct, model and method (Hevner et al., 2004; Peffers,

Rothenberger, Tuunanen, & Vaezi, 2012) to build the IS system. Constructs are concepts, symbols to define the problem and to provide a solution. For example the Entity-relationship diagram (ERD) (Chen, 1976) is an example of a construct which defines the data schema and structure. ERD concepts are well known for building a stable relational database system for IS systems. A prototype is the implementation of an artefact to demonstrate its main utility.

Although various evaluation methods are described in DSRM, there are no guidelines on the suitability of an evaluation method for a particular type of artefact (Peffers et al., 2012; Venable, Pries-Heje, & Baskerville, 2012).

Venable et al. (2012) identified two types of artefacts: product and process. Evaluation of an artefact depends on the type of artefact. Product artefacts are built as a tool or software. A process artefact is a guide to accomplish a task. For example method, procedure, symbols. Product artefact can be technical or socio-technical. Socio-technical artefacts involve users to interact with them to validate its utility. Based on the evaluation methods described in literature (Hevner et al., 2004) five classes of evaluation methods are described: descriptive, observational, analytical, experimental and testing methods including white box and black box. The observational method could include a case study and field study. Analytical methods include an analysis of the performance of the architecture. Experiments can be controlled or simulated. Descriptive methods include scenarios with arguments. Further based on their previous framework (Pries-Heje, Baskerville, & Venable, 2008), the various DSRM evaluation methods in naturalistic and artificial environments for ex ante and ex post are demonstrated in Table 3.2. Selecting one set of ex ante or ex post evaluations may not resolve complex conflicting goals. Thus a hybrid strategy may be required in such cases.

Table 3.2: DSRM Evaluation Method Selection Framework (Adapted from (Venable et al., 2012))

DSRM Evaluation Method Selection Framework	Ex Ante	Ex Post
Naturalistic	• Action Research • Focus Group	• Action Research • Case Study • Focus Group • Participant Observation • Ethnography • Phenomenology • Survey (qualitative or quantitative)
Artificial	• Mathematical or Logical Proof • Criteria-Based Evaluation • Lab Experiment • Computer Simulation	• Mathematical or Logical Proof • Lab Experiment • Role Playing Simulation • Computer Simulation • Field Experiment

Peffers et al. (2012) reviewed 148 DSRM articles in IS, CS and engineering journals. They analysed different evaluation methods associated with an artefact type. The results of such an analysis will give confidence to DS researchers to choose and justify an evaluation method. Most research in engineering and CS had technical experiments conducted on an algorithm developed. Case study evaluations using qualitative analysis were common in IS journals. Case studies are criticised for not being generalised. However multiple case studies were undertaken by Wagter, Proper, and Witte (2013) to test the theory on building an enterprise architecture. Observations and interview questions were based on the case study data collection (Yin, 2009).

Mettler, Eurich, and Winter (2014) found that 96% of DSRM evaluations through experiments were in a lab setting. 70% of the experiments included a survey questionnaire on artefact demonstration and interaction with users. They further found that the objectives of evaluation were effectiveness 34%, usability 22%, efficiency 14%, comprehensibility 6%, economic factors 2% and other/unclear factors 22%. Thus most objectives were to identify effectiveness of the artefact and to determine usability which makes the artefact easy to use.

Further to evaluation, adoption and acceptance theories used in DSRM are reviewed for its suitability in the current body of study. Known theories such as usability studies

from Human Computer Interaction, technology acceptance and technology adoption (Yen & Bakken, 2011) are applied to evaluation of DSRM.

3.11 Technology Acceptance Model (TAM)

Technology Acceptance Model (TAM) is an information systems theory that models how users accept a new software system. It is widely used in IS evaluations (Holden & Karsh, 2010; Y. Lee, Kozar, & Larsen, 2003; Legris, Ingham, & Collerette, 2003). In most cases with a large number of participants, a quantitative analysis survey is undertaken. The model suggests two main factors that will influence users on their decision in accepting technologies:

- Perceived usefulness (PU) - Davis defined it as "the degree to which a person believes that using a particular system would enhance his or her job performance".
- Perceived ease-of-use (PEOU) - Davis defined it as "the degree to which a person believes that using a particular system would be free from effort" (Davis, 1989).

TAM developed in the 1980s suggests PU and PEOU as two main factors for behavioural intention (BI) to use (Davis, 1989) a new system. TAM has been widely applied in different information systems. Holden and Karsh (2010) reviewed over 20 studies of clinicians using HIS for patient care. Most studies used TAM as a theoretical framework to design a survey questionnaire.

According to Lim, Saldanha, Malladi, and Melville (2009) and Bichler et al. (2016) TAM is the most prominent theory used in IS research. Purao and Storey (2008) demonstrated that TAM can be used to evaluate DSRM efforts. DSRM in many cases is a proof of concept, as such a case study and observation type of evaluation is difficult to achieve. Hence TAM measure for perceived usefulness and perceived ease of use was used to evaluate the potential for adoption among potential.

Freundlieb and Teuteberg (2012) used TAM to evaluate the prototype implementation in their DSRM approach. Interviews were conducted after the survey questionnaire to obtain positive and negative feedback on their prototype. Qualitative results on the feedback contributed to a deeper understanding of usability issues and led to improvements in the prototype. Haugstvedt and Krogstie (2012) used TAM to evaluate the mobile augmented reality application built using the DSRM approach. The

prototype was built on the principles of usability and the survey questionnaire on perceived usefulness and ease of use demonstrated the participants' intention to use the application.

TAM2 (Venkatesh & Davis, 2000) includes additional constructs to perceived usefulness such as subjective norm, experience, job relevance. In the current body of study, as the clinicians have similar experience using other clinical systems, these factors are not considered. However as TAM evaluation depends on the users' opinion and their experience, a small sample may not be sufficient. Hence other forms of evaluation through usability using qualitative analysis are required.

3.12 Usability

Usability is a means to evaluate a new system for its effectiveness which enables intended users to carry out their tasks with ease. ISO 9241-11 defines usability as:

"The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use."

ISO 9126 defines six main characteristics: functionality, reliability, usability, efficiency, maintainability, portability.

Effectiveness is testing the software application for all functional and non-functional requirements. It also tests accuracy and completeness by which users achieve specified goals. Efficiency is assessing an artefact for its performance in comparison with another solution.

Several usability principles for EHR systems have been proposed in literature (Middleton et al., 2013; Yen & Bakken, 2011; J. Zhang & Walji, 2011) which are considered in the design and evaluation in the current body of work. Journals such as AMIA, Journal of Medical Internet Research (JMIR) have research articles on recommendations to resolve EHR usability issues with special reference to patient safety and privacy. Use-cases are suggested to establish EHR functionalities such as correct patient selection, correct clinical documentation about the patient.

3.13 Related Studies using TAM and Usability

Lin (2013) proposed a combined research model where usability attributes were included to find their relationship with TAM attributes. Effectiveness and efficiency attributes were defined to determine their correlation with perceived usefulness.

Similarly learnability and memorability were defined to find their relationship with perceived ease of use.

A small sample of eight users were considered in the research study (Lin, 2013) although five were found to be sufficient (Nielsen & Landauer, 1993; Virzi, 1992) to identify 80% of usability issues. TA protocol was used to measure usability attributes on task time, errors, dwell and search time. The users then completed the TAM questionnaire. More participants were chosen for the TAM survey to get credible results. Their findings reveal that TAM results contradict the usability test results in areas such as effectiveness. However learnability and memorability were consistent with TAM perceived ease of use.

Benbunan-Fich (2001) used three evaluative criteria to analyse think-aloud protocol. The criteria: content, navigation and interactivity had evidence of evaluating usability issues for a web site. Think-aloud transcripts were used to identify and tabulate all the problems interacting with the interface. They were categorised by the main criteria and design solutions were recommended.

Money et al. (2015) employed think-aloud protocol and semi-structured interviews with 10 participants to realise the perceived adoption of technology. Initially a deductive themes based on TAM variables about PU, PEOU and actual use were employed. An inductive approach for sub-themes from the interview transcripts was applied for the TAM variables. The themes for actual use were a clear indication that the use of technology would be limited and that the older adults would need the practitioner's assistance.

Cervera, Albert, Torres, and Pelechano (2015) used the TAM and TA protocol as combined methods of measurement for usefulness and ease of use. TAM provided the subjective evaluation of the new system developed while TA allowed the tool to be evaluated objectively. They obtained consistent positive results for PU and PEOU using the two methods.

3.14 Summary

In order to build an ecosystem capable of accepting suitable mobile app data, issues and solutions around data interoperability were considered. Data from heterogeneous sources (different mobile apps of patients' choice and suitable for clinical consultations) to be combined in an ecosystem were sought. Data interoperability has been an issue in

clinical systems and patient data is stored in silos not available for sharing. In most cases this was due to concerns around data privacy and security. However when patients migrate from one medical centre to another their existing data is not transferable. World wide there is a need for shared data driven systems for better informed consultations and decision making (Bodenheimer, Ghorob, Willard-Grace, & Grumbach, 2014).

Clinical standards and health information exchange standards have aided to some extent to maitain the semantic meaning of clinical data. However such standards are not sufficiently defined for wellness data. A review of exisitng standards and the potential to extend these for wellness data is explored in this chapter.

Usability issues have resulted in the low adoption of clinical systems. The background of designing systems on principles such as UCD will eliminate known issues of usability. TAM has also been a popular method to evaluate the PU and PEOU of a system. A review of exisitng literature helped to adopt some of the methods in the current body of work.

4 Research Methodology

The main methodology followed in the body of work was Design Science Research (DSRM). DSRM has gained significant importance in Information Systems (IS) research and is expanding to other allied fields such as Computer Science (CS) and engineering (Peffers et al., 2012). March and Smith (1995) proposed a simple definition of DSRM - Build an artefact and evaluate it. Although the main objective of DSRM remained the same, the research process of building and evaluating an artefact is defined by various researchers through guidelines and frameworks

4.1 Design Science Research Methodology (DSRM)

Hevner et al. (2004) suggested seven guidelines to design and develop an artefact to solve a business problem as depicted in Table 4.1. The business problem could be specific to an organisation or generic across organisations. Not all guidelines need to be followed or need to be in the order stated. An artefact is built based on innovative ideas demonstrating a technical capability which may not be developed as a complete IS. It can be a conceptual model such as mathematical proof or proof of concept to demonstrate the artefact. The artefact so built needs to be evaluated for quality and efficacy as part of the behavioural science theory. The artefact is also evaluated for utility in solving a given problem.

Table 4.1: Design-Science Research Guidelines (Adapted from ((Hevner et al., 2004)))

Guideline	Description
Guideline 1: Design as an Artefact	Design science research must produce a viable artefact in the form of a construct, a model, a method or an instantiation.
Guideline 2: Problem Relevance	The objective of design science research is to develop technology-based solutions to important and relevant business problems.
Guideline 3: Design Evaluation	The utility, quality and efficacy of a design artefact must be rigorously demonstrated via well-executed evaluation methods.
Guideline 4: Research Contributions	Effective design-science research must provide clear and verifiable contributions in the areas of the design artefact, design foundations, and/or design methodologies.
Guideline 5: Research Rigor	Design-science research relies upon the application of rigorous methods in both the construction and evaluation of the design artefact.
Guideline 6: Design as a Search Process	The search for an effective artefact requires utilising available means to reach desired ends while satisfying laws in the problem environment.
Guideline 7: Communication of Research	Design-science research must be presented effectively both to technology-oriented as well as management-oriented audiences.

Vaishnavi and Kuechler (2008) and Peffers, Tuunanen, Rothenberger, and Chatterjee (2007) provided frameworks and guidelines to conduct DSRM as projected in Table 4.2. These are compared to the guidelines provided by Hevner et al. (2004) where similar trends are observed.

Table 4.2: Comparison of Design-Science Frameworks and Guidelines

Hevner et al. (2004)	**Vaishnavi and Kuechler (2008)**	**Peffers et al. (2007)**
Design as an artefact	Development	Design and development
Problem relevance	Awareness of problem	Problem identification and motivation
Design evaluation	Evaluation	Evaluation, demonstration
Research contributions	Conclusion	Part of communication
Research rigor	Suggestion	Demonstration
Design as search process	Iterative process	Demonstration, evaluation and iteration if necessary
Communication of research	Conclusion	Communication

The iterative nature of designing and building an artefact is identified in all cases and was previously stated by Markus, Majchrzak, and Gasser (2002). IT artefacts are classified (Hevner et al., 2004) as constructs (vocabulary and symbols), models (abstractions and representations), methods (algorithms and practices) and instantiations (implemented and prototype systems). These constitute well defined prescriptions for researchers and practitioners to develop information systems (March & Smith, 1995) (Nunamaker Jr, Chen, & Purdin, 1990). Walls, Widmeyer, and El Sawy (1992) defined the Information System Design Theory (ISDT) where four components are defined as demonstrated in Table 4.3. Nunamaker Jr et al. (1990) demonstrated the concept of using existing theories, contributing to existing theories and creating new knowledge through the multi-methodological approach.

Table 4.3: Components of an Information System Design Theory (ISDT) (Adopted from Walls et. al., 1992)

		Design Product
1.	Meta-requirements	Describes the class of goals to which the theory applies.
2.	Meta-design	Describes a class of artefacts hypothesized to meet the meta-requirements.
3.	Kernel theories	Theories from natural or social sciences governing design requirements.
4.	Testable design product hypotheses	Used to test whether the meta-design satisfies the meta-requirements.

Weber (1987) described the importance of theory in evaluating an IS design.
"Researchers show how their designs are based in some theory of information systems. The theory can be used to predict the likely success or failure of a design and these predictions can be tested empirically. Traditional evaluation criteria can then be applied".

Although the use of theory and knowledge contribution in IS research is required there is no real evidence of it (Gregor, 2006). Of the five theories defined by Gregor (2006), '*design and action'* was related to artefact design with the process guided through methods and techniques. In recent publications design theory has been overlooked as an outcome in DSRM (Venable, 2013) and only 27% of the articles published in DSRM related journals used kernel theories (Thakurta, Müller, Ahlemann, & Hoffmann, 2017). Walls, Widmeyer, and El Sawy (2004) examined the various DSRM articles and the use of ISDT in these articles by researchers and asserted that there was no guidance on kernel theories. This would be the nature of applying innovative ideas in creating an artefact. Hevner et al. (2004) suggested that the artefact itself is the research outcome. The artefact which is an innovative solution to an unsolved problem may extend the knowledge base or apply existing knowledge in an innovative way. March and Smith (1995) had earlier argued that theory is not an end outcome of DSRM.

The design and build of an artefact with defined user requirements dictate the iteration of build and evaluate. This rigorous process results in a product which address the business problems and is relevant in the organisation where it needs to be applied. In the process of discovering requirements to build an artefact interviews with experts in the field are useful.

Hooker (2004) argued that design cannot be theorised as design is a practice which follows pre-theoretical principles. Three cycles of DSRM: Relevance, Design and Rigour will guide the iterative cycles of design and evaluation.

Several evaluation methods for artefact are discussed by Hevner et al. (2004) such as observational: case study and field study; experimental: controlled and simulation. Pries-Heje et al. (2008) proposed a framework as a 2 x 2 diagram for a DSRM evaluation of the IT artefact. The four quadrants of the diagram represented the ex ante and ex post along with naturalistic and artificial settings. Ex ante is evaluation prior to the construction of the artefact. It evaluates the design specification to determine whether or not to proceed with the proposed artefact. On the other hand, ex post is

evaluation of the artefact after its construction. In a naturalistic setting real data are established through experiments and user feedback. Abstract (artificial) settings are those where historical data and user opinions are used in experiments.

Vaishnavi and Kuechler (2008) and Peffers et al. (2007) have identified a similar set of guidelines such as problem identification, design, develop and evaluate artefact in an iterative way, conclude and communicate the research contributions. Once the artefact is built and evaluated it contributes to the knowledge base. The process needs to be well communicated with the wider community and stakeholders. Gregor and Hevner (2013) outlined a publication pattern for a DSRM. The artefact description is a major component of the publication, where it is defined with an appropriate level of abstraction.

4.2 Problem Identification

The current body of work was to evaluate and demonstrate the utility of the artefact as a proof of concept in a practical situation of patients at a GDM consultation clinic.

Over the last few years the diabetes clinic at Auckland Hospital has been overwhelmed with women with GDM. Most of these women belong to ethnic communities from Asia, South Asia and the Pacific Islands (National Women, 2014).

Public health resources are limited and women are given a free glucometer. Unlike Type 1 diabetes, women with GDM have the diabetes condition for only a short period during pregnancy and have no prior understanding on managing their blood sugar levels. Ex-Ante evaluation explored current technologies such as mobile apps to manage FD and exercise. Most women owned a smart phone, imposing no extra cost on the clinic. Semi-structured interviews analysed the design specifications as part of the ex ante evaluation. Ex post evaluation involved semi-structured interviews and usability studies to explore acceptance of the new system. Similar approaches of conducting semi-structured interviews have been reported. Arnott (2006) conducted semi-structured interviews of the decision support system built for an organisation following the DSRM approach. As the case study under investigation involves exploring contemporary phenomenon of using patient managed wellness data from mobile wellness apps, data sets from patients were not available, hence realistic data sets were constructed. Similar data sets were constructed where no real data was available to evaluate a new workflow mechanism for information distribution through emails (Zhao & Akhil Kumar, 2000).

FD and exercise data were fed into the selected mobile apps and extracted from the mobile apps in the format allowed.

4.3 Research Approach in the Current Body of Work

The DSRM approach undertaken in the current body of work as depicted in Figure 4.1 follows (Hevner, 2007) framework and guidelines.

The DSRM approach offered clear guidelines and framework. The relevant literature and examples gave confidence to design the artefact to prove its utility.

The environment consists of the people in the organisation (diabetes clinic) and depends on the availability of technology to improve the self-management of GDM. However the wellness data from patients relevant at consultation is isolated from the clinical systems. Existing knowledge on PHR, GDM self-management, clinical standards for glucose readings, food databases, nutrition and data integration techniques were required as outlined in Chapter 3 Literature Review to build a socio-technical artefact and add value and contribute to new findings about patient managed wellness data integration for clinical use.

An ecosystem was built to include data from existing wellness apps and a BG meter, which formed the main artefact through a wellness data integration prototype for the research methodology. The prototype received input from data extracted from wellness apps and glucose meters and generated required reports for clinicians.

The research process was guided through theories and solutions identified from various domains to build an artefact to solve a new problem in the organisation. Such a process is described as exaptation (Gregor & Hevner, 2013). The diabetes clinic has patients who have access to smart phones and are using mobile apps to track their exercise and FD. The main new problem is their usage of a range of apps which are not integrated to the IT systems used in the clinic.

Existing PHR and EHR systems do not send patient data from one system to another seamlessly. Clinical standards such are LOINC, HL7, SNOMED CT are used to represent clinical data about patient's diseases and improve the semantic meaning of the data. Such a lack of data integration of heterogeneous sources is not a problem restricted to the clinical world but has been an issue in data warehousing. Although solutions such as ontologies have been published in literature, creating a new ontology for FD does not

suffice as it needs to be of a standard used universally. Hence known standards for clinical data which included diseases, food and diet are of interest in the current body of research.

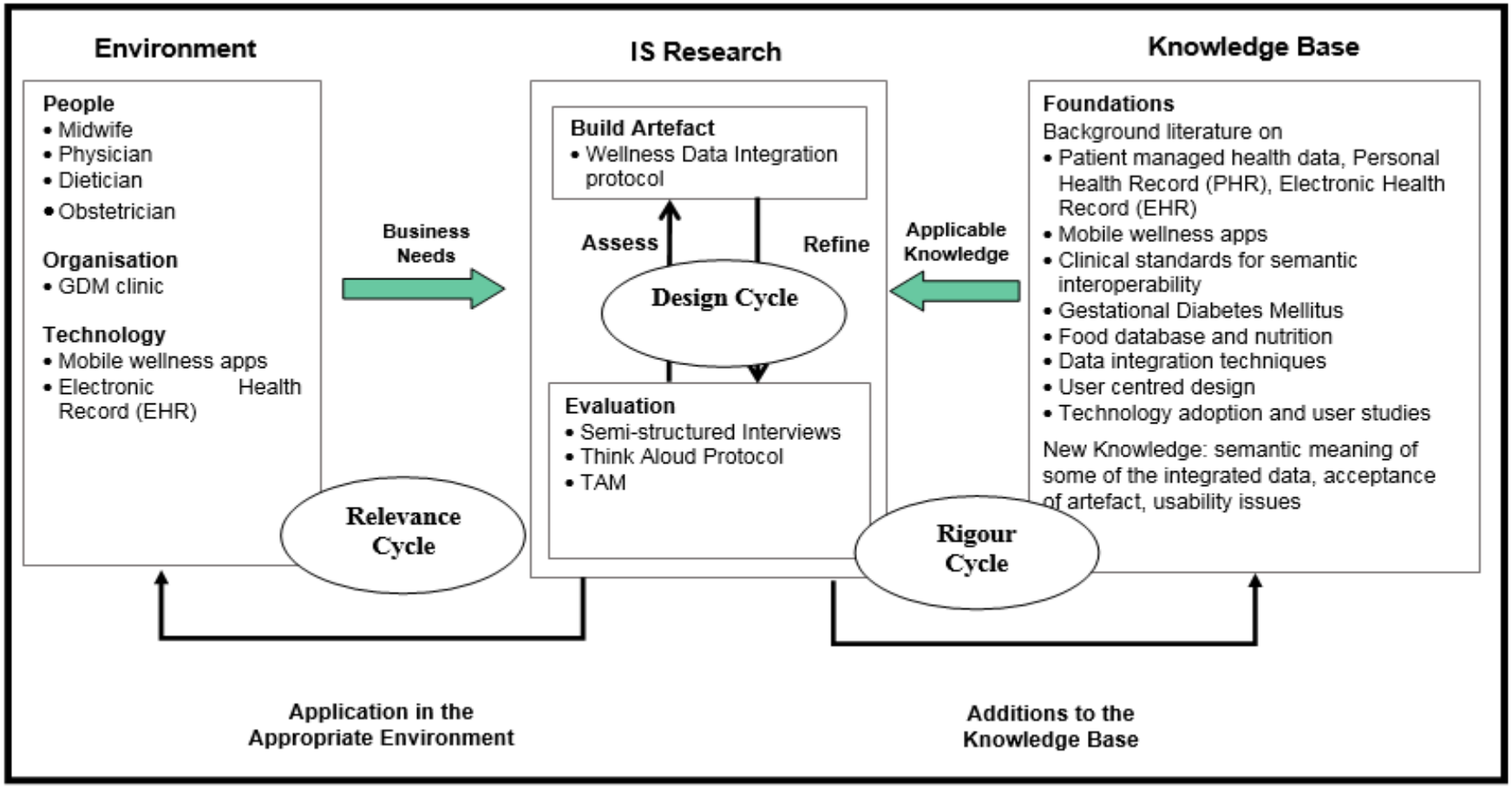

Figure 4.1: Research Approach (Adapted from (Hevner, 2007))

4.4 Ethics Approval

Ethics approval from the AUT Ethics Committee was obtained as the research study involved clinicians and women with GDM. Participation was voluntary and all data collected was securely stored as per guidelines from AUTEC.[29] Research participation invitation was displayed in the staff room at Auckland District Health Board, Women's Health Maternity / Pregnancy Care, Diabetes Centre. Potential participants responded to the invitation through email to the researcher. Participants were then emailed back with an information sheet and a consent form. They were requested to respond within a week. Once the clinicians (physician specialist, obstetrician, midwives and dieticians) had responded, five clinicians were randomly chosen for interviews and usability testing to evaluate Prototypes Version 1 and 2.

More participants were required to evaluate Prototype Version 2. A second research participation invitation was communicated as before. Of the respondents, a further five clinicians were randomly selected for interviews and usability testing to evaluate Prototype Version 2. Thus five of the original participants and five new participants evaluated Prototype Version 2.

Printed invitations were given to clinicians to invite patient-participants to review Prototype Version 2. Of the respondents, five patients were randomly selected for interviews and usability testing to evaluate Prototype Version 2. Thus a total of fifteen participants reviewed prototype Version 2.

There was a mixed practice in the clinic where some women used mobile apps such as MyFitness Pal, mySugr to keep a log of food consumption and exercise details while others used electronic spreadsheet templates and paper diaries. It is expected that such mobile apps usage will increase in future. Apps such as MyFitness Pal had the ability to share patient data through a web portal. Individual apps had their own portal and there were no means to automatically extract data into the wellness prototype. Hence actual patient data was not used in the prototype. Realistic wellness data was created through suitable mobile apps which could export data in a suitable format for the evaluation of the prototype. The data was validated by clinicians in the first iteration of Prototype 1 review.

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[29] http://www.aut.ac.nz/researchethics/guidelines-and-procedures/final-storage-of-data-and-consent-forms-18

4.5 Participants' Profile

Five participants with various roles in GDM consultations responded to the invitation to provide requirements and feedback in building the ecosystem. These participants provided the requirements in building the ecosystem prototype and participated in the Ex ante mock-up prototype interviews, ex ante Prototype Version 1 review interviews and ex ante Prototype Version 1 TA protocol sessions. There were two dieticians, two obstetricians and one midwife among the participants as depicted in Table 4.4. The role of the physician was missing among these clinicians being part of the diabetes care team, which was fulfilled by a physician providing necessary information, guidance and feedback as an advisor. The participant details were kept anonymous including their job role in the clinic.

Table 4.4: Participant Role and Profile

Role	Profile	Design and Evaluation Method
Dietician	Nutrition assessment of patients with gestational diabetes.	Semi-structured Interviews 1(INT1), Semi-structured Interviews 2 (INT2), Think Aloud Protocol 1 (TAP1), Think Aloud Protocol 2(TAP2), Semi-structured Interviews 3 (INT3)
Obstetrician	Provide care during pregnancy and birth whose pregnancy had complication set in because of gestational diabetes.	Semi-structured Interviews 1(INT1), Semi-structured Interviews 2 (INT2), Think Aloud Protocol 1 (TAP1), Think Aloud Protocol 2(TAP2), Semi-structured Interviews 3 (INT3)
Midwife	Provide primary care related to gestational diabetes during pregnancy, monitor weekly/fortnightly progress.	Semi-structured Interviews 1(INT1), Semi-structured Interviews 2 (INT2), Think Aloud Protocol 1 (TAP1), Think Aloud Protocol 2(TAP2), Semi-structured Interviews 3 (INT3)
Women with GDM	Diagnosed for GDM and has no prior diabetes condition.	Think Aloud Protocol 2(TAP2), Semi-structured Interviews 3 (INT3)

More participants were recruited for the evaluation of Prototype V2 as discussed in Chapter 4 Section 4.4 Ethics approval. Women with GDM were part of the participants evaluating the prototype V2 in ex post TA protocol sessions, and review interviews.

The research questions were investigated in depth via the construction and evaluation of a prototype with the goals being:

- To capture heterogeneous data from various mobile wellness apps to support lifestyle change and clinical decision making in the management of GDM.

- To use data integration tools, allowing semantic interoperability using clinical standards, food and nutrition values.

- To evaluate the prototype in partnership with end users (clinicians and women with GDM) for its effectiveness, efficiency and acceptability (adoption).

The following criteria were used in evaluating the prototype.

1. Appropriate data source (wellness data) from mobile apps was acceptable by clinicians.

2. The prototype effectively maps heterogeneous data to a global schema defined in the prototype.

3. The prototype generates appropriate reports to clinicians from the translated and mapped data.

4. The prototype interface is easy to use, effective and reliable.

Criterion 1 was tested with a set of datasets captured from mobile wellness apps. These datasets required some manual cleaning and this was discussed with the clinicians to reach consensus.

Criterion 2 tested the prototype to determine whether the data source (input) was mapped successfully to the target source in the prototype. The program code was tested through white box testing for any data not mapped appropriately or missed out.

Criterion 3 was tested by clinicians for the appropriateness of reports generated after data integration from various heterogeneous data sources. Semi-structured interviews provided feedback to improve the prototype.

Criterion 4 was tested for usability and acceptance with respect to TAM. TA protocol facilitated the process.

4.6 Prototyping using UCD

Proof-of-concept level prototyping has been discussed in literature about DSRM (Peffers et al., 2007). The prototype was built using UCD involving ex ante and ex post evaluation techniques described below.

In a UCD approach the prototype is built not to justify a technology achievement, but to

fulfil user goals. Gould and Lewis (1985) proposed three principles which utilised in designing a useful and easy to use prototype in the current body of work:

1. Early focus on users and task: In the prototype for clinicians the different users in the 'diabetes in pregnancy' team were identified. Each type of user's requirements were identified. User behaviour and context of use in the current system was discussed in the initial interviews. Limitations of capturing patient maintained wellness data, duplication of certain patient data by various users and inability to collate wellness data in the current clinical system were identified as obstacles for the affected clinicians.
2. Empirical measurement: Specific user tasks are designed to evaluate the prototype at different stages of its development. The TA protocol evaluated the usability and ease of use of the prototype.
3. Iterative design: The software system was developed in two stages as prototype Version 1 and 2 which allowed the design to be refined based on users' feedback.

A robust design process is achieved through application of the principles of UCD and DSRM (Djamasbi, Strong, Wilson, & Ruiz, 2016; Schnall et al., 2016), adding relevance and rigour. UCD can follow the DSRM approach to apply research theories and practices while a UCD approach applied independently can help to structure the design and evaluate it by assigning metric values.

The DSRM process as depicted in Figure 4.2 involved building the artefact as ex ante evaluation from clinicians through semi-structured interviews. Focus group meetings with all clinicians (physician, dieticians, obstetrician and mid wives) together was difficult to conduct because of the nature of the job being on shift duty, working in different premises and availability. A stakeholder requirement analysis document was created to share with clinicians by email. The document contained the scope of the research project, set of requirements, interface design, navigation options and target database schema. It also had a review of available mobile apps to be included in the ecosystem

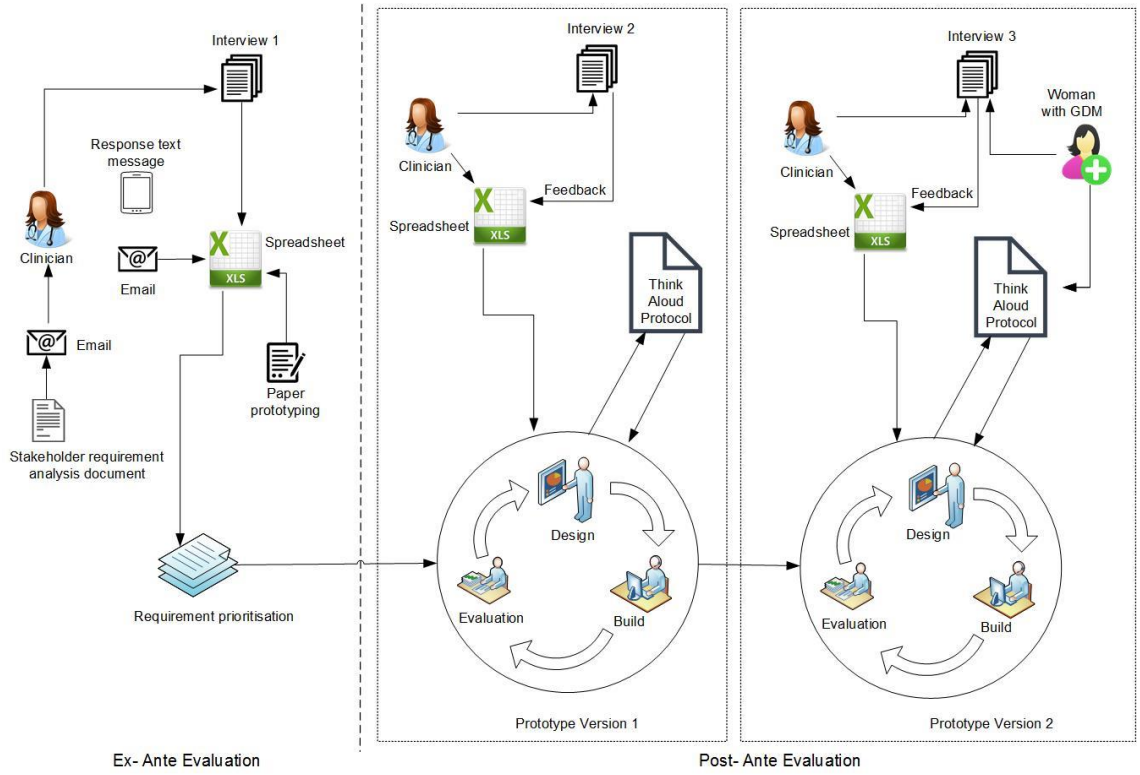


Figure 4.2: Design and Evaluation of Artefact through Prototyping

The first interview was conducted to obtain requirements and design specifications to build the ecosystem which is a common practice recommended in a DSRM artefact design (Yen & Bakken, 2011). Ex ante evaluation proved it was practicable to proceed to building an artefact as proof of concept demonstrating the concept of building an ecosystem by integrating data from suitable mobile apps. The prototype was developed using a user-centred design. It involved end users (clinicians) to evaluate the prototype through semi-structured interviews employed in a progressive manner to answer key questions. Further discussion with the clinicians took place by emails, phone calls and SMS to reach consensus on various issues about prototype requirements and suitability of mobile apps.

The second interview was to refine the design process of the prototype. It also was an ex ante evaluation by five clinicians who worked together in the diabetes clinic. The clinicians were among five participants in the first two rounds of interviews. They were the expert evaluators of the artefact under construction. The Prototype 1 review helped in the ex ante evaluation to include new and refine existing requirements to improve the prototype. A pilot TA protocol evaluation and TAM survey was conducted to fine tune the think aloud protocol testing for the next round of reviews. This process was per the DSRM as depicted in Table 4.5.

Table 4.5: DSRM and Research Process

DSRM Hevner et al. (2004)	Research process
Design as an artefact	Build Prototype Version 1 using UCD, data integration techniques, review suitable existing mobile apps, wellness data model. Improve Prototype Version 2, include food composition data, SNOMED CT for food details, LOINC codes for BG readings.
Problem relevance	Meetings, emails and semi-structured interviews with clinicians. Review related literature review.
Design evaluation	Prototype Version 1 evaluation by clinicians. Semi-structured interviews with clinicians. Prototype Version 2 evaluation by clinicians and patients. TA protocol testing and semi-structured interviews.
Research contributions	A prototype built as an ecosystem of combining data from mobile apps and glucose meters. Patient managed wellness data integrated for clinical usage. Improve and complete the semantic value of the data.
Research rigor	Rigorous construction and evaluation of Prototype Version 1 and Version 2
Design as search process	Iterative process of build and evaluation of prototype
Communication of research	Thesis documentation, journal articles, summary results to participants

Various existing methods of data integration and clinical standards to improve semantic value of data were researched. In order to understand the structure and type of data stored in medical information systems, the standards in clinical data were studied.

4.7 Wellness Data Integration Prototype

A wellness data integration prototype was built as part of the artefact design as shown in Figure 4.3, where data from mobile wellness apps and glucose meters were integrated into the target database of the prototype. Wellness data from various mobile apps was in different formats such as CSV, XML and HTML. Reports from wellness apps in pdf format were not considered. Hence a mapping process was required to map data from heterogeneous sources to a target database in the prototype.

Women with GDM used various mobile apps for keeping track of their exercise and FD. Only selected mobile apps approved by clinicians were considered in the prototype. Women with GDM (users) emailed the data extracted from mobile apps to the clinician, which was temporarily saved in the clinician's system. The data was then transferred

and saved in the data integration prototype database.

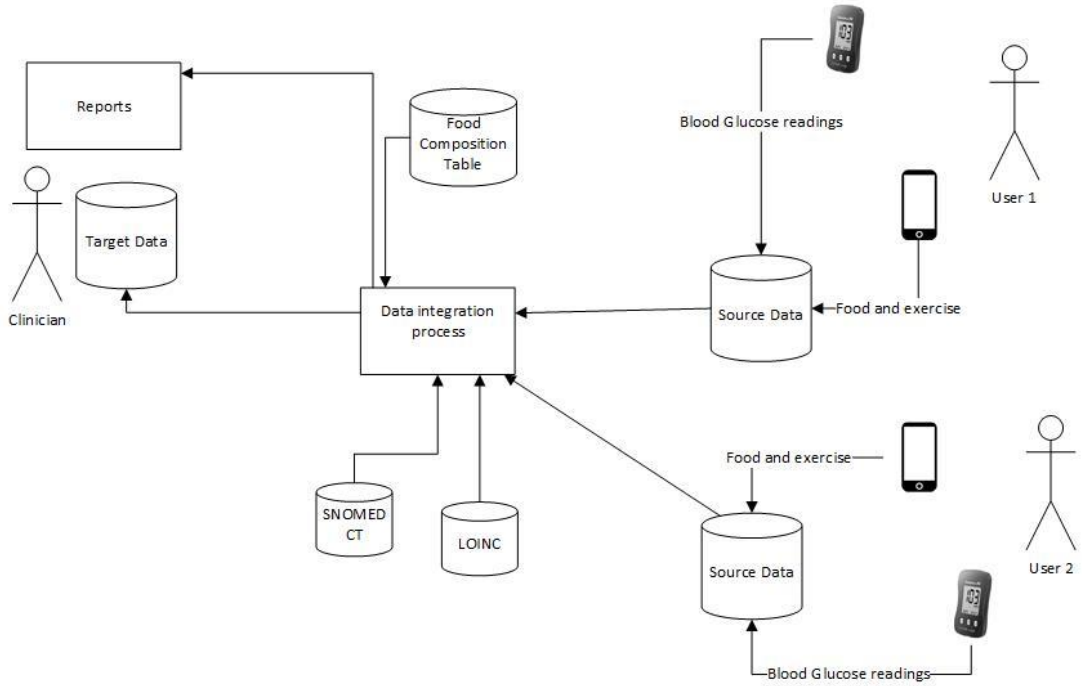


Figure 4.3: Wellness Data Integration Prototype

In order to build the wellness data integration prototype, literature and background knowledge about adding semantic value to data was researched. Semi-automatic heterogeneous data mapping tools and techniques were studied. Data from various apps and devices were in different formats. Semantic mapping through WordNet and open source software such as MOMIS (Bergamaschi et al., 2011) were useful. However while the mapping could be done for a set of data for a patient and a global schema generated, for another patient with a different set of data, a global schema different to the first patient was generated. The ecosystem is not ideal to have different schemas for different patients. This was not recommended to solve the business problem for the GDM consultation at the clinic. Secondly although the tool had a user interface (GUI), non-technical users such as clinicians would have difficulty mapping source data to global data and writing queries similar to SQL. Other software tools such as Spicy++ and Talend had similar issues for non-technical users.

Hence an ecosystem was built where different apps and glucose meter data were manually mapped to a target scheme. These mappings were hard coded in the prototype. The data was initially trialled in different data integration tools. It gave the researcher confidence to fix the target schema satisfying the user requirements and coping with

different data formats. The target schema was discussed with the five clinicians. The data from mobile apps relating to portion size was combined with food and had to be split into different data pieces in the target database. Example: 1 cup rice. Measurement units were different and hence unit of measurement had to be recorded separately from the numeric value. Date and Time format was another issue as it was recorded in a different format in the apps and had to be converted to suit the target schema. A 24-hour time format was followed to avoid confusion with different formats.

Wellness data once captured in apps and devices had no clinical standards that were similar to clinical data. The intention of the body of work was to add semantic values to data such that it meant the same in another system. Patient managed data captured in the ecosystem should be of sufficient calibre to enable it to be used in a clinical environment and other hospital systems. Hence LOINC codes were assigned to record BG readings before fasting and 2 hours after meals recorded in the glucometer. The LOINC code for fasting BG reading was recorded as 14770-2 and for non-fasting it was recorded as 14743-9.

SNOMED CT has concepts defined for substances which include dietary substances, including cooked food, raw food and drinks. These codes although used in the food intolerance and allergy identification in the dietary assessment were useful to add semantic values to the wellness data captured. Using existing codes in nutrition and dietary assessment improves the semantic values of wellness data which resides outside the clinical system.

As apps have limited data about food nutrition, the New Zealand Food Composition Table was used to identify food details in the clinical system. The prototype can link food described in the FD to all related food defined in the New Zealand Food Composition Table. A dropdown menu can help to pick relevant food items from the Composition Table and provide nutrient values of the food. Certain important nutrients such as carbohydrates, protein, calcium and iron were profiled. Although these would not come directly from some mobile apps it could be fetched from the Composition Table.

4.7.1 Data Extraction

The first steps involved extracting relevant wellness data from suitable mobile wellness apps along with other essential readings such as BG levels and time at measurement (time stamp).

CareSens[30] was the glucose meter used at the clinic. It could hold BG readings along with date and time. The device comes with software support called 'Smartlog' for BG data management. The software can hold information on the daily insulin dosage for a patient. It has functionalities to display the trend for different readings each day or for a range of dates. The device also has the functionality to email the data. The software is designed to support the individual patient (user) and can transfer the data to their home PC/laptop. More recent models of CareSens have functionality to transfer the data to mobile phones using Near Field Communication (NFC).

Although these devices have the ability to transfer data to a phone or laptop and this data can then be emailed to the clinician, the Smartlog software has no other type of user roles to enable clinicians to get access to all patients' data.

Suitable mobile apps to self-manage diet and exercise were included in the ecosystem of the prototype. Clinicians required details of the food and portion size. Apps which could satisfy the clinicians and dieticians requirements were considered in the ecosystem. The apps also needed to be able to share the data including food details with clinicians. Most apps could only keep track of calories which was not acceptable.

Thus data from apps acceptable to clinicians and dieticians for GDM consultation were of interest in the proposed body of work. The data required some manual formatting to be acceptable as input to the wellness data integration prototype.

4.7.2 Data Format in Mobile Wellness Apps

Mobile apps have provision to send data as a report (pdf) or in various formats such as CSV, XML and HTML. Data from pdf will require some third party tool to extract the data if structured as a table. Hence data formatted as pdf was not considered in this body of work.

As there are not many mobile apps available which can export data, all apps related to diet and exercise were evaluated. Women with GDM need to follow a healthy diet (Rowan et al., 2011) which is also recommended for the whole family. Hence apps which could extract all details of the FD were considered. Some apps were specific to GDM while others could manage other types of diabetes.

[30] http://www.caresens.co.nz/

4.8 Design and Evaluation

The research process through DSRM, using design principles from UCD paved the way for the design of the artefact (prototype) and its evaluation. After analysing the literature on DSRM and types of artefacts which could be developed and evaluated, consideration was given to the socio-technical aspects of the product developed as the artefact. The evaluation of such artefacts is further explored through UCD design principles and evaluation methods.

4.8.1 Use of TAM and Usability

Historically TAM has been used as a measure for adopting new systems by validation of hypothesis and statistical analysis. For any statistical computation the sample size should be sufficiently large to get consistent results. In the current body of work the number of participants is small (n = 15) for any statistical analysis. However a small sample is sufficient for a usability study to improve the prototype through user-centred design. Money et al. (2015) applied a TA protocol and conducted interviews with 10 participants. The review consisted of using a computerised 3D interior design application to design a home environment to install safety equipment for older patients transferring from hospital to home care. The interview transcripts and TA protocol resulted in inductive sub-themes for the TAM variables. A similar approach to evaluation is undertaken for the prototype in this body of work.

4.9 Prototype Evaluation Methods

The prototype was evaluated on the theories of user-centred design, usability and TAM. It was checked for effectiveness, efficiency, ease of use and usefulness. Effectiveness involved functional requirements including validating that data captured from the mobile wellness apps was suitably mapped to the prototype global schema and generated the required reports to clinicians. Usability reviews of the prototype was through semi-structured interviews and TA protocol. Clinician feedback was obtained through TA protocol and interview procedures at various stages of the prototype development (Prototypes Version 1 and Version 2). Multi-method evaluation has been used to check the usability and usefulness of a PHR system from patients' (n=22) and care providers' (n=8) perspective (Ozok, Wu, Garrido, Pronovost, & Gurses, 2014). The methods included interviews, TA protocol, focus groups, surveys; methods such as interviews and TA protocol were undertaken in this body of work.

Evaluation at two stages in the prototype development aided in ex ante and ex post

evaluation methods (Pries-Heje et al., 2008). There were two sets of ex ante evaluations of the artefact and one final ex post evaluation at the end as depicted in Table 4.6.

Design specification, user requirements and low fidelity prototype as paper mock-ups evaluated the artefact as ex ante during and after the first set of interviews with five clinicians at the Auckland Diabetes Centre as discussed in the Chapter 5 Requirement Analysis. Participants had confidence that the prototype could aid in getting all necessary data together for GDM consultation and be able to share it with the team. The second round of ex ante evaluation as part of evaluating Prototype Version 1 gave feedback to improve the prototype in terms of its functionality and usability attributes. It also checked for quality and efficiency if the required data captured from suitable mobile wellness apps could generate appropriate reports to clinicians.

Table 4.6: Prototype Evaluation Measures

DS Evaluation Type	**Method**	**Objectives**	**Techniques/Theories**	**Participants**
Ex ante Mock-up Prototype	INT1	Design specification, user requirements	UCD	n=5 Clinicians
Ex ante Prototype Version 1	INT2	Effectiveness PU PEOU BI	TAM Usability	
Ex ante Prototype Version 1	TAP1	Effectiveness Efficiency	Usability	
Ex post Prototype Version 2	TAP2	Effectiveness Efficiency	Usability	n_1=10 Clinicians n_2 = 5 Women with GDM
Ex post Prototype Version 2	INT3	Effectiveness PU PEOU BI	TAM Usability	

Ex post evaluation of the artefact was conducted with ten clinicians and five women with GDM. As the sample size was small, the study was exploratory in realising the perceived usefulness and ease of use of the prototype. The prototype was demonstrated through video clip recordings and the participants were interviewed on the porotype effectiveness, usefulness and ease of use. The TA Protocol facilitated to check the efficiency of the prototype. Qualitative feedback was provided through these methods. Purao and Storey (2008) used TAM (Davis, 1989) as an evaluation method in DSRM to

prove the prototype adoption. TAM on its own has been criticised for checking the perceived ease of use and usefulness depending on the participants' experience. TAM is based on subjective evaluation; participant's personal experience and background influencing the perceptions of PU and PEOU. Adoption of a new health system also depends on the usability study (Yen & Bakken, 2011). End users as participants of the usability study can give rich insights on the effectiveness and ease of the use of the new system. Usability testing is an objective evaluation. Nielsen and Landauer (1993) acknowledged five users should be enough to identify 80% of the usability problems in a new software system. Hence a mixed approach has been used in the evaluation of the artefact in the body of work. Multiple evaluations provide a comprehensive method to identify usability issues (Walji et al., 2014). Each method is not sufficient by itself but when combined with other methods can give a better insight for improvements of the system for adoption

4.10 Ex Ante Evaluation to Refine Requirements

User requirements to the software system were refined through various iterations of the prototype development. Prior to the development of the prototype an ex ante evaluation was done by interviewing five participants to identify the current issues in the consultation of GDM patients. A paper mock up interface was demonstrated to show the main functionalities of the prototype. Participants were able to visualise the proposed prototype and navigation. A stakeholder consultation document was created and emailed to participants to get continuous feedback on the refinement of the requirements, prototype user interface and navigation and selection of mobile apps to be included in the ecosystem. The communication was through email and mobile phone text messages. It was difficult to arrange focus group meeting with clinicians. User requirements through Interview 1 are presented in Chapter 5 Requirement Analysis.

Thus ex ante evaluations and refining user requirements were in progress throughout the development of Prototype 1. Both prototype reviews consisted of prototype demonstrations, semi-structured interviews and TA protocols.

4.10.1 Demonstration

A demonstration of prototype gave a visual understanding of the working of the new system. Participants could easily understand the main functionalities. Questions were raised about their role in using the prototype. The researcher took notes on key discussion points. In the final review of Prototype Version 2 demonstration videos were

saved in Google drive and shared with participants. A user Manual was also distributed to demonstrate the main functionalities of the prototype. This gave a strong background of the research before the researcher met the participant for the interview and review of the prototype. This also significantly reduced the interview time with the participants. However such an approach was not taken during the Prototype Version 1 as design specification and user requirements were discussed in depth during the demonstration.

4.10.2 Semi-structured Interview

A qualitative analysis of the interview data gave a better understanding of the prototype requirements from end users. The interview recordings were transcribed verbatim. Qualitative interview strategies were applied supporting a user-centred design approach while designing the prototype. The semi-structured interviews with clinicians examined their experience of supporting their 'patients' in self-management and giving feedback about Prototype Version 1 and 2.

As the interviews were open end questions, the analysis of interview transcripts was through content analysis to identify themes. A detailed process of content analysis is outlined in the next paragraph.

4.10.3 Content Analysis

Content analysis is a research method used to analyse text, verbal and videos in qualitative research techniques. Content analysis is applied in three different ways: conventional, directed or summative (Hsieh & Shannon, 2005). The three approaches differ in their coding schemes. In the conventional method coding categories are directly taken from the source data, whereas in the directed method relevant keywords are used. The summative method involves computed values of certain keywords or comparisons of different keywords or content.

When data is collected through semi-structured interviews, data is read word by word to identify codes. These codes are labelled either directly from the source data or a synonym is given to represent the code more meaningfully. Codes can then be organised into categories. These categories are then grouped as clusters. Hence a hierarchy of main topics and sub topics emerge.

4.10.4 Think Aloud Protocol

TA protocol is a usability evaluation tool. Clinicians verbalised their actions while using the prototype. Various tasks (case scenarios) were set. A video recording of the screen and clinician's voice was captured for coding the video at a later stage. A similar

approach has been used by Kushniruk, Patel, and Cimino (1997) in their study to evaluate HIS. Participants' responses to the interview questionnaire were positive although they had difficulties in interacting with the system. Thus along with semi-structured interviews the TA protocol approach can be applied to health care systems (Jaspers, Steen, Van Den Bos, & Geenen, 2004) to depict the true evaluation of the prototype built.

4.10.5 Evaluation Methods

As the practice for maintaining patient-managed wellness data varied among clinicians the interview process helped in collating user requirements to achieve a common solution through the prototype. Although the problem was explored at a single diabetes clinic, it offered a rich experience in understanding how pregnancy outcomes for women with GDM could be improved through sharing the patient data electronically. Most hospital systems manage clinical data and have little or no provision to store patient managed health data.

Evaluation of the artefact is a very important phase in DSRM as stated by Hevner et al. (2004) and March and Smith (1995). As stated earlier in this chapter on Methodology, guidance for evaluation is not well defined. Evaluation of the artefact was through prototype development, applying a case study (Peffers et al., 2012) for a real world situation. The user-centred design paved way for constant feedback from users at different stages of development. Interview questions (INT1) were on requirements of designing a new system as an artefact. The open-ended interview questions (INT2) were sought to evaluate the artefact (prototype) on the principles of TAM for PU, PEOU and Behavioural Intention to Use (BIU) the system. These evaluations were conducted as two different stages of the artefact: Prototype Version 1 and Prototype Version 2. The interview was followed by the TA protocol (TAP1 and TAP2) to evaluate the usability issues such as usefulness and ease of use of Prototype Version 1 and 2. Participants had a first-hand try at using the prototype and being observed and recorded for further analysis. Thus a mixed approach of using the interview questionnaire and TA protocol was utilised in the evaluation of the prototype. While the process evaluated the prototype in terms of BIU, the TA protocol evaluated the experience of the participants undertaking sample tasks.

TAM evaluation in most cases undertakes surveys with a quantitative analysis of a large number of participants (Y. Lee et al., 2003; Legris et al., 2003). However evaluation in the current body of work was through a qualitative analysis. Core stakeholders were

involved in providing the requirements to the artefact and later evaluating it on the basis of TAM for a rich understanding of the new system for adopting it. A similar approach has been taken by (Money et al., 2015) where deductive and inductive analysis of interview and TA protocol data was conducted. To start with a deductive perspective was initiated using TAM on PU, PEOU, BI. Later inductive themes were identified under each category for analysis of adopting the prototype.

4.11 Research Methods Not Considered

The artefact built was proof of concept of sharing patient managed wellness data. Data from mobile apps was unsuitable for integration directly into the prototype as some data cleaning such as splitting data values and date formatting was required. As not all women used the acceptable mobile apps suitable for FD requirement in the clinic, setting up clinical trials in a real environment was difficult. This research study was exploratory in nature to determine the feasibility of setting up an ecosystem of using relevant mobile apps and integrating their data into the prototype. The study also involved the adoption factors as PU, PEOU and Behavioural Intention to use the new system.

DSRM is applied along with other research methods such as action research to continuously improve the artefact. However in the current context the researcher was not part of the organisation and the organisational problem was seen from an external context. Action research involves identifying solutions for problems in the organisational context whereas DSRM involves design and proof of utility (Peffers et al., 2007). The current body of work involved designing an artefact and determining its utility and hence the main research approach was through the guidelines of DSRM and did not incorporate action research.

It was difficult to arrange meetings when clinicians were busy with their regular clinical consultations. Most meetings were arranged in between patient consultation appointments at the clinic. The researcher was not present during the consultations due to privacy issues. However the opportunity to visit the clinic and meet women with GDM in the reception area was useful in observing the practice at the clinic. Hence true action research techniques could not be applied.

Although the design process involved users as in a user-centred design, some elements of software engineering were incorporated. There have been recent articles published on

using agile methodology with DSRM efforts (Conboy, Gleasure, & Cullina, 2015) and using agile methodology with UCD (Brhel, Meth, Maedche, & Werder, 2015). Some of these software engineering practices applied in the current body of work were a little design up front, iterative design, prototyping, requirements conceptualisation and prioritisation, interviews with users and stakeholders and usability testing. Practices such as little design up front, iterative design, prototyping and usability testing were prominent in research involving agile and user-centred design (Brhel et al., 2015).

4.12 Summary

The selection of DSRM and following the guidelines described by Hevner et al. (2004) set the starting point to structure the research process. The research methodology has matured through various conference publications in design science research in information systems and technology (DSRIST) and other publications as journal articles. The methodology has embraced other research methods such as action research and case studies to improve its relevance and rigour in applying the solution artefact to solve the problems in the organisation. Although the methodology was initially suited for IS and IT, it is now applied in CS and engineering fields. It is suited to technological innovations that also include the socio-technical aspect of evaluating the artefact.

DSRM also emphasises using existing theory and contributing to new knowledge. Theories from other domains are useful. Examples of such theories such as TAM and UCD are utilised in this body of work.

DSRM has embraced other software engineering techniques such as agile and human computer interaction (HCI), to build artefacts to suit users. UCD allows users to define their user requirements to the proposed system to be developed in iterations. Continuous feedback from users into the build envisions not only the functional requirements of the system but also the usability issues of interface design. Thus relevance to the organisational problems was actively sought.

Adoption techniques were also explored in conjunction with the DSRM approach. Although TAM is used to prove a hypothesis using statistical methods with a significantly large sample, qualitative methods were also employed in the past by other researchers (Money et al., 2015) when the sample size was small. A similar approach was therefore employed in this body of work. Various methods were employed to add rigour to the research evaluation. The TA protocol and interviews with participants were

employed to explore the usability and acceptance of the new system.

This chapter described the structure of the research process. The various parts of the research artefact design and evaluations were briefly explained and are applied in the next few chapters. The use of various research methods and techniques, their importance and justification for use were outlined in this chapter.

5 Requirements Analysis

Wellness data integration is important as it facilitates communication between various wellness apps and legacy systems of clinics. This chapter presents the specific requirements of a wellness data integration prototype for use in a clinical setting. The need for a wellness data integration prototype is realised because of the issues faced by clinicians at the Diabetes Centre at Auckland Hospital.

DSRM initiates the research through a problem identified in the business organisation. The relevance of the research process is continually reviewed through the requirements analysis by stakeholders and potential users of the artefact. In this case the team of clinicians identified the shortcomings in the current practice at the diabetes clinic for managing pregnancies for women with GDM. They saw an opportunity to harness wellness data from mobile apps. Patients can manage their BG readings and diet through these apps and share this information with clinicians.

5.1 GDM Consultation at the Clinic

Pregnant women when identified with GDM are assigned to a team consisting of physicians, obstetricians, dieticians and midwives. The midwife is the primary contact person for regular consultation. However from time to time when blood sugar levels rise or other complications set in the women get an appointment with other clinicians in the team. The dietician will require the food diaries of these women to make any modifications in the diet plan. The physician will observe the readings downloaded from the glucose meter along with other notes on FD to prescribe changes in medication.

The initial meeting with a physician at the clinic provided a background understanding of the organisation and the problems encountered during GDM consultation due to patient information dispersed over several clinical systems and the prevalence of hand written clinical notes among the clinical team.

5.2 Problem Conceptualisation

The current software system maintained by the team is unable to capture all patient managed health and wellness data. Dieticians record the usual breakfast, lunch, dinner and snacks in the system as part of dietary assessment. Food intake may vary daily; when the glucose levels get elevated, the FD becomes an essential part of the information for the team. The glucose meter readings are downloaded, printed and

saved as physical files with the midwife. During consultation with a physician or dietician the midwife needs to provide data collected about the women's glucose readings and diet. Hence the main requirement is to electronically share the patient's data about wellness and BG readings among the team of clinicians. Wellness data is maintained in various formats. Some women save data on food consumed and insulin dosage on a spreadsheet template provided by the clinic while others keep paper diaries. Some fill the template electronically using their PC while others fill it in by hand.

Appropriate mobile wellness apps are essential for the self-monitoring of GDM condition. The apps must include relevant wellness data to support clinicians to make informed decisions.

The integration of wellness data from selected mobile apps managed by patients and data from the glucose meter was proposed as a technological solution for clinicians managing their patients in a patient-centred approach. An ecosystem built to integrate data from various mobile wellness apps to a developed prototype has the potential to benefit women with GDM and their clinicians.

The literature review on GDM and self-managing the condition in Chapter 2 gave a background understanding. Most literature was from a health perspective and there were not many studies with technological solutions for managing this condition. There is recently published literature about designing mobile apps to aid in the self-monitoring of GDM (Garnweidner-Holme et al., 2015; Hirst et al., 2014; Kaplan, 2014). These articles discuss designing new mobile apps to manage BG readings using a user-centred design approach. The current research does not design new mobile apps, however uses suitable existing apps in building the ecosystem. The Android and iPhone app market store is flooded with new apps from which consumers have plenty of choices. Food and diet for Type 1 and Type 2 diabetes track calories and carbohydrates. Women with GDM require a healthy diet as with any pregnancy and should also be cautious of the blood sugar readings. Hence a mobile app for diabetes or general well-being can suit women with GDM. Clinicians at the clinic recommend a healthy diet for the whole family as it is easy for these women to manage the family's and their diet at the same time. Women with GDM whose BG cannot be controlled through diet are prescribed insulin. However at the same time there is no guidance for reviewing and using these apps. Chapter 9 Section 9.4 discusses the suitability of mobile apps in a clinical environment.

In order to build the ecosystem using suitable mobile apps and integrating their data into the prototype, interviews were conducted with experts. The experts in this case were clinicians caring for women with GDM. The clinical systems in the organisation are not capable of storing all patient generated health and wellness data. In-depth interviews were conducted with five clinicians to investigate the issues in managing and integrating patient's health and wellness data for use in a clinical environment.

5.3 Identifying Requirements through INT1

With the current practice prevailing in the clinic, interviews with five clinician participants were arranged to identify more detailed requirements for the prototype.

The interview questions (INT1) were designed on the user-centred design (Martin et al., 2012) as stated in Appendix C and also stated below. Responses to open ended questions provided an understanding of the current process of clinical consultations with women with GDM. It explored how health and wellness data such as FD, glucose readings and insulin dosage were recorded.

INT1.1 How are clinical consultations with women with GDM under investigation relating to wellness data like FD and glucose readings currently performed?

INT1.2 What are the problems that clinicians currently encounter with these clinical consultations? What are the consequences for patients, and clinicians?

INT1.3 Whether there is a felt need for the proposed system?

INT1.4 What type of wellness data is required from women with GDM as input into the proposed system?

INT1.5 How should be the design of the proposed system?

INT1.6 What factors may affect the safe and effective uptake of the proposed system within the clinical environment?

The interview format was semi-structure and other related questions were discussed in the meetings. Some of these are listed below:

What problems did the clinicians currently encounter with these consultations? Did the

clinicians feel a need for the proposed system? What type of wellness data is required from women with GDM as input into the proposed system? How to identify good mobile wellness apps to record wellness data suitable for the self-management of GDM?

The aim of the interview was also to determine the design of the proposed system and what factors may affect the safe and effective uptake of the proposed system in a clinical setting.

To undertake the requirements analysis as this stage, five clinicians were interviewed individually. Their roles and profiles are discussed in the section below.

5.4 INT1: Participants' Profile

Five participants with different roles in GDM consultations responded to an invitation to provide requirements and feedback in building the ecosystem. There were two dieticians, two obstetricians and one midwife among the participants as described in Table 5.1. The role of the physician missing among these clinicians being part of the diabetes care team was fulfilled by a physician providing the necessary information, guidance and feedback. The participants details were kept anonymous including their role in the clinic.

Table 5.1: Participants Role and Job Description

Participant	Role	Job description
Participant 1,2	Dietician	Nutrition assessment of patients with gestational diabetes.
Participant 3,4	Obstetrician	Provides care during pregnancy and child birth where the pregnancy has complications due to gestational diabetes.
Participant 5	Midwife	Provides primary care related to gestational diabetes during pregnancy, monitor weekly/fortnightly progress.

The first set of interviews raised generally functional requirements for the prototype. Participants did not discuss any interface design issues although the paper mock up interface was demonstrated to introduce the main functionalities and interface design of the prototype.

5.5 Ex Ante Evaluation to Refine Requirements

User requirements for the software system were refined through various iterations of the

prototype development. Prior to the development of the prototype an ex ante evaluation was undertaken by interviewing five participants to identify current issues in the consultation of GDM patients. During the interview process participants were able to visualise the paper mock-up prototype and navigation. However limited feedback was given on the paper mock-up prototype. Participants raised the issues and problems for collating patient generated health and wellness data in the clinic.

After the first two interviews with the dieticians and a physician a stakeholder requirements analysis consultation document was created and emailed to all participants to get continuous feedback on the refinement of requirements, prototype user interface and navigation, selection of mobile apps to be included in the ecosystem and data schema of the prototype database to capture required data from mobile apps. The communication was through email and phone text messages. Focus group meeting with clinicians was difficult as participants were unavailable to meet at a given time. Hence individual meetings and consultations through email were sought. The ex ante evaluation and refining of user requirements were in progress throughout the development of Prototype Version 1.

A summary table of the main issues raised by each participant is listed in Table 5.2. The corresponding design considerations are recommended. Similar issues were raised by multiple participants and hence a frequency count was maintained for setting priorities for these requirements. Some of the issues were related and hence common design requirements were set and evaluated to a common priority.

Table 5.2: Prototype Design Consideration

Participant	Issues raised	Prototype design consideration	Frequency (n)	Requirement #
Participant 1-5	Limited information can be stored in the current system. Need to keep paper notes about food and BG along with other clinical data. A template for FD and BG is provided, which is manually or electronically maintained by patients.	Encourage an electronic data entry. Import data from external devices such as mobile apps and glucose meters into the new system.	7	RP1

Participant 4, 5	BG readings recorded in the glucose meter are deliberately recorded differently by patients on paper form to avoid higher doses of medication.	Data exported from BG meter is used as input into the prototype which is the actual data recorded in the glucose meter.		
Participant 1-5	Same information is recorded in different forms in the current system.	Need to collate the information captured from patients and display as a combined report about food, BG readings and other health and wellness data.	5	RP2
Participant 1, 2, 3, 5	Portion size is important while keeping the FD	Unit of measurement for food needs to be considered in the database design.	4	RP 3
Participant 1, 2, 3, 5	Some important food nutrients to be recorded like carbohydrates, calcium, proteins (if vegetarian), added sugar.	Food data elements to be considered in the database design and interface display.	4	RP 4
Participant 1, 2, 5	Regular exercise and lifestyle needs to be recorded.	Import exercise details from mobile apps.	3	RP 5
Participant 2, 3, 5	Body weight during pregnancy is captured at different times by different clinicians, however there is no graph to show the trend in weight gain or loss.	Display a line graph to show weight during pregnancy.	3	RP 6
Participant 2	BG readings recorded in the glucose meter have a timestamp. However it does not indicate whether it is a reading before or after meals.	Improve the semantic meaning of the data in the system by assigning LOINC code to indicate BG reading taken by women with GDM at home and before/after meals.	1	RP 7
Participant 3	Need to integrate patient managed wellness data with the current system used in the clinic.	Provision to be made to export data from the prototype in a format recognisable by other systems. Suitable clinical codes such as SNOMED CT, LOINC and health information exchange standards such as FHIR are recommended.	1	RP 8
Participant 3, 4	Choose mobile app with less data entry.	Mobile app with suitable food database can be chosen to select food from drop down lists which best match the food	2	RP 9

		consumed.	
Participant 3	Smart phones adoption and use of mobile apps may work with certain ethnicities. Ethnic groups from lower socio economic backgrounds may find it harder to own and learn new technologies.	Outside the prototype design scope. To be considered for the adoption and education of the new system.	1

The first round of interviews (INT1) aided in identifying the requirements for the new system (Prototype Version 1). It also helped to categorise the main scope, functional and user interface requirements of the system.

RP1: Import data from mobile apps and glucose meter.

RP2: Combine data from mobile apps about FD, exercise and glucose meter (heterogeneous sources) as a single combined report.

Data elements from various heterogeneous sources (mobile apps) were considered and mapped to a target data schema using Talend and MOMIS data integration tools. This process helped to fix the data schema for entities such as 'FoodDiary', 'Exercise', 'Medication' (insulin dosage) and 'GlucoseReading'.

RP3: Portion size is important in FD. Hence the element 'ServingUnit' was designed in the 'FoodDiary' entity.

RP4: Important food nutrients such as carbohydrates, protein and calcium were considered as part of the 'FoodDiary' entity.

RP5: Exercise data needed to be recorded from mobile apps. Some apps store the exercise data along with the FD. The apps considered in the Prototype Version 1 had both FD and exercise details stored in the same app. A separate entity called 'Exercise' stored the necessary data elements.

RP6: Weight was captured in various systems at the clinic, however the clinicians were not able to see the weight gain/loss chart. Hence this requirement was incorporated in the prototype. The values were allowed to be fed in manually into the prototype or taken from an app.

RP7: Record BG reading as pre or post meal in the system. Although the device could record this as a boolean value, the semantic meaning of the data was improved by assigning a LOINC code. The LOINC codes for various BG tests were unique including

different codes when different units of measurement such as mmol/L or mg/dl were used with the glucose meter. The LOINC codes of interest in this body of work were:

Glucometer Fasting BG 14770-2 mmol/L

Glucometer Non –fasting BG 14743-9 mmol/L

These were the codes relevant to the glucose meter readings recorded by patients in their homes and are different to laboratory results. The interface allowed the clinician to correct the status of the reading to either pre or post meal. This option was necessary as many women did not know how to record the fasting and post meal status on the device.

RP8: Provision to export patient managed data to other clinical systems. Data elements about 'Patient' entity were kept similar to the FHIR resource so as to allow exchange of data. Food descriptions defined in SNOMED CT terminology have been used to identify food allergies and dietary intolerance in clinical systems. These SNOMED CT concepts are defined as 'Substance' with a sub-concept called 'Dietary' to branch out to other food items. Such codes are also used in FHIR, a health data exchange standard.

5.6 Artefact Scope

The main scope of the new system was to capture health and wellness data such as FD, BG and exercise from suitable mobile wellness apps and BG meter. Data being from various mobile apps was not expected to be homogeneous in format. Wellness data from various devices had to be integrated in a software system for clinicians to use in a clinical setting. A combined report about FD, BG readings, insulin and exercise had to be generated in the software system developed as a prototype in the body of work.

The requirements were grouped into four categories to build the prototype: functional requirements, relevant mobile wellness apps, data elements to be included and user interface requirements.

5.6.1 Functional Requirements

The main functional requirements were to create authenticated users, upload data from glucose meter and various mobile apps identified in the current ecosystem and to display the combined report from the uploaded data. A detailed requirements list was elaborated in the requirements analysis consultation document attached as Appendix D. This document was constantly reviewed and modified until the final Version 7. Thereafter the prototype was evaluated and continuously modified to respond to the

participant's feedback.

5.6.2 Data Elements to Identify Global Schema

Data elements for storing BG readings, insulin dosage and food diaries had to be identified and agreed to by the clinicians to enable them to make an informed decision at consultation times. Most data elements were selected from the paper based forms used in the clinic and data exported from the glucose meter and mobile wellness apps. A problem arose when different mobile apps were considered to be part of the ecosystem; the data structure and format varied from app to app. Clinicians were interested in only certain aspects of the data gathered in the mobile apps and there was a need to identify those.

5.6.3 User Interface Requirements

Paper prototyping techniques which are widely used in user-centred design (Gulliksen et al., 2003) identified key issues in navigation of menu choices from one screen to another. Functional requirements were assigned to related menu choices. Literature on usability was sought to improve the interfaces as discussed in Chapter 3 Section 11. The interface design was intended to be modified through the prototype iterations and evaluations.

5.6.4 Relevant Mobile Wellness Apps

Mobile apps suitable for inclusion in the current ecosystem were reviewed with the clinicians. Chapter 6 and 9 analyse the evaluation and inclusion criteria. The functionality and capability of mobile apps such as Glucose Buddy, OnTrack, My Meal Mate were demonstrated at the interview with the clinicians. Two of the clinicians had downloaded apps such as MyFitnessPal and had experience in using them. Most women with GDM owned a smart phone and had used mobile wellness apps previously but not necessarily for the self-management of GDM. The team of clinicians overall did not have much experience in using such apps. One of the participants, a dietician, was part of the review group for nutrition apps listed on Healthnavigator website[31]. Another participant was aware of such app review processes available and had discussed this in team meetings at the clinic. Apps such as My Meal Mate were favoured as it had dropdown options to select food from a food database and hence could reduce data entry details. Food selected from the food database had nutrition information. However in the case of My Meal Mate, the food database was UK based and not identical to the food

[31] https://www.healthnavigator.org.nz/app-library/d/diabetes-apps/

available in New Zealand supermarkets. Food Switch, an app developed in New Zealand could scan barcodes of most food from supermarkets. However the app was not designed to keep a log of all the scanned food. It was designed to make healthy food choices around fat, sugar and salt content while shopping in a supermarket and not as a FD for an individual. Hence the initial interviews could not select the appropriate apps to be included in the prototype.

A follow up on the selection of mobile apps through emails and phone text messages helped to select two mobile apps to start with in Prototype Version 1. Focus group discussions were not possible as clinicians worked on shift duties at different clinics and premises. Email and phone communications were used to get consensus from clinicians about the selection of mobile apps to refine and prioritise requirements through iterations for building the prototype. The requirements analysis document had the main requirements listed with screenshots of the prototype. A low fidelity throwaway prototype was built using Visual Studio 2015 IDE. Various menu choices and screen inputs and outputs were suggested. A format of the combined report was also presented. Participants thus had an early understanding of the capabilities of the new system. The email communication helped to improve the requirements and design of the system. The clinicians also used their phones for email and text messaging to keep in contact.

Selection of Mobile Apps in Prototype Version 1

Most mobile apps can track calories and BMI. Apps with only calories details were not suitable for FD. Clinicians required food details with name of the food, portion size and main nutrient contents. Most women with GDM were unlike Type 1 diabetes patients who could manage carbohydrate counting. Women with GDM had minimal time available for training and education to manage their diabetes. Hence mobile apps which could keep track of healthy lifestyles and promote the self-management of GDM were selected. Consideration was also given to mobile apps that were able to export or share data as a file or through external storage such as cloud or Dropbox.

As part of the evaluation of mobile apps, Glucose Buddy and OnTrack apps were chosen in Prototype 1. As the research study progressed more in-depth understanding of suitable apps and new apps were discovered.

5.7 Summary

This chapter discussed the problem in the organisation which was the initial phase of

DSRM. Requirements to build the ecosystem were identified, numbered and prioritised. Interview sessions with the five participants (clinicians) and regular communication through emails facilitated identifying the requirements necessary for the self-management of GDM. These requirements had to be satisfied through the ecosystem.

Relevant mobile apps which could keep track of necessary wellness data for the self-management of GDM were discussed as part of the requirements. These requirements were planned in the design of the prototype.

6 Design of Ecosystem and Prototype Version 1

The artefact design as a prototype was discussed in Chapter 4 Research Methodology. The process of designing the prototype is discussed in this chapter. The main methodology was DSRM with the design process employing a user-centred approach. The first set of interviews (INT1) with five clinicians provided the requirements as discussed in Chapter 5 Requirements Analysis, to build a prototype where suitable mobile apps were part of the ecosystem. The prototype had to be sufficiently flexible to be able to include new mobile apps in future. The DSRM followed an exaptation approach (Gregor & Hevner, 2013) where known solutions from different domains were applied to new problems. An example of such research has been demonstrated in a community healthcare information system (Berndt, Hevner, & Studnicki, 2003) using data warehouse concepts. Existing techniques from literature on data integration of heterogeneous sources were sought and discussed in Section 6.3. The literature discussed in Chapter 2 and 3 on clinical terminologies and designing PHR and EHR systems added value by improving the semantic meaning of any relevant clinical data in the prototype. The data captured in the prototype should be compatible to integrate into a clinical system such as EHR or PHR in future as discussed in Chapter 9 Section 9.5.

The criteria for including additional mobile apps suitable for clinical consultations is discussed separately in chapter 9 Section 9.4. Framework for Mobile Apps Review. As the prototype was developed iteratively, Prototype Version 1 had provision to accept data from two mobile apps: OnTrack and Glucose Buddy. The clinicians required mobile apps which allowed logging of food diaries and exercise. Priority was given to apps which allowed the sharing of wellness data suitable for GDM consultation through email to their clinicians (Requirement RP1). Women with GDM are new to managing diabetes conditions during pregnancy and as such apps which were easy to use with minimal data entry were desirable (Requirement RP9). The selection of the two apps in Prototype Version 1 is discussed below.

6.1 Prototype Version 1 - Mobile Apps

OnTrack and Glucose Buddy were two apps identified out of 30 similar apps investigated that were suitable to log FD and exercise and were capable of sharing it as a file with clinicians. Details of these apps are listed in Appendix H. Some of the functionalities and features of these apps have changed significantly since then (2014).

The glucose meter used in the clinic was also investigated for its data to be used in the wellness data integration prototype.

6.1.1 OnTrack

OnTrack is an app shown in Figure 6.1, is available on Android and iOS platform. It allows the user to maintain a log of BG readings, body weight, carbohydrates in food and exercise details essential for the self-management of GDM. Data in the app managed by the patient is shared with clinicians in simple non-proprietary formats such as CSV, XML and HTML files. These data attributes (elements) were compatible for storage in the relational database of the prototype.

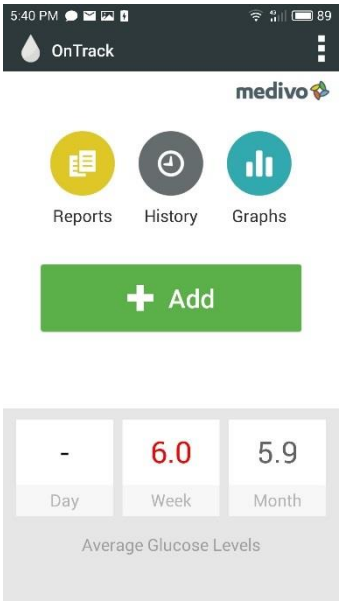


Figure 6.1: OnTrack App

Sample data extracted from the app as on 18 May 2014 is depicted below in Table 6.1. Clinicians who had participated in the initial set of interviews INT1 were consulted. Data from the app had BG readings, carbohydrates in grams and exercise details such as walking or running in kilometres. As the clinic had software support to download BG readings from the glucose meter, the clinicians trusted the data to be accurate. Logging BG readings into the app was an additional workload for women with GDM and may not reflect the true readings if manually logged. Hence BG readings were removed from the sample data. This sample data was used in consultations with clinicians and in the prototype. Unit of measurement for food and exercise was not in the data shared and had to be considered in the prototype database. Food details were not recorded in the app. However the app had provision to share other details such as exercise and carbohydrates as a file through email while many other apps reviewed did not have this

option. The women or the clinicians had to feed in additional details about food before uploading it into the proposed wellness data integration prototype.

Table 6.1: Sample OnTrack Data

DateTime	Type	Exercise	Event	Value	Food
30/04/2014 14:07	Exercise	Walking		4	
30/04/2014 19:06	Food		Dinner	30	Brown bread
30/04/2014 10:07	Exercise	Walking		6	
30/04/2014 13:00	Food		Lunch	50	Rice

Events such as breakfast, lunch, snack time and dinner were predefined in the app. For each 'Food' type in an event the user was required to specify the carbohydrates in the food. There was no internal food database and as such data entry in the app depended on the user feeding all the details including portion size as a value. The unit of measurement of the value depended on the user. Although the app data schema was not perfect it was sufficiently flexible to allow data entry for the self-management of GDM where food details that could be included in the shared file were allowed along with portion size. The clinician had the option to view the shared HTML file on a browser as shown in Figure 6.2. The data values for BG, food, exercise and weight are shown as separate graphs and not viewed together as clinicians expected it in the wellness data integration prototype. Data values are displayed in four hourly intervals for 24 hours in a day.

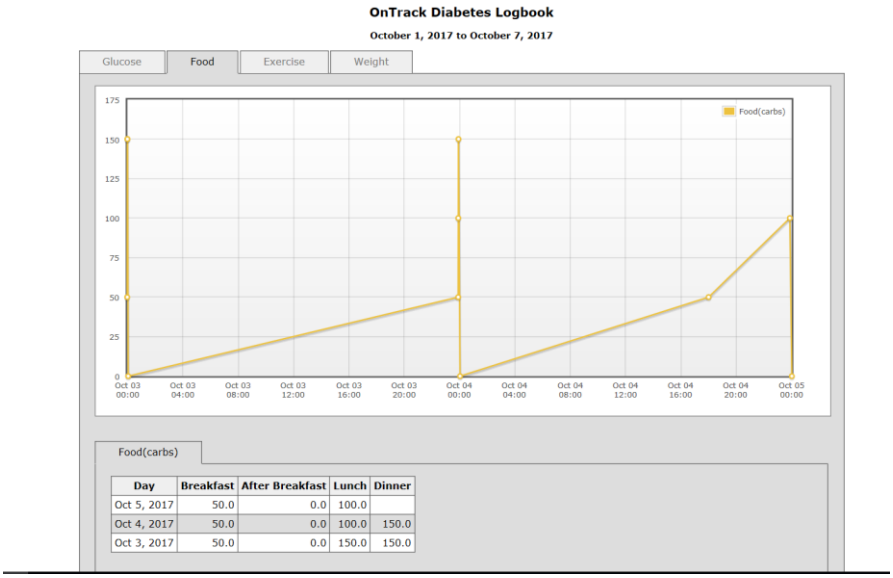


Figure 6.2: OnTrack Wellness Data Share

Most other apps had a feature that allowed the sharing of data through email; however

the data schema and structure was important as data values useful for GDM consultations were required. OnTrack had the most suitable data values for sharing with clinicians. Hence it was considered for inclusion in the ecosystem.

6.1.2 Glucose Buddy

Glucose Buddy was another app available on Android and iOS. The main screen interface is shown in Figure 6.3. Similar to other mobile apps it too allowed the user to log food and exercise entries. The data collected and available for sharing with clinicians was suitable for setting up the ecosystem.

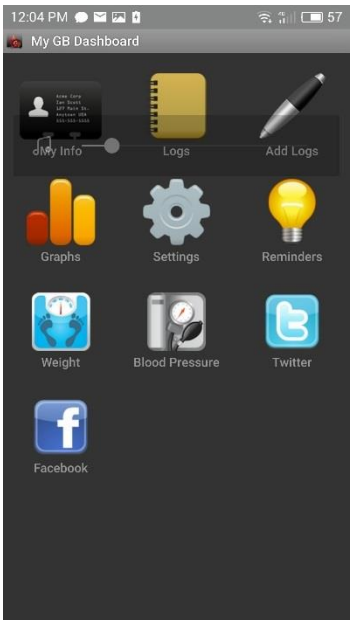


Figure 6.3: Glucose Buddy App

The app shared patient managed wellness data in the simplest data format as CSV demonstrated in Table 6.2, a sample created on 18 May 2014.

Table 6.2: Sample Glucose Buddy Data

Date	Time	Type	Event	Name	Value	Units
04/19/2014	1:39	Activity	After Lunch	walking	60	mins
04/19/2014	8:30	Food	Dinner	rice	50	grams
04/19/2014	1:30	Food	Dinner	lamb	50	grams
04/19/2014	1:30	Food	Lunch	rice	50	grams
04/19/2014	8:30	Food	Breakfast	bread toast	50	grams

Attributes similar to OnTrack were available in Glucose Buddy; however the data

schema were not exactly the same. It was noticed that date-time component was combined as one attribute in OnTrack, while it was split as two different data attributes in Glucose Buddy. The target data schema in the prototype had to consider these types of heterogeneous local source data. Unit of measurement was missing in the OnTrack app, but was clearly defined in Glucose Buddy. Exercise data was measured in units of time (minutes) in Glucose Buddy whereas in OnTrack data was measured units of distance (kilometres).

In terms of GDM consultations, both the apps were appropriate with the necessary attributes to save food and exercise details and had the facility to share wellness data through email as an attachment file. The file structure was in the simplest format such as CSV, HTML and XML which were compatible to be stored in the target database.

Apart from the two apps to start with in the first prototype Version 1, BG readings from the glucose meter were also considered. The clinic used Caresens, the most basic public health funded glucose meter for women with GDM.

6.1.3 Carsens Glucose Meter

Caresens glucose meter is funded and provided to patients at a subsidised fee. Smartlog software available on the Caresens website was used to download glucose readings logged in the glucose meter.

The current practice at the clinic is to download the women's BG readings from their glucose meters into a PC at the clinic. The midwives usually download, print and file the readings. There is no practice of electronically saving the data.

A sample data log from 28 April 2015 is illustrated in Table 6.3 which shows necessary data attributes such as date and time, glucose value in mmol/L, whether it is a post meal (status) and insulin dosage. The user needs to record accurately whether the test is post meal by pressing a button on the device. If this is not correctly indicated the BG test is treated as the default fasting type (pre meal). Most women use the device to record BG and are not aware of other functionalities available. Other details such as exercise can be managed on the Smartlog software downloaded on a computer or laptop. However women generally do not access the Smartlog software and only use the device to record BG readings. Hence limited data is captured. It was identified that date and time is a single attribute which is similar to OnTrack app data.

Table 6.3: Sample Glucose Meter Caresens Data

name		birthday	sex	serial number	data unit	user idx	NHI_number	DATEFORMAT	
Natasha		28-Jul-80	F	A5A246B01161	mmol/L	2	abc123	DD/MMM/YYYY	
time	org_glucose value(mg/dL)	glucose value(mmol/L)	manual	cs	memo	exercise	meal	insulin_type	insulin_amount
29/04/2015 20:45	139	7.7	N	N			Y	Humalog	31
29/04/2015 15:30	108	6	N	N			Y	Humalog	32
29/04/2015 11:23	101	5.6	N	N			Y	Humalog	33
29/04/2015 8:15	98	5.4	N	N			N	Humalog	34
28/04/2015 20:09	126	7	N	N			Y	Humalog	35
28/04/2015 20:08	136	7.5	N	N			Y	Humalog	36
28/04/2015 12:34	143	7.9	N	N			Y	Humalog	37
28/04/2015 12:33	136	7.5	N	N			Y	Humalog	38
28/04/2015 9:27	91	5	N	N			N	Humalog	39

More recent models of Caresens have an interface to connect mobile phones through Near Field Communication (NFC). However these types of glucose meters were not available for the research study. Currently the women visit the hospital to download their meter readings into a PC at the clinic. Some women may need more training than others in using the device and sharing data from the device with their midwives. Data from the glucose meter illustrated in Table 6.3 above was available to be included in the prototype to combine BG reading data with other wellness data such as FD and exercise from mobile apps.

6.2 User Requirements as Use Cases

Requirements listed in Chapter 5 Requirements Analysis were depicted as a use case diagram to design the prototype. Use cases are useful process models to convey all the functionalities to be fulfilled in a prototype. However their use was limited while discussing with clinicians as it may be difficult for them to comprehend (Gulliksen et al., 2003). The use case model as depicted in Figure 6.4 helped to focus the design. The use case diagram was also mapped to the user requirements as illustrated in Table 6.4 thus satisfying all requirements analysed through INT1.

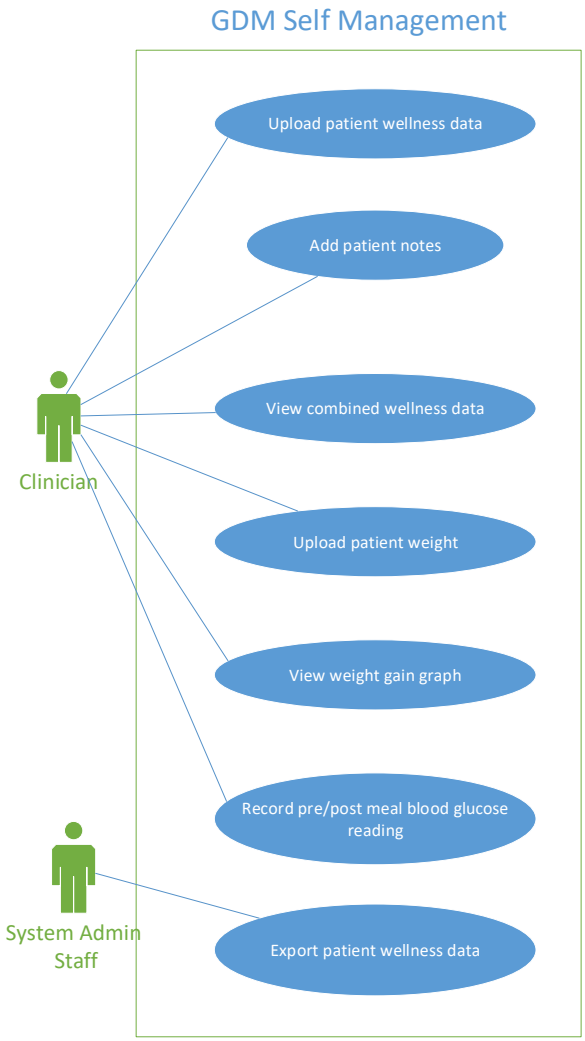


Figure 6.4: GDM Self-management Use Case Diagram

Table 6.4: Use Case and Related Requirements

Use Case	Related requirements
Upload patient wellness data	RP1, RP3, RP4, RP5, RP9
Add patient notes	RP7
View combined wellness data	RP2
Upload patient weight	RP6
View weight gain graph	RP6
Record pre/post meal BG reading	RP7
Export patient wellness data	RP8

The prototype was required to accept data from various wellness mobile apps and glucose meter. In order to accept data from heterogeneous sources and integrate them in the prototype, various data integration techniques and open source projects were

investigated.

6.3 Data Integration Techniques

The concepts of mapping source data to a target schema was taken from literature (Cruz & Xiao, 2005; Fagin et al., 2009; Lenzerini, 2002). The Clio project (Fagin et al., 2009) presented algorithms to map data from source schema to a target schema. Declarative schema mappings had been previously used in related research (Fagin et al., 2005; Lenzerini, 2002). Such data integration projects require the user to understand basic concepts of data schema to map data from source to target. Lenzerini (2002) discussed the theoretical concepts of mapping data from various sources to a target schema.

Data integration approaches can be broadly classified as global-as-view (GaV) and local-as-view (LaV) (Lenzerini, 2002).

6.3.1 Global-as-view(GaV)

In a GaV approach global schema is associated as a view over the local source schema. In a GaV the global schema is built based on data from local source. Queries written based on global schema will fetch data from local source. The data resides in local sources; a query based on global schema will fetch data as a view over local source. These queries are easy to program in a GaV approach.

6.3.2 Local-as-view (LaV)

In a LaV approach global schema is specified independently of the sources. Local schema are defined as views over the global schemas.

Schema or semantic matching techniques are semi-automatic (Doan & Halevy, 2005). The rule-based technique has been employed to find mapping created through schema information such as data type, attribute name and integrity constraint (Doan & Halevy, 2005). However the technique needs more elaborate methods to check data instances (values).

Semantic integration has been achieved through ontologies (Cruz & Xiao, 2005; Noy, 2004). Data integration through semantic mapping using WordNet is demonstrated through projects such as Mediator envirOnment for Mutliple Information Sources (MOMIS) (Bergamaschi et al., 1999) and made available as an open source project (Bergamaschi et al., 2011). Another project called Xyleme (Reynaud et al., 2001) used synsets in WordNet to find semantic mappings of XML data.

Two data integration tools namely MOMIS and Talend were evaluated as to suitability for data integration from mobile wellness apps.

6.4 Data Integration Tools

Sample wellness data from two selected mobile apps - OnTrack and Glucose Buddy as demonstrated in Table 6.1 and 6.2 were chosen to run in two data integration tools: MOMIS and Talend. The experience of integration and deriving a global schema gave the confidence to fix a schema for the database of the prototype. The target database schema was shared with clinicians through the stakeholder requirements analysis consultation document to reach a consensus to fix the choice of mobile apps data which were comprised of the local data in the tool.

6.4.1 MOMIS Project

MOMIS project was used to trial different wellness data such as food and exercise from various mobile apps such as Glucose Buddy, OnTrack and glucose readings from a Caresens glucose meter.

MOMIS architecture has a graphical interface for users to select heterogeneous data sources also called local sources to create a global schema. In a GaV, the global schema saves the schema or the structure of the data as XML file. The actual data resides in local sources. Users write queries on global schema to fetch data from various local heterogeneous data.

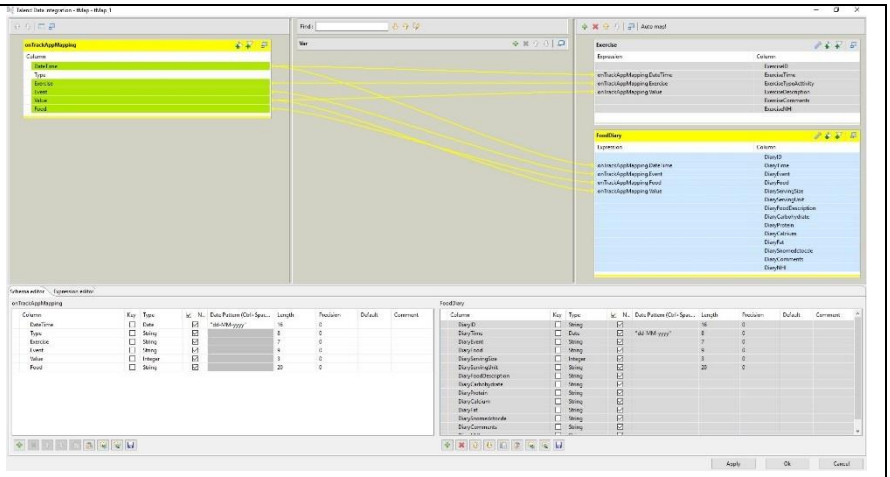
In the MOMIS project, integration was completed in two steps - common thesaurus generation and global virtual schema (Beneventano, Bergamaschi, Guerra, & Vincini, 2001). The integration process was semi-automatic; a graphical user interface (GUI) was provided to select the local sources in different data formats including XML. The project could automatically annotate local data sources to WordNet lexical database or external domain glossary. The automated annotation could be improved manually by a data integration designer. The final step was to generate the global schema. End users could then write queries in the Query Manager. A query on global schema works as a view over local sources. Global schema does not store the actual data and only has the schema to create view and fetch data from local sources. However queries in Query Manager are written in syntax similar to that of a SQL scripting language, which is not easy for non-technical end users.

The MOMIS system was implemented using the Integrated Development Environment

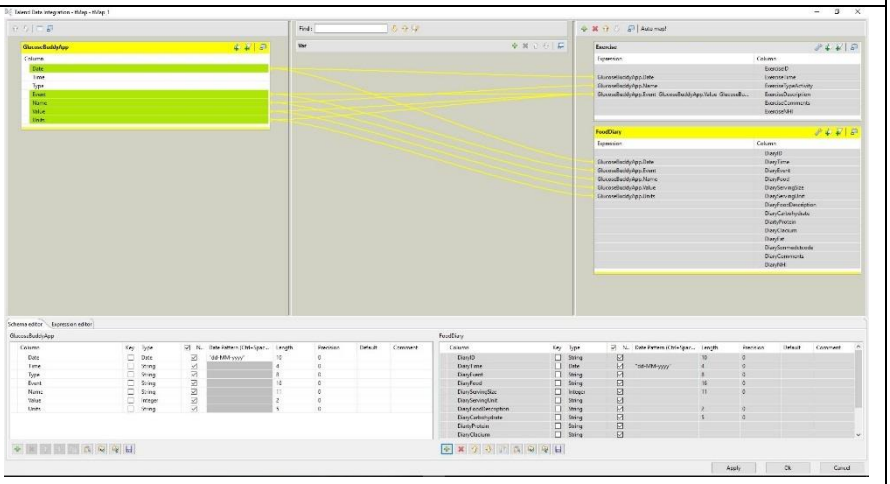
(IDE) Eclipse Indigo Release and other suites of tools such as My SQL 5.0, Tomcat 6.0 and Maven 3.2. Data extracted from Glucose Buddy and OnTrack were trialled in the MOMIS system. The MOMIS system generates automatic annotations to a global schema which can be edited manually if they are not correct. This is useful for users with limited domain knowledge about data. The global schema was saved in the system itself and cannot be used outside the system which was a limitation when applying it in a prototype developed outside the MOMIS system. Within MOMIS, an interface was built using the global schema to query data along with BG readings, food and exercise data. The global schema in this case was fixed for the source data from the Glucose Buddy, Ontrack and Caresens meter. If new mobile app data is required to be added then the global schema needs to be reconstructed. The annotation process and writing queries using the global schema is also not easy for end users such as clinicians with limited knowledge about databases. Moreover the global schema cannot be used outside of the MOMIS system. The data integration architecture within MOMIS was complex. Although it helped to generate a global schema for fixed local source data, it re-created a new global schema if new mobile app data was introduced. This was not flexible for storing the data in the fixed database designed in the prototype. Hence it was decided to use the global schema and manually map and program it to accept new data sources in a prototype developed outside of the MOMIS system.

6.4.2 Talend

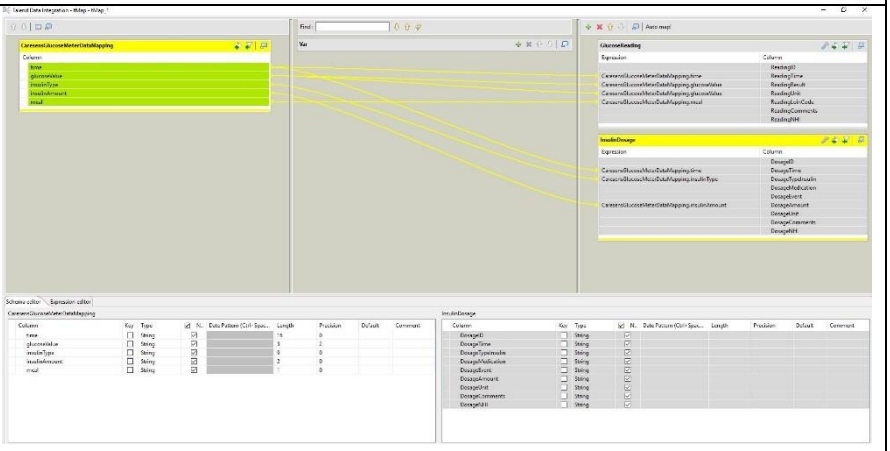
Talend was another data integration tool available as an open source community edition. It had a graphical user interface (GUI) and wizards to help in data integration from various heterogeneous sources. The data mapping wizard helped in mapping local data to the target data schema. An understanding of basic database concepts was required to use the tool. Various techniques discussed in data integration literature were available in the tool to split, combine or format source data to suit a target schema. A similar global schema derived from the MOMIS system was trialled in Talend as shown in Figure 6.5 which gave confidence to fix the data schema for the prototype to accept any new mobile app data which may be desirable to be included in the ecosystem at a later stage.



OnTrack Data Mapping



Glucose Buddy Data Mapping



Carsens Data Mapping

Figure 6.5: Data Mapping using Talend

The tools facilitated discussions with the clinicians to fix a target schema which became the database schema of the prototype. To avoid potential complications for clinicians

using the integration tools, program scripts were built into the prototype for each specific mobile app selected to map to the target database schema.

The target schema derived was designed in the prototype outside the MOMIS and Talend systems.

6.5 Prototype Database Schema

The database suitable for the prototype was determined after considering two suitable mobile apps capturing FD and exercise details. The data elements and schema were discussed with the clinicians before finalising it in the prototype. They were part of the consultations with clinicians discussed in Chapter 5 Requirements Analysis.

User requirements from INT1, RP3 and RP4 were considered in the database design. RP3 was required to define data elements to capture food portion size. As different apps had different data formats for metric scale, measurements as serving size and serving units these data were required to be defined in the prototype database. RP4 required the main nutrients such as carbohydrates, calcium and protein to be defined in the database.

Most mobile apps recorded food intake but had limited details about the food as a report output. Calories were used in most apps to guide the user toward weight loss; however dieticians required more information about food details and portion size. A country specific food composition table provided additional useful information about certain nutrients (macronutrients) required by dieticians and clinicians. Clinical terminologies such as SNOMED CT and LOINC identified wellness data similar to clinical data. SNOMED CT codes identified the food while LOINC codes identified a postprandial or fasting BG reading. Data elements similar to FHIR specification were considered in the prototype database as shown in Figure 6.6. Although a complete conversion of the prototype data as FHIR was not undertaken, a sample data about BG reading was tested on FHIR server further discussed in Chapter 9 Section 9.5.2.

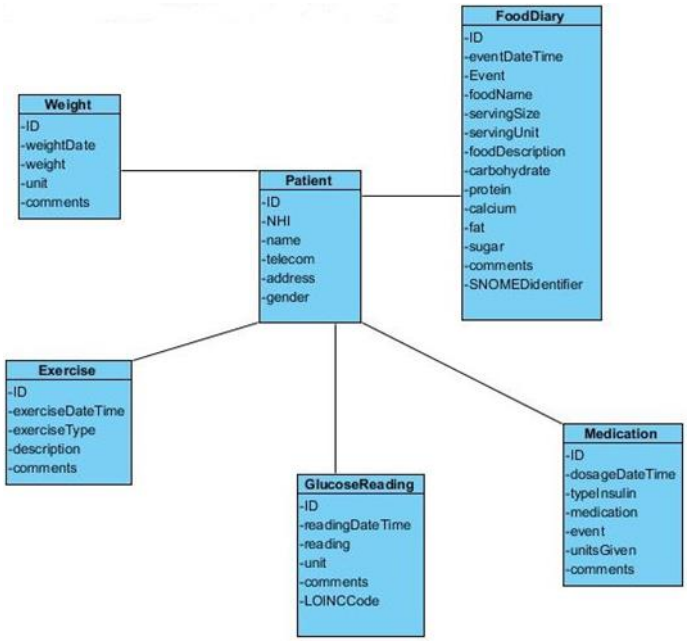


Figure 6.6: Database Schema in the Prototype

Clinical terminologies used in HIS were checked for relevance in patient managed health and wellness data systems. Health and wellness data managed by patients comprising of BG measurements from glucose meter and food diaries maintained in various mobile apps do not necessarily follow clinical data standards. Clinical terminologies such as SNOMED CT, LOINC are applied to health related data maintained in hospital systems. Such terminologies are not prevalent in PHR systems, wellness apps and fitness devices used by consumers.

The wellness data integration prototype designed as the main artefact incorporated clinical standards such as LOINC and SNOMED CT. Existing LOINC codes defined for glucose readings from glucometer added semantic interoperability while integrating patient managed wellness data in a clinical system. The LOINC codes for various BG tests were unique including different codes when different units of measurement such as mmol/L or mg/dl were used with glucometer. The LOINC codes of interest in this body of work were:

Glucometer Fasting BG	14770-2 mmol/L
Glucometer Non -fasting BG	14743-9 mmol/L

These codes identified the glucometer readings recorded by patients in their homes and are different to laboratory results.

Similarly other clinical coding standards such as SNOMED CT has defined concepts for diseases. It also includes most food items for allergy and food intolerances while recording dietary plans. Food items fall under the ‘Substance’ category in SNOMED CT with identifier 105590001.

The concept ‘Substance’ has a child concept called ‘Dietary Substance’ which further extends as ‘Drinks’ and ‘Food’ sub-category. Unique identifiers are defined for all drinks, cooked and uncooked food which add semantic meaning to the food data entered by patients. Similar semantic integration about food entries are achieved in clinical systems. The SNOMED CT codes for most food were taken from HL7/FHIR website (https://www.hl7.org/fhir/valueset-food-type.html). 255620007 is the SNOMED CT code for food category which has a unique SNOMED CT for each food type under this category.

Design of the database schema for the prototype was through a process of matching data from two mobile apps to a target schema. Although it could have been done manually, initially open source projects and tools were investigated so that the prototype could be built on existing open source projects.

6.6 Prototype Architecture

The prototype accepted data about BG readings and mobile app data through email from women with GDM or by directly downloading the data into the clinician’s computer. The prototype was built as a proof of concept using Visual Studio IDE. The data was stored in an SQL Server as shown in Figure 6.7.

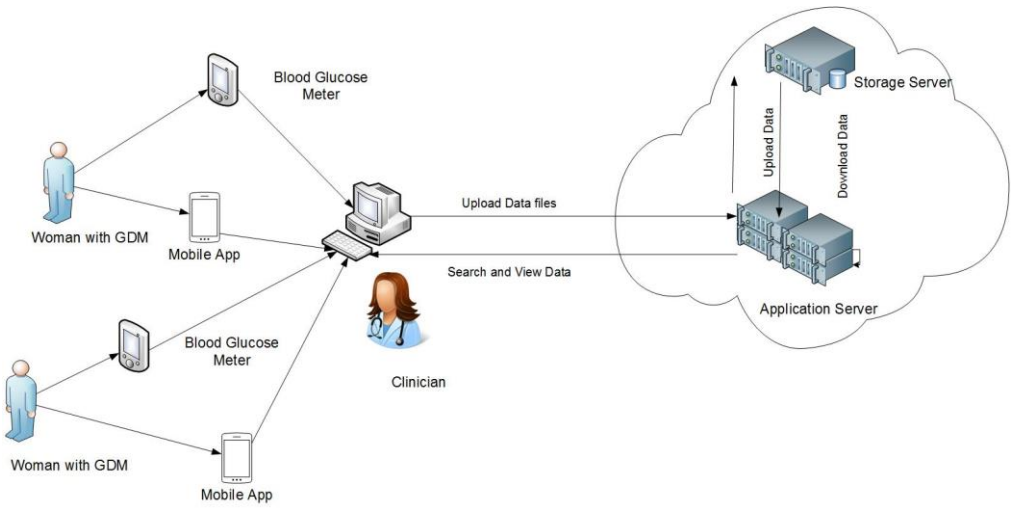


Figure 6.7: Prototype Architecture

6.7 Prototype Design Process

The prototype was designed in two main iterations Version 1 and Version 2. As the interview reviews progressed, minor changes were made within each prototype version. The main requirements from users as discussed in Chapter 5 Requirements Analysis were considered. The paper mock-ups and prototype interface screens as illustrated in the stakeholder requirements analysis document were considered in the prototype interface design.

The following steps were undertaken to apply the principles of UCD: These followed the UCD principles (Gould, 2000; Gould & Lewis, 1985; Gulliksen et al., 2003; Norman, 1988) discussed in Chapter 3 Literature Review Section 3.8.

Step1: Open ended structured interviews (INT1) were conducted with five participants to elicit requirements of the prototype. Paper mock-ups were discussed for interface design and navigation.

Step 2: A requirements analysis document was created and shared with the participants by email. This document also included screen shots of the interface design, review of mobile apps and database design to include necessary health and wellness data. Feedback from participants was considered in the design process.

Step 3: Videos of the prototype demonstration were saved in Google Drive and shared with participants. A user manual with screen shots of the prototype was also distributed to demonstrate the main functionalities. This presented a strong background for the

prototype design before the researcher met the participant for the interview (INT2) and review of the prototype.

Step 4: A second set of interviews (INT2) with clinicians was arranged. The prototype was demonstrated to individual participants. The demonstration was interactive with participants querying the functionalities and design of the prototype. Usability issues were highlighted at this stage.

Step 5: TA protocol (TAP1 and TAP2) were conducted to identify usability issues and to check if participants were comfortable in undertaking the basic task of uploading the mobile wellness data and BG readings into the system and viewing it as a combined report of BG, FD, exercise and insulin dosage for each day.

The paper mock-ups used at the initial interview meeting (INT1) with the clinicians are illustrated below in Figure 6.8. Paper mock-ups have served as a useful technique to engage users in designing interface and navigation (Gulliksen et al., 2003). In the current body of work the researcher went through the paper mock-ups describing the basic functionality of searching for a patient and uploading data from a selected mobile app and glucose meter into the prototype. The overall layout of the combined report was also explained. The clinicians had a fair understanding of the prototype through this demonstration at the initial interview settings.

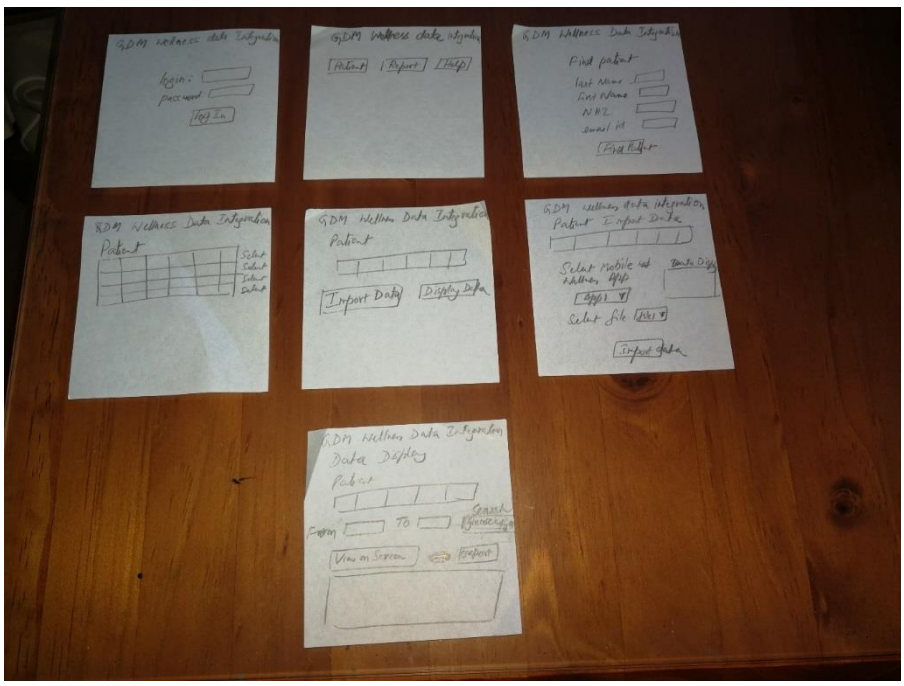


Figure 6.8: Paper Mock-ups Demonstrating Initial Prototype Design

The paper mock-ups were translated into screen mock-ups using the Visual Studio IDE which was later used to develop Prototype Version 1. The interface screens were demonstrated in the stakeholder requirements analysis document emailed to the team of clinicians. Thus a continuous work in progress of the prototype design was consulted with the clinicians.

Some of the interface screens are illustrated below to describe the two main functionalities of the prototype.

RP1: Import data from mobile apps and glucose meter.

RP2: Combine data about FD, exercise and glucose meter (heterogeneous sources) from mobile apps into a single report.

Figure 6.9 demonstrates the first functionality RP1 of displaying the choice of apps in a drop down list and corresponding data on the right side in a display box. The user then has the choice to import this data into the prototype.

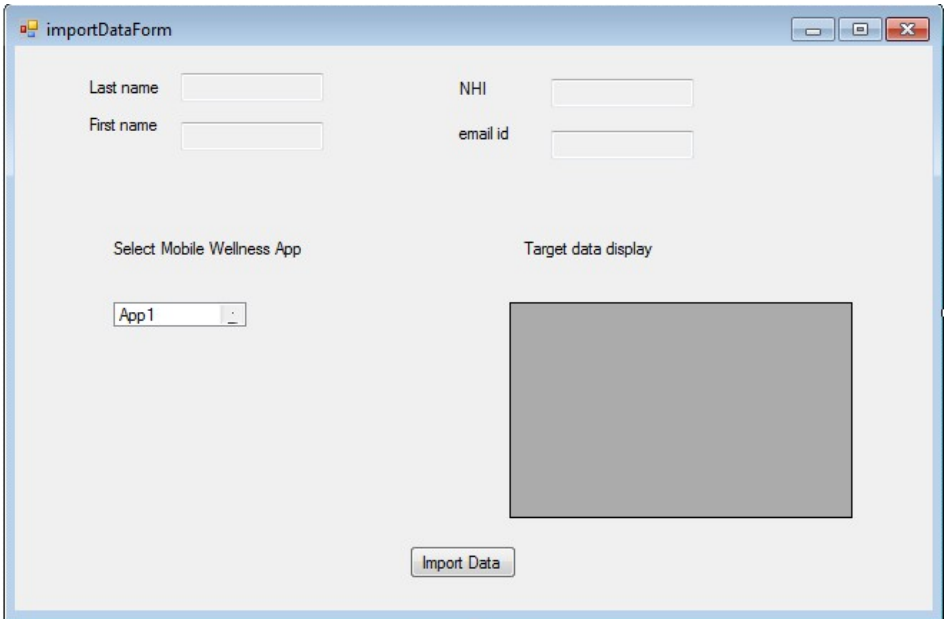


Figure 6.9: Prototype Design Import Data from Mobile Apps and Glucose Meter

Figure 6.10 demonstrates the second functionality RP2 of combining data from mobile apps and glucose meter. The report is specific for a woman and has a start and end date. The combined report is displayed in the box below which can be printed or exported in other data formats such as XML and JSON as required. These data formats were acceptable for health data exchange using FHIR and meeting the requirement RP8.

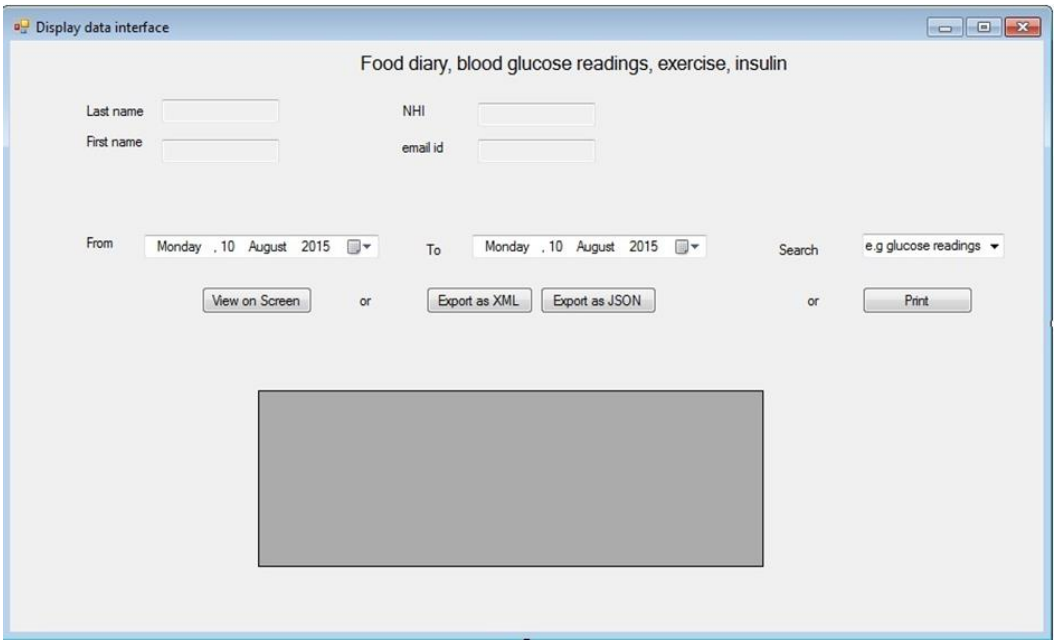


Figure 6.10: Prototype Design to Display Combined Data from Mobile Apps and Glucose Meter

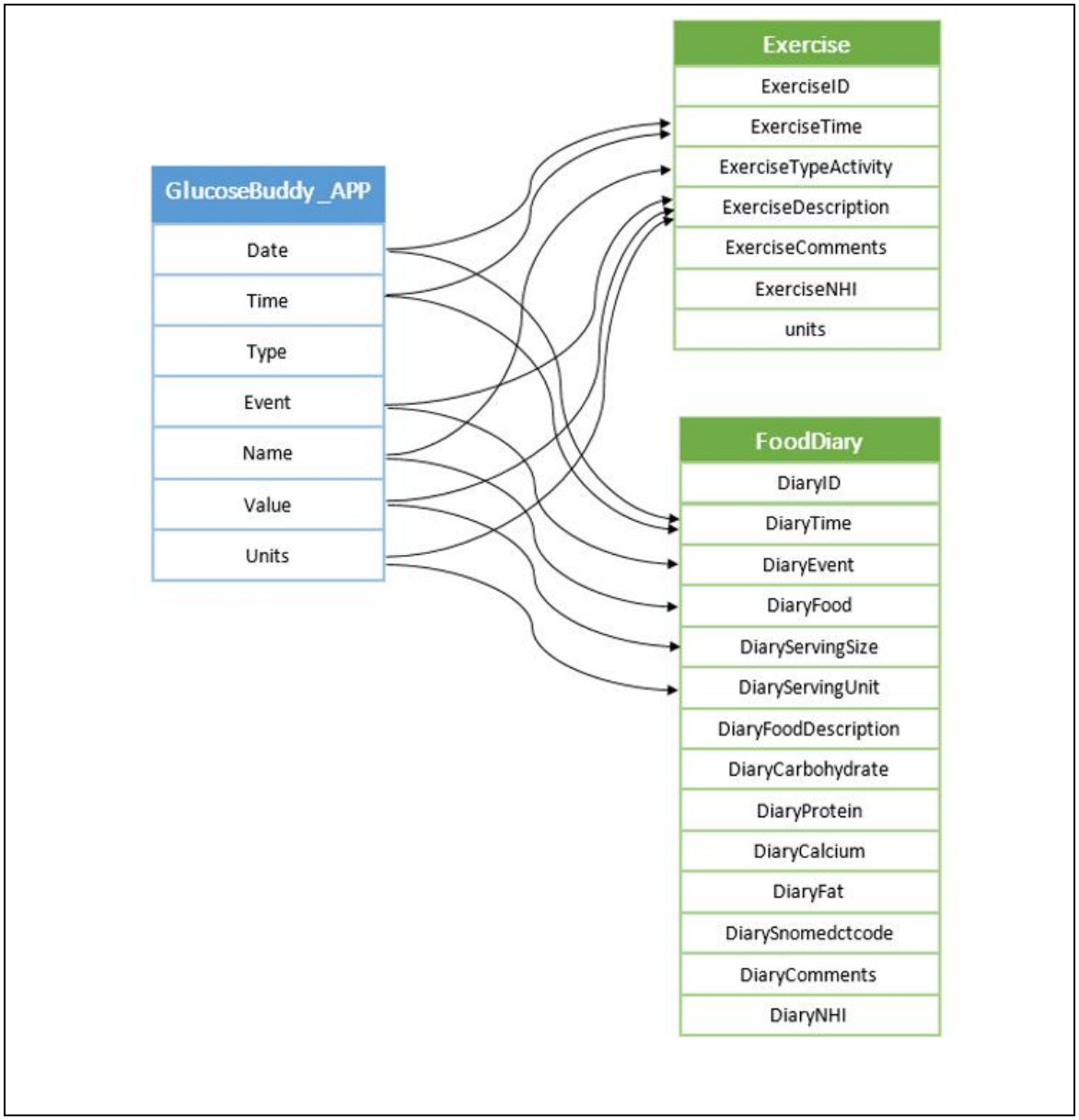
6.7.1 Prototype Version 1 User Requirements

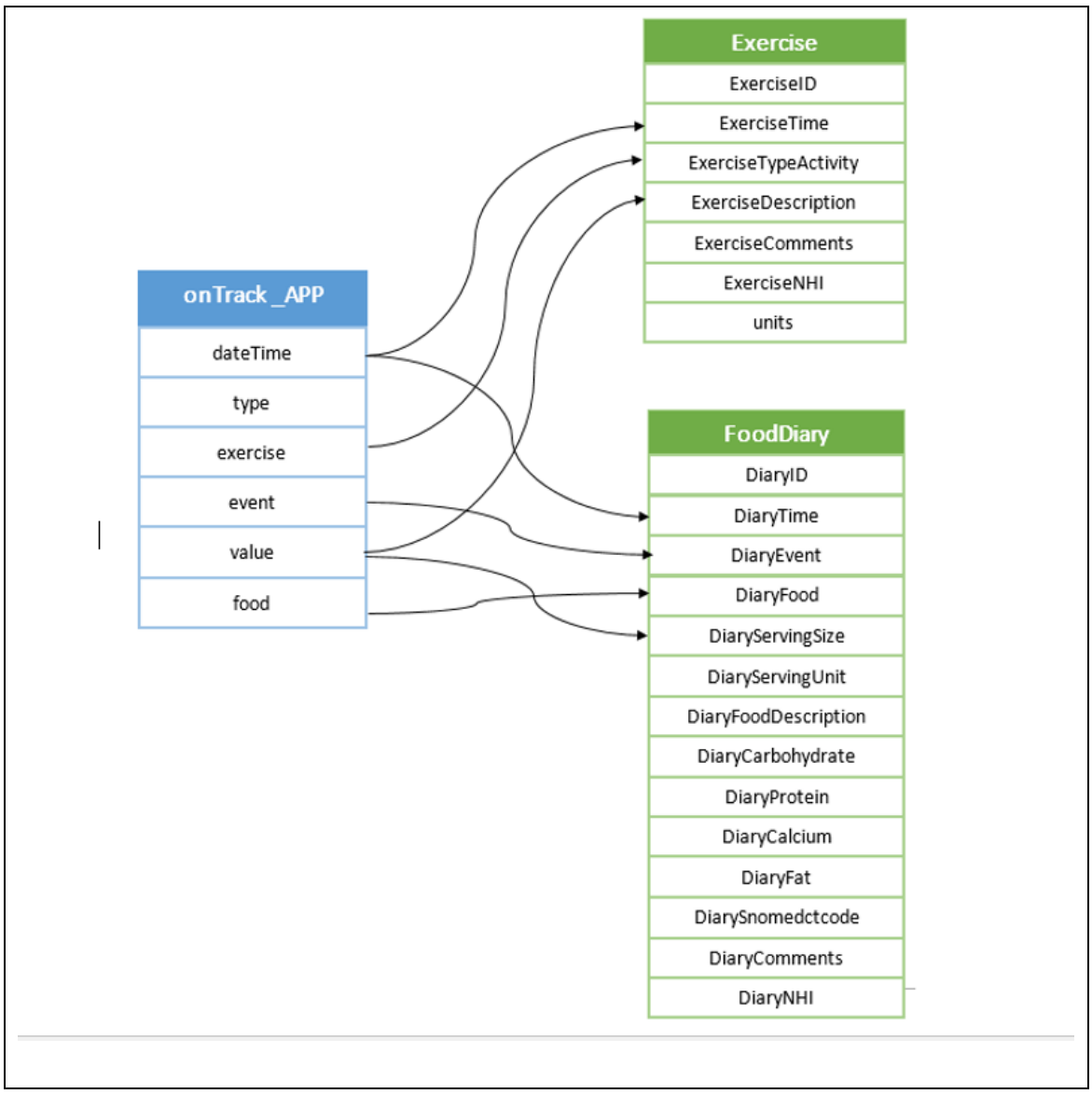
As stakeholders' consultations progressed the Prototype Version 1 was developed as an ASP.Net web application using C# programming language in Visual Studio Version 2013 IDE. It was later upgraded in Visual Studio 2015. The database schema as outlined in Figure 6.6 was developed in SQL Server 2014 in the prototype. Programming scripts were written for each type of mobile app data to map to the target database schema. The data from mobile apps were in different formats and schema. Some of the data integration involved managing the date and time element. In some apps the date and time was a combined value as in OnTrack whereas in other cases such as Glucose Buddy it was split as two different elements. Tools such as Talend had built-in functions to take care of this in its environment. Similar functions were applied in the prototype to store data as a single attribute. The reports such as combined report, list of BG readings and FD were generated using the GridView option in Visual Studio.

Food data was available in different forms in the mobile wellness apps. Each meal, for example breakfast, had several food items to be recorded. In some apps it was described by food name with portion size such as grams or cup as a unit of measurement. Food description had to be split in order to store this information in its simplest form in the prototype database.

Food name | Number of units | Unit of measurement

The data from mobile apps and glucose meter were able to map to the prototype database as depicted in Figure 6.11.




Exercise
ExerciseID
ExerciseTime
ExerciseTypeActivity
ExerciseDescription
ExerciseComments
ExerciseNHI
units
onTrack _APP
dateTime
type
exercise
event
value
food
FoodDiary
DiaryID
DiaryTime
DiaryEvent
DiaryFood
DiaryServingSize
DiaryServingUnit
DiaryFoodDescription
DiaryCarbohydrate
DiaryProtein
DiaryCalcium
DiaryFat
DiarySnomedctcode
DiaryComments
DiaryNHI

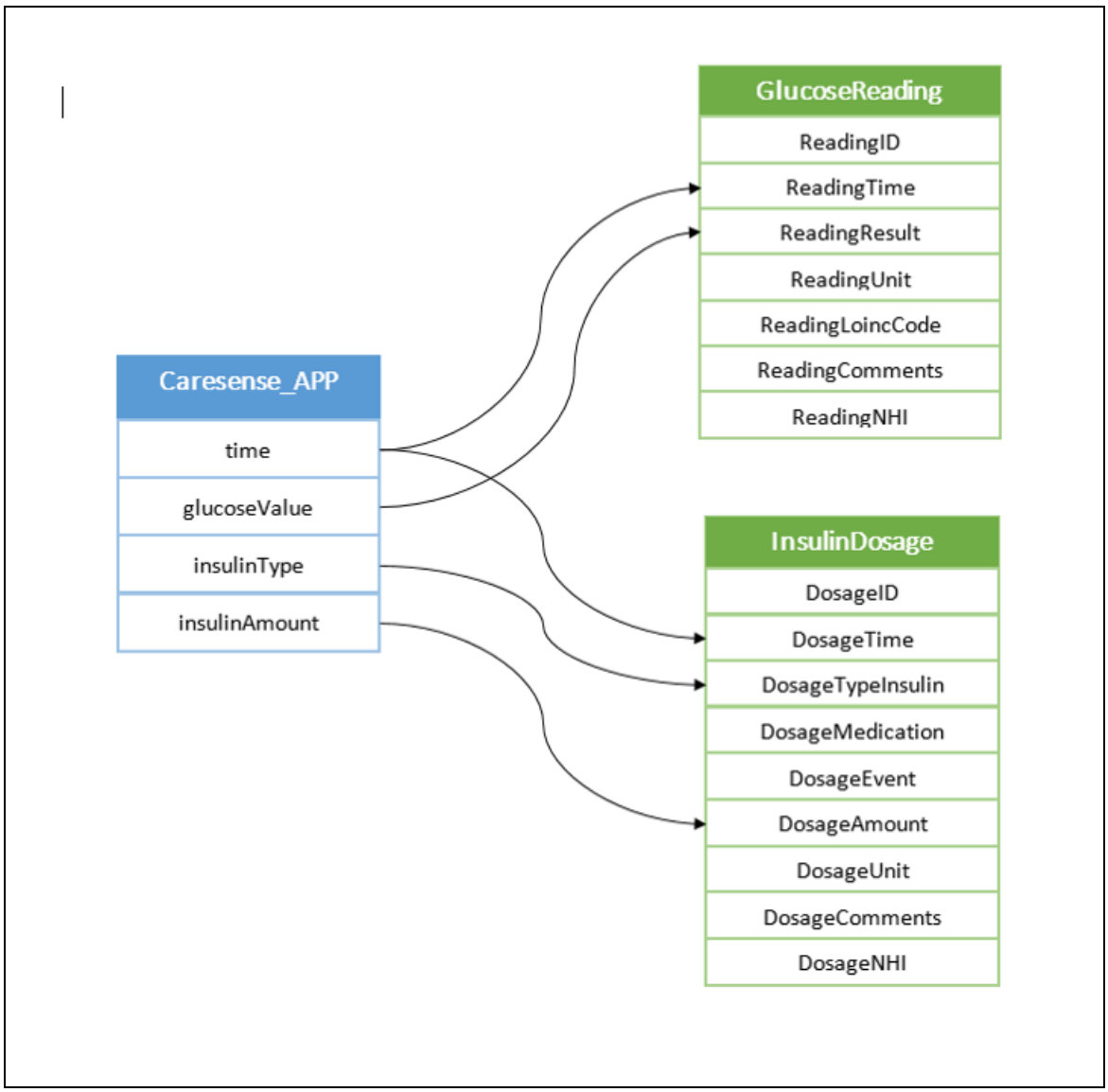


Figure 6.11: Data Mapping of Mobile Apps and Glucose Meter

Prototype Version 1 thus satisfied the two main functional requirements RP1 and RP2. The interface screen illustrating RP1 in Figure 6.12 had options to select the appropriate mobile app and glucose meter in the ecosystem and store the wellness data from these into the prototype.

The prototype displayed data from mobile wellness apps and glucose meter together as a single report satisfying RP2. Mealtimes and BG readings are not fixed for all the days for a patient. BG readings are relative to mealtimes and hence it was important to keep track of the time by the hour. Hence the report displayed the food, BG, insulin dosage and exercise by the hour.

Exercise data was able to be logged in mobile apps together with FD. Hence the requirement about exercise details as RP5 was satisfied together with RP1. Weight was also allowed in mobile apps and the requirement to display as a graph (RP6) was an

option in the prototype.

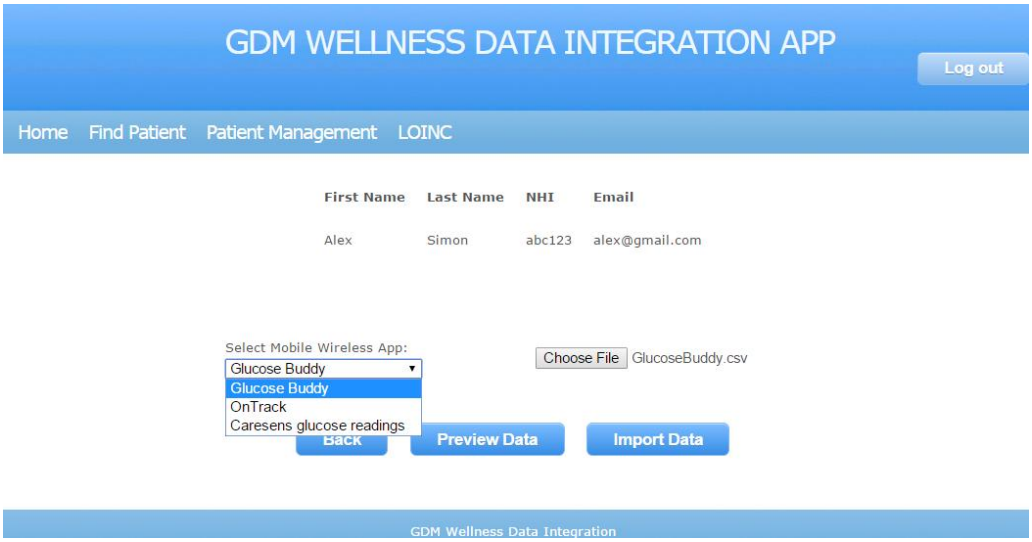


Figure 6.12: Prototype Interface Illustrating RP1

Although the functional requirements were fulfilled, usability issues were highlighted by clinicians during the Prototype Version 1 review process discussed in Chapter 8 Evaluation Think Aloud TAP1. With the feedback received from the Prototype Version 1 review, the second iteration Prototype Version 2 was designed.

6.8 Summary

The Prototype Version 1 satisfied the requirements RP1 to RP6. RP1 and RP5 were satisfied through two selected mobile apps which electronically logged FD, exercise and BG readings. The prototype was able to save the logged data in its database. The prototype was able to display wellness data as a combined report (RP2) for clinicians to view as part of the consultation to make an informed decision about diet and insulin dosage for each individual with GDM. Other requirements RP3 and RP4 were helpful to design the database and its schema. RP6 displayed weight as a graph as this information was captured in mobile apps available to the prototype.

The prototype design process also discussed the mobile apps and its data to be incorporated into the prototype database. Data integration tools were useful as a visual interface to discuss with the clinicians about mapping data from mobile apps into the prototype. The design using UCD principles facilitated the build and evaluation of the prototype in two iterations.

7 Evaluation through Interviews INT2 - Prototype Version 1

Prototype Version 1 was evaluated for its usefulness and ease of use as per TAM theories. Evaluation of the artefact is an important phase in DSRM and various methods of evaluation can be applied. In the current body of work as the artefact was designed according to UCD principles, users were involved from the ex ante to ex post stages of evaluation. The ex ante evaluation illustrated in this chapter, introduces inductive themes for TAM on PU, PEOU and BI.

The evaluation process was carried out at the clinic as follows:

Step1: Research study information was emailed to the participants. Participants queried the details of the proposed ecosystem, suitable downloadable mobile apps and prototype either through email and phone text messages. Prototype demonstration videos were saved on Google Drive and shared with the participants. A User Manual related to Prototype Version 1 attached as Appendix E was also distributed to demonstrate the main functionalities of the prototype. This gave a strong background of the research before the researcher met the participants for the interviews and reviews of the prototype. This two way communication between researcher and participants continued throughout the evaluation process.

Step 2: The Prototype Version 1 was demonstrated to the individual participant. The demonstration was interactive with participants querying on the functionalities of the prototype. Usability issues were highlighted at this stage. The researcher took notes on key discussion points.

Step 3: Semi-structured interviews were conducted with open end questions with each participant. The interview took around 30 minutes of the participant's time. The questionnaire is set out in Appendix C.

Step 4: TA Protocol was conducted to check if participants were comfortable in undertaking the basic task of uploading mobile wellness data and BG readings into the system and viewing it as a combined report of BG, FD, exercise and insulin dosage for each day.

The results of the Step 2 and Step 3 process through prototype demonstration and interviews is illustrated in this Chapter 7 Evaluation through Interviews INT2. The

process was aimed at evaluating the two main measures of TAM: PU and PEOU. The results of Step 4 is illustrated in Chapter 8 Think Aloud TAP1 - Prototype Version 1 to explore usability issues.

7.1 TAM through INT2

The iterative nature of the design and evaluation of the prototype through Prototype Version 1 facilitated the investigation of the research questions as illustrated in Chapter 1. The prototype was evaluated in partnership with the end users; only the clinicians were planned to evaluate the prototype for its perceived usefulness and perceived ease of use as described in Table 7.1.

Table 7.1: Ex ante TAM Evaluation Measures

DS Evaluation Type	Method	Objectives	Techniques/Theories
Ex ante Prototype Version 1	INT2	Effectiveness PU PEOU BI	TAM Usability

The following criteria were re-enforced in the evaluation:

The appropriate data source (wellness data) from mobile apps was acceptable to the clinicians.

The prototype effectively maps heterogeneous data from mobile wellness apps to a global schema defined in the prototype.

The prototype generates appropriate reports to clinicians from the translated and mapped data.

The prototype interface is easy to use, effective and reliable.

7.2 Patient Data Sharing at the Clinic

All women with GDM at the clinic were given a Caresens glucose meter to obtain four BG readings per day. The midwives were the main contact person at the diabetes clinic. Each consultation with the women involved downloading the Caresens meter readings into the clinic standalone PC. This data however was not further used electronically. The midwives printed the report containing BG readings and maintained a hard copy in

their file. A paper FD and electronic FD template was provided to the women to either write the food details or maintain it electronically. Those women who maintained it electronically found it convenient to email it to their clinicians.

In most cases a physical patient file contained details of all the weekly BG readings and FD. There was no provision for keeping a log of BG readings and FD in the hospital systems. Hence midwives kept all the paper work related to BG and FD in the patient file. The hospital system could record only one reading about fasting BG and one reading about postprandial BG and usual FD for a patient.

7.3 INT2: Participants' Profile

Five clinicians took part in the evaluation of Prototype Version 1 through Semi-structured Interview 2 (INT2). These participants also took part in Semi-structured Interview 1 (INT1) and will also participate in the Think Aloud Protocol 1 (TAP1). The profile of these clinicians is discussed in Chapter 4 Research Methodology.

7.4 Interview Questions

The current practice was not changed at the diabetes centre. Clinicians reviewed Prototype Version 1 and the interview questions were designed to evaluate on TAM perspectives and behavioural intention to use the new system.

The following interview questions were evaluated as stated in Appendix C which were considered during the Ethics application.

1. How well is the data set made available for testing in the prototype, appropriate and sufficient to represent wellness data from mobile apps and glucose readings?
2. How robust is the prototype to address the problems identified by clinicians in supporting their patients' self-management of GDM?
3. How well does the prototype combine heterogeneous data from various data sources (wellness data)?
4. Does the prototype generate appropriate reports to clinicians from the combined data? If yes, how? If no, why?
5. What is your opinion regarding the 'perceived usefulness' of the prototype?
6. What is your opinion regarding the 'perceived ease of use' of the prototype?

Each of these questions are individually analysed in the following sections:

7.5 Wellness Data Representation

The wellness data collected from selected mobile apps were about the FD and exercise. Data from the mobile apps was useful to clinicians as it had the provision to record all details of food and exercise. The insulin dosage was also recorded by women on the Caresens glucose meter along with BG readings. However all these different pieces of data were disparate, disperse and not recorded in any single system to bring them together. In most cases, the data was not electronically recorded.

The sample data from two mobile apps OnTrack and Glucose Buddy were presented to the clinicians during the Prototype Version 1 evaluation. The clinicians found the mobile app data represented what was required to be completed as part of the FD. They wanted food details with portion sizes. As most mobile apps had a calorie counter, this was not necessary as part of the FD and was not included in the prototype's database.

Some comments from the clinician participants directly answered the first question about the appropriateness of the wellness data for the self-management of GDM.

The clinicians wanted a full FD from the women with GDM to guide them in managing their BG levels and weight. Hence mobile apps which could give details about food, exercise were appropriate. They were satisfied with the sample data from the two mobile apps and Caresens glucose meter.

> Participant 1
> Yes, it is including pretty much everything that you want to know about: BG, FD, exercise.
> Calories will not tell you what you have eaten. Need to choose apps which are usable. You need app which get the calories, carbohydrate breakdown, protein and fat.
>
> Participant 2
> Give us information at the right time and it integrates wellness app data with BG, which is often a missing link.
>
> Participant 3
> Wellness data is representative. Easy to compare FD, exercise, insulin dosage in comparison with BG
>
> Participant 4
> Reflects physical activity and FD together with treatment and dosage and sugar level.

One of the participants (P #5), a midwife, pointed out that while BG readings were essential for monitoring the condition, insulin dosage was not. This was essentially a current practice as most women recorded their BG level using the device which was stored in the device itself. The BG readings were

downloaded in the clinic by the midwives. Women were not aware or technically savvy enough to use the Smartlog software on their computer to download the readings from the Caresens device and record insulin dosage. Moreover the device was connected to the computer using a cable and did not have provision for wireless connection using Bluetooth or NFC. Newer models of the device had provision for wireless connection and would benefit some women to using Smartlog and keeping track of BG readings and insulin dosage.

> Participant 5
> BG is important, insulin not so.

7.6 Prototype Robustness

To create a robust prototype the data input had to be verified with clinicians for its suitability. Various data sets were created in the two mobile apps selected: OnTrack and Glucose Buddy. The datasets were discussed with clinicians prior to the Prototype Version 1 evaluation. These were included in the stakeholder requirements analysis document while continuous feedback dialogue between the researcher and participants took place.

The data was disparate in nature even with the two mobile apps data selected in the first evaluation iteration. For example food was measured in different units such as grams or cups. Clinicians preferred the cup measurements over grams as it was easy for patients to specify in their FD. The database schema of the prototype was flexible enough to store both values as unit of measurement was included along with the values.

However robust a system, data should be accurately fed into the prototype for it to be meaningful. Clinicians pointed out that the data entered into the mobile apps by patients should be accurate and they should know to enter food details by portion size. Data entry in mobile apps by patients with limited knowledge could be challenging.

> Participant 1
> Patients should have knowledge what they are eating and record it correctly in app.

The clinician participants also mentioned that the advantage of using mobile apps is that the data entry into the apps is done prospectically. As mobile devices are handy and data entry can be done any time anywhere without the need to access a personal computer or laptop and without the need for internet access. Most of the women had smart phones with mobile data. However in a clinical system, clinicians entered the events about the patients retrospectively. Often the patients had difficulty remembering the events and

had to walk through various scenarios to remember the events. Although some women kept a log book, the data was still in various places about food and BG readings.

There was provision for exclusion of high BG readings by patients to avoid high dosage of Metaformin or insulin. Hence clinicians did not trust the hand written notes about BG readings. The prototype accepted data extracted from the Caresens BG meter which is accepted as robust data as it represents actual and accurate data recorded.

Finally, to build a robust prototype with no errors, the prototype code trapped errors through exceptional handling and error messages where possible. Pilot evaluation by users with software development experience checked for termination of the program through errors. Intuitive screen interfaces were built through user-centred design concepts and continuous consultations with clinicians. User input and menu navigation were carefully planned in consultations with the clinicians. Meaningful error messages were also displayed so as to guide the user.

7.7 Heterogeneous Data Integration

It was made clear to the participants that although only data from two apps were trialled in the first iteration of the prototype, there were plans to include more apps in the next iteration. The clinicians agreed that the data from the two apps sufficiently represented what was required for the self-management GDM. Newer apps to be included in the ecosystem needed to include the necessary FD requirement of women with GDM and to allow sharing of data from the app through options such as email. The provision to accept data from a range of apps was necessary to demonstrate the robustness and flexibility of the prototype and to provide a sufficient choice of apps for women.

One dietitian had experience in using MyFitnessPal with her patients. The food database was New Zealand based and hence useful to select the correct food options. The app also had the option to scan the barcode of the food for easy data entry options as requested earlier in the requirements analysis phase (RP9). The app was recommended for inclusion in the next iteration.

7.8 Appropriate Reports with Useful Information

All participants agreed that the BG, insulin dosage, FD and exercise when displayed together saved a lot of their time when looking for pieces of information from disparate sources. In the proposed prototype all details about FD and exercise from suitable

mobile apps and glucose readings were stored in a single database in the ecosystem and displayed together as a combined report. Further there was provision to include insulin dosage in the combined report.

The prototype satisfied the requirement RP2 as stated in Chapter 5 Requirements Analysis and brought different pieces of data together. Although the heterogeneous data was brought together as a report, the wellness data was not presented well on the screen. Usability issues were highlighted.

7.8.1 Declutter Information on Screen

FD was recorded and displayed by the hour as there was no specific meal time. This created 24 columns for a day. In many columns the data would break into multiple lines as the display columns were narrow and the text about FD were verbose. The clinicians found it difficult to read; they were optimistic this could be solved in the next iteration.

> Participant 2
> Visually very hard to read at the moment. It is somewhere to start from and drag that information to one place.

The suggestion of writing down only carbohydrates was not agreed to by all the clinician participants including the dietitians. Women with GDM were asked to keep a full FD which was of interest to the clinicians as they wanted to know about other nutrient intake for a balanced diet in pregnancy. Including only carbohydrate details would have reduced the amount of text about FD; however this solution was not acceptable to the clinicians.

One clinician discussed showing minimum text in the columns and more details appearing when the mouse hovers over the selected text. Although it declutters the interface screen it is difficult to analyse the different pieces of data when comparing BG readings with FD and insulin. It defeats the main purpose of combining the data in the report for comparison and analysis. Hence this was not acceptable. The columns by the hour were combined to represent different events in the day such as breakfast, lunch, dinner and snack time. The column width size was increased and could accommodate more lines of FD text.

7.8.2 Colour Scheme for Normal and Abnormal BG Readings

Other usability issues such as colour text for different BG readings were suggested. BG readings identified as hyper or hypo need to have a different colour text; however the obstetrician was not sure what range of BG readings were considered as hypo or hyper. Discussing this further with midwives it was learnt that the range could differ for each

woman and could not be generalised. A reading over 6.0 mmol/L was eventually considered acceptable as hyper.

Printing in colour was additional cost to the organisation, although it could be printed in black and white as well. While most text would remain in black and white, some of the key highlighting text such as abnormal readings could be in colour. Midwives were encouraged to use the electronic version.

Green or black text was the colour choice for most clinicians for normal BG readings. Although red was the colour choice for abnormal (hypo or hyper) readings, one participant (P#4) did not agree to it as it cast something negative. Purple was another colour suggestion for highlighting abnormal readings. Other participants discussed that since the interface is designed for clinicians and purple is sometimes hard to visualise at a glance while viewing reports, it was recommended to keep the colour in red. They also did not want a colourful screen hence the normal readings were planned to be kept as black. This way the red colour for abnormal readings would be highlighted better while reading the report.

7.9 Navigation Suggestions

Menu choices and navigation of user interface screens were confusing, for example once an import of data from a selected mobile app was completed the user had to navigate to another screen to continue. More on these issues are discussed in Chapter 8 Evaluation Think Aloud TAP1.

7.10 Perceived Usefulness (PU) and Perceived Ease of Use (PEOU)

The prototype was evaluated for an early indication of the PU and PEOU of the prototype. Participants were asked about their opinions regarding PU and PEOU. The open ended questions generated a qualitative evaluation of the prototype through interviews which is discussed further.

The interview process was part of the ex ante evaluation of the prototype. Deductive themes from TAM variables PU and PEOU were the starting point of finding inductive themes in the interview transcripts.

The second round of interviews gave an ex ante evaluation of Prototype Version 1 as an early feedback to improve the prototype. The interview recordings were first transcribed verbatim. Deductive themes from TAM variables: PU, PEOU, BIU were the starting

point for finding inductive themes in the interview transcripts (Money et al., 2015). The deductive and inductive themes are illustrated in the thematic mind map diagram Figure 7.1.

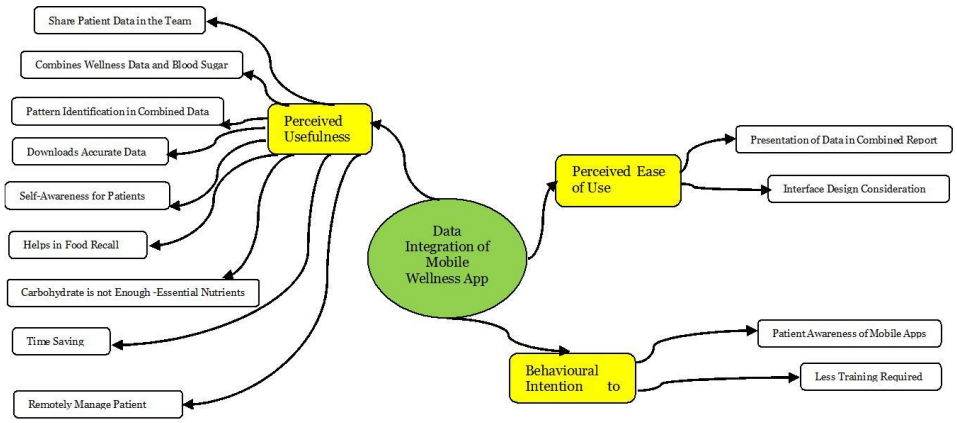


Figure 7.1: Inductive Themes from TAM Perspective

7.11 Perceived Usefulness

For any new system to be adopted, the clinicians had to visualise the PU of the prototype in progress. Hence in the interview transcripts inductive themes for PU were identified which are discussed below.

7.11.1 Share Patient Data in the Team

There is no provision for keeping a log of BG readings and FD in the hospital systems. Hence midwives keep all the paper work related to BG and FD in the patient file. All participants agreed that in the new prototype, BG, insulin dosage, FD and exercise were displayed together which saves a lot of their time looking for pieces of information from various sources.

> Participant 2
> The prototype help share data within the team and I do not have to ask the midwife for the patient file.

7.11.2 Combines Wellness Data and Blood Sugar Readings

The hospital system can record one off readings about BG and usual FD for a patient. In the prototype, daily details about FD from mobile apps and glucose readings from a glucose meter are stored in a single database and brought together as a combined report.

Participant 1
Yes, it is including pretty much everything that you want to know about: BG, FD, exercise. Calories will not tell you what you have eaten. Need to choose apps which are usable. You need app which get the calories, carbohydrate breakdown, protein and fat.

Participant 2
Give us information at the right time and it integrates wellness app data with BG, which is often a missing link.

Participant 3
Wellness data is representative. Easy to compare FD, exercise, insulin dosage in comparison with BG.

Participant 4
Reflects physical activity and FD together with treatment and dosage and sugar level.

7.11.3 Pattern Identification in Combined Data

Women with GDM report to midwives on a regular basis. They usually get a one-off appointment with a dietician in the short duration of their pregnancy when the condition is identified. However if their condition deteriorates and they are not able to manage their BG levels then subsequent appointments with a dietician are arranged. The clinic is busy and does not have provision for additional appointments. The new prototype will bring the data together and identify odd patterns and provide support for subsequent consultations thereafter.

Participant 2
I can see people's pattern of their eating and timings as well.
You notice frequency and when people are doing something different which is part of the learning and teaching we give a lot of information.
Useful, I see the patients once, and could just run an eye over the report thereafter even if I don't have an appointment.

7.11.4 Downloads Accurate Data

Women with GDM often falsify their high BG reading with a lower value when recording from a glucose meter onto a paper sheet or electronic spreadsheet template. The log entries would look good and please the midwives. With the automatic download from glucose meter there would not be the opportunity to manipulate the BG readings. The same could work with mobile apps and they would honestly feed in data not knowing what the trend would relate to the clinician.

Participant 5
BG readings are fudged to please midwife.

7.11.5 Self-awareness for Patients

Self-management is achieved by being aware of the different components that positively or negatively affect their condition. The women can keep a close eye on their

blood sugar, diet and weight through the device and app which makes them aware of these to self-manage their condition.

> Participant 4
> Self-awareness help women to keep their sugar and their weight under control.

7.11.6 Help in Food Recall

Women fill the paper FD retrospectively not having the paper sheet with them at all times. Mobile apps would help in these cases as being portable they are carried with them everywhere they go. Apps with an easy interface would aid in correctly capturing data.

> Participant 1
> App could help with recall
> Patients should have knowledge what they are eating and record it correctly in app.

7.11.7 Carbohydrate is not Enough - Essential Nutrients Required

Managing blood sugar for women with GDM is not merely about managing carbohydrates. Important essential nutrients are required. Moreover women with GDM have no experience managing their BG level and carbohydrate intake even in subsequent pregnancies unlike the Type 1 patient. Hence FD should be in common person's terms which is easy to follow and would be the same as recommended for a healthy balanced diet. However certain nutrients important for pregnancy such as iron, calcium, protein should be included. Women may not be experts in identifying the nutrients in their FD. Hence they should record everything they eat and allow the dieticians to analyse their diet and complete a nutrition assessment.

> Participant 1
> Calories will not tell you what you have eaten. Need to choose apps which are usable.
> I want to know everything they are eating.
> What's the carbohydrate amount is important, also accessing them for nutrient adequacy.

7.11.8 Time Saving

With the increase in GDM cases at the clinic clinicians were asked to adopt smart ways to manage an increased workload. It also saves time when a physician, obstetrician or dietician can see the patient without the need for the physical file held by the midwife.

> Participant 2
> When a woman come to my room, I don't have to find a midwife what she said to her and we don't waste time.

It was also commented that most of the data entry is completed by the women in their own app and would save clinician's time feeding the data into the hospital systems retrospectively which is often not accurate. Currently the prototype database is not

integrated into the hospital systems, there is no seamless data synchronisation between the two systems. Clinicians assess the wellness data from women with GDM in a prototype separate to the hospital system. However the provision to save the wellness data using health information standards such as FHIR is discussed in Chapter 9 Design Prototype Version 2.

7.11.9 Remotely Manage Patient

With the electronic sharing of mobile app data the clinician can upload the data into the system and review it remotely. However women need to be educated about managing the device and apps. Midwives usually ask their patients to share their weekly BG readings. Women need to go to the clinic to share their data. When women are trained and can self-manage, they are asked to email the reading weekly and visit the clinic fortnightly or monthly. The prototype is useful to collate the weekly readings into the system database sent by email to clinicians. The data captured in the prototype can reduce clinic visits by patients and clinicians can remotely assess the women's conditions and recommend diet or insulin dosage.

> Participant 2
> We can all log into our computers and access the information about the patient whom we want to see.

7.12 Perceived Ease of Use

It was observed while coding the interview transcripts that clinicians gave equal importance to the ease of use of the software. With the open end interview questions they had the opportunity to discuss the navigation and interface design of the software. Overall they were optimistic they could learn to use the software and it would be easy to use. The extracts of such discussions were captured and are discussed below.

7.12.1 Presentation of Data in Combined Report

Presentation of data horizontally across the screen was preferred by clinicians. They had similar past experience in seeing paper based records. Each day's readings were displayed as a row. It was easy to compare the readings with other days along an hourly timeline. The BG readings and food consumed were plotted on a timeline which made it easy to compare. High and low BG readings were colour coded to draw attention to these values. Prototype Version 1 had time slots by the hour which made the columns of data very narrow to display food details. In some cases the food names could break into different lines which impeded readability. This was identified as a design constraint to be addressed in Prototype Version 2.

> Participant 1
> Glucose readings across the day with carbohydrate intake is preferred.
>
> Participant 3
> Time in hours as heading across is ideal to read. Easy to compare FD, exercise, insulin dosage in comparison with BG.
> I think colour scheme and it is not just black and white. Maybe it is easier to read.
> Text in narrow column breaking into multiple lines. It is challenging if all details are entered, difficult to fit in narrow columns.

7.12.2 Interface Design Consideration

Interface navigation was straight forward; however with certain tasks the participants had some dwell time thinking how to proceed further. The paper mock replicated the interface screen and the issues were not picked up at that point. With the iterative cycles of development of the prototype the interface design had opportunity for improvement.

> Participant 4
> I might have little problem in the beginning about navigation. How to move forward when the button on screen says 'Back'.
> Once you have learnt the navigation and menu it won't be a problem.

7.13 Behavioural Intention to Use

Participants' intention to use a validated system was prominent through their confidence in adopting the prototype. Participants are aware of, and were keen to keep up with patients' technological progressiveness.

7.13.1 Patient Awareness of Mobile Apps

Patients were aware of mobile apps and devices used to track steps, calories and sleep. Patients were already using mobile apps and devices to manage wellness data and clinicians acknowledged that they were slow in adopting technologies which would have otherwise improved patient centred consultations.

> Participant 2
> Lot of the patients are using technology and they often ask for app for recommendation.

Participant 1 and 5 had patients using mobile apps such as MyFitnessPal and mySugr and shared their FD with their clinicians.

> Participant 1
> My patients use 'MyFitnessPal' and share their data with me through email. It has New Zealand food database. Mobile phone can scan the barcode of food and the details about the food.

7.13.2 Less Training Required

As the prototype developed was work related and similar to other health information systems used in the clinic, the clinicians were confident it would not be difficult to use

the prototype. Learning a new system may be difficult at the beginning but soon repetitive tasks will make it easy to use. The new system was similar to an existing Type 1 self-management system; however this system was not ideal for GDM patients as it required carbohydrate counting and GDM was not funded the same as Type 1 pregnant women.

> Participant 1
> I don't think it will be too difficult just like anything and just learn and then it will be second nature.
>
> Participant 2
> I am not good at computer. I am good at repetitive task.

7.13.3 Adoption Issues

Although the new prototype was beneficial to clinicians and they were willing to adopt this, they raised a few concerns. Food diaries will only be as accurate as the data the patient feeds in; Missing data did not mean that the activity was not carried out. Some patients from lower socioeconomic communities are not equipped with new gadgets such as smart phones and apps. Although apps with food database and drop down options and barcode scanning were suitable, overall minimal data entry from users was desirable. As the system was built for clinicians, the patient perception was unknown. The clinicians had a better insight into the problem and did not feel it was safe for patients to directly upload the data into the system.

7.14 Summary

Prototype Version 1 satisfied the basic requirements which enabled a successful demonstration to the clinicians. The participants as clinicians were able to review the prototype built as part of the ecosystem accepting wellness data from mobile apps. The interview questions examined the acceptance of the prototype for integrating relevant wellness data required for the self-management of GDM, robustness of the prototype and the integration of heterogeneous data from various mobile apps.

The prototype was tested for PU, PEOU and BI. Although the prototype was useful for the self-management of GDM, patients would still need to consult their midwives and other clinicians and these consultations would be more fruitful if all the information required was brought together in one place. Clinicians foresaw remote consultations taking place with the ecosystem.

8 Evaluation of Think Aloud TAP1 - Protocol Version 1

The TA protocol is a usability evaluation tool. As stated earlier in Chapter 4 Research Methodology, acceptance of the wellness data integration prototype was evaluated based on TAM perspectives: PU and PEOU, in a qualitative way. To obtain a rich insight into the perceived ease of use aspect of TAM, the prototype was further evaluated through TA protocol (Benbunan-Fich, 2001).

TA protocol is used as part of the usability evaluation of a new system. Participants verbalise their actions while using a system under evaluation. Various tasks (case scenarios) were set up to understand usability issues. A video recording of the system screen and the participant's voice helped in coding the video at a later stage. Kushniruk et al. (1997) used a similar approach in their study to evaluate HIS. Participants' response to the interview questionnaire was positive although they had difficulties in interacting with the system.

8.1 Background to Think Aloud Protocol

The TA protocol are performed through some defined tasks for the participants. These tasks are part of the problem solving while interacting with the system. It illustrates the cognitive behaviour of the participants undertaking the tasks (Jaspers, 2009). The TA protocol process is helpful in understanding the processes of cognition alongside their occurrence. It gives a direct insight into how participants interact with the system. Verbalisation illustrates the participants' current working memory. It does not depend on long-term memory constructs or retrospective thoughts. TA protocol can be of high value in understanding usability issues in a new system.

The efficacy of HIS has been hampered by poor user interface designs. TA protocol has been used in literature to evaluate the usability of new systems (Benbunan-Fich, 2001). Jaspers et al. (2004) in their research study designed an efficient and satisfactory system for oncologists to prepare patients records for patient visits. TA protocol was used during the early stages of requirement engineering. The computerised system helped the oncologist retrieve patient data better than the conventional paper based record (Nygren & Henriksson, 1992). Clinicians retrieve patient records to analyse the patients' symptoms to give better advice on their treatment. TA protocol and thematic coding thereafter helped in the design of retrieving patient records for patient visits (Fafchamps,

Young, & Tang, 1991). A similar approach of TA protocol and coding of the transcripts in analysing EHR systems for dentists collecting patient records and acting upon it for treatment was demonstrated in recent research studies (Thyvalikakath et al., 2014). Thus in the current body of work along with semi-structured interviews analysing the TAM perspectives of PU and PEOU, the TA protocol approach was applied to explore usability issues of the new system. The TA protocol applied during the two phases of developing the artefact (Prototype Version 1 and Prototype Version 2) helped in refining the system reflecting the requirements from the clinicians.

8.2 Data Analysis of Think Aloud Protocol (TAP)

TA protocol enables the collection of data in 'real time' (Koro-Ljungberg & Barko, 2012). The data collected is 'unfiltered' as participants do not pre-plan their responses and verbalisations. The analysis of the data collected revealed rich insight into themes while coding. There are opportunities to capture such ideas and stories from participants which would otherwise not be expressed through interviews or observations. Participants are inspired to use the new system and reflect on their regular practices.

An initial coding identified all nouns and noun phrases (Fonteyn, Kuipers, & Grobe, 1993) in each participant's verbalised data. Themes emerged from such coding which were provisional and were refined as more data was analysed. A top-down coding scheme was adopted with deductive themes from TAM perspectives and inductive themes from TA protocol were undertaken later (Money et al., 2015). After the TA protocol, semi-structured interviews were conducted to obtain a retrospective understanding of the new system in terms of the TAM perspectives. Some of these discussions took place along with the TA protocol sessions.

Peute, Spithoven, Bakker, and Jaspers (2008) reviewed literature on usability studies of HIS and identified that 73% of research studies applied usability methods on the final system and only 19% applied usability methods such as TA protocol at the design specification stage. Usability studies are undertaken late in the software development life cycle with the potential risk of not fulfilling user requirements. Hence a user-centred approach applied as iterative cycles and reviewing the prototype through TAP1 after the first iteration was useful to identify potential usability issues.

8.3 TAP1: Set Up

In the current body of work, TA protocol was applied as part of the ex ante evaluation

of Prototype Version 1 reinforcing the design specifications and user requirements.

In each of the TAP1 sessions, participants were provided with a user manual and video demonstration of the prototype. This was shared through emails prior to the TAP1 session. The participants had an understanding of the system. On the day of the TAP1, there was a short interview on the TAM perspectives of the new software. Participants were then given multiple tasks as illustrated in Section 8.4. Each participant was asked to verbalise their actions while completing the tasks. A video recording of the screen and the participant's voice was captured through Camstudio software. The researcher also kept notes on the TAP1 sessions and the participants. Participants themselves were not video recorded and their facial expressions and attitudes were not captured. Time was not a factor in the TAP1 sessions as most participants were analysing and discussing the information retrieved from the prototype. Hence some TAP1 sessions went over an hour while most were completed within 45 minutes. The TAP1 session concluded with a short interview to obtain any retrospective feedback on the prototype.

TA protocol was conducted in two stages as depicted in Table 8.1. The discussions on TAP2 will be covered in Chapter 10 Evaluation Think Aloud Protocol TAP2.

Table 8.1: Think Aloud Protocol Evaluation

DS Evaluation Type	Method	Objectives	Techniques
Ex ante	TAP1	Effectiveness Efficiency	Usability
Ex post	TAP2	Effectiveness Efficiency	Usability

8.3.1 TAP1: Participants' Profile

Five clinicians took part in the TAP1 evaluation. These participants also took part in INT1 and INT2. The profile of these clinicians is discussed in Chapter 4 Research Methodology.

8.4 TAP1: Tasks

The ex ante TAP1 evaluations helped in refining the design and navigation of the prototype. Two tasks were designed – Task 1 and Task 2. Each task had sub-tasks.

Task 1 satisfied requirements RP2, RP3, RP4 and Task 2 satisfied requirements RP1 and RP5.

Task 1: View combined wellness report

Task 1.1 Login as a clinician

Task 1.2 Find patient

Task 1.3 View combined report for a range of dates

Task 2: Import wellness data

Task 2.1: Find patient

Task 2.2: Import data

Task 2.3 View combined report for a range of dates

All participants had no issues in logging into the system with the given user id and password. They could easily find the patient through three different methods: finding patient by lastname, firstname, email id; where there were many patients by the same lastname or firstname, a list was displayed and the clinician could select the correct patient from the list. Two participants had to be prompted to verbalise their actions. The main requirements put through INT1 process were reviewed to confirm if they had been accomplished.

Table 8.2: Design Consideration and User Requirements Accomplished through Prototype Version 1

Requirement #	Prototype design consideration #	User requirements accomplished
RP1	Import data from external devices such as mobile apps and glucose meters into the new system.	Completed in Prototype Version 1. Participants were satisfied to see all the wellness data together.
RP2	Display wellness data from mobile apps and glucose meter in a single report.	Completed in Prototype Version1. Usability issues to show all data on one screen. Usability improvements to be

		considered in Prototype Version 2.
RP3	Data elements for important nutrients like carbohydrates to be considered in the database design and interface display.	Completed as part of the Prototype Version 1 database design.
RP4	Data elements to be considered in the database design and interface display.	Completed as part of the Prototype Version 1 database design.
RP5	Import exercise details from mobile apps.	Completed as part of the Prototype Version 1
RP6	Line graph to display weight gain or loss.	Completed as part of the Prototype Version 1
RP7	Assign LOINC code to indicate glucose reading and before/after meal.	To be considered in Prototype Version 2.
RP8	Integration of wellness data into clinical system.	Partially completed in Prototype Version 1 with 'Export Data' option. To be considered in Prototype Version 2.
RP9	Mobile app with suitable food database can be chosen to select food from the drop down list which best match the food consumed.	Considered mobile apps such as MyFitnesspal, Easy diet. However data sharing needs premium account and licenses.

Most user requirements were accomplished in Prototype Version 1. The clinicians were satisfied with the combined data from various sources about FD, exercise and BG readings. However usability issues were emphasised.

8.5 TAP1: Themes and Codes

The verbalisation in TAP1 highlighted issues related to ease of use of the prototype as the participants completed the tasks given. Usability issues were identified in these TAP1 sessions and collated to improve the prototype as listed in Table 8.3. Usability issues were categorised as navigation, interface design, feedback and terminology. Similar themes have been identified in other usability studies (Kirwan, Duncan, Vandelanotte, & Mummery, 2013). However the codes differed as the functionalities of Prototype Version 1 were to meet the needs of a specific user group.

Table 8.3: Codes and Corresponding Usability Themes through Think Aloud Prototype Version 1

Themes	Definition	Codes
Navigation	Navigation refers to the options available to the user to move to next or previous to fulfil certain tasks.	Menu Button Scrolling
Interface Design	Interface design refers to the screen layout, background, position of menu and contents on the screen.	Content placement Columns of text Text colour Background Date/Calendar format
Feedback	Feedback messages guide the user in recovering from errors and acknowledgement when the task is completed.	Error message Acknowledgement
Terminology	Appropriate terminology and language used for user to understand the purpose of each step undertaken within a task.	Language Purpose of button Error message Date format

For each theme the participant's quotes were matched to better understanding to improve the design considerations in Prototype Version 2.

8.5.1 Interface Design

The interface design was modified and re-worked following the prototype reviews. Three main issues were identified:

(i) One screen-full of data – The combined report of BG, FD, insulin dosage and exercise data was more than one screen-full and hence the user had to scroll across and down the screen to view the data. The pdf option showed one screen-full of data at a time and had the print option, which was appealing to user.

(ii) Selection of options to complete a task - The task required users to identify a specific patient and view the combined report for specific dates. There were three steps on one particular screen interface as depicted in Figure 6.12; select the specific dates, select the right search listing option (exercise, BG, FD, insulin dosage and combined data) from the dropdown menu and then finally preview the data on screen. Users were eager to preview data without changing the default options about start and end dates and type of search listing. The interface was therefore set to display the default option for users to minimise data entry options. The date range was set to maintain the end date as

current date and start date as two weeks prior. As in most cases the important report was the combined report about BG, FD, insulin dosage and exercise. This was set as default option in the next iteration.

(iii) Food diaries had details of food consumed, extracted from the selected mobile apps. They were verbose and lengthy as compared to BG readings and insulin dosage. The columns in the report by the hour were narrow and text would break into multiple lines. As women with GDM did not have a fixed meal break and BG readings are taken with respect to meal times, the report had to be flexible to consider all patients and their meal times. Various options were discussed by participants: (a) display the full text when a mouse is hovered over it or (b) increase the column width.

Option (a) would allow to view one data piece at a time and not allow a comparison with other data pieces. Option (b) appeared to be more practical. BG readings were displayed by the hour in columns. To display food diaries close to the BG readings, five meal event columns were designed. A 24-hour timeline was followed although there was less activity at night. Each meal could be described within those columns. Breakfast was allocated from 1:00 to 10:00 (1:00 AM to 10:00 AM), morning tea from 10:00 to 12:00 (10:00 AM to 12:00 PM), lunch from 12:00 to 15:00 (12:00 PM to 3:00 PM), afternoon tea from 15:00 to 17:00 (3:00 PM to 5:00 PM) and dinner from 17:00 to 24:00 (5:00 PM to midnight). Exercise data was also displayed in the same columns. Participants acknowledged that food diaries can be detailed if each and every ingredient is specified, which is challenging to display in columns by the hour. For example, a chicken sandwich could be described as two brown bread slices, 25 grams chicken, 1 tablespoon mayonnaise sauce, 1 tablespoon mustard sauce, rocket leaves, 2 slices of tomato, 2 tablespoon of mashed avocado which was impractical. It was discussed that mobile apps which had a built-in food database would be useful. Users could choose the food item that best described what they consumed, Example chicken sandwich. The overall ingredients and nutrients are stored in the food database in the mobile app.

8.5.2 Feedback

Clinicians found the prototype easy to operate as it was related to their work environment. However certain suggestions were made regarding the names of the buttons as it was confusing to them. The button ‘Back’ referred to the previous screen after completing the current task. It was confusing to them as they were going forward after completing a task.

Users did not have much difficulty understanding error messages. The error messages aided in continuing with the task. The default date format was American, which was pointed out by all participants. This was marked for change in the next iteration.

8.5.3 Terminology

Clinicians did not have much difficulty in the medical terminologies as it was work related. However options on the screen and their relevance were confusing. 'Import' data button was confusing. 'Import' data button name was retained as it meant to extract data from external devices into the system.

8.6 Theme 1 – Navigation

Essential menu options were planned and discussed with participants as paper mock-ups as in the stakeholder requirements analysis document. It did not attract much feedback initially at the first interview as the clinicians were reviewing the main functionalities of the system and the selection of mobile apps to be included in the ecosystem. Through the review of Prototype Version 1 comprising of open-ended semi-structured interviews (INT2) and TA protocol sessions (TAP1), participants found the prototype useful for clinical consultations for women with GDM. The participants associated the prototype to systems used in the clinic and made suggestions to improve the navigation aspects of the prototype. Navigation around Prototype Version 1 was designed to display minimum options on screen whether those options were in the form of horizontal menus or 'buttons' on screen. TAP1 was useful in that it generated the right comments to support appropriate and relevant options for every interface screen. Details of the coded themes for navigation are discussed below.

8.6.1 Menu

When menu options were initially explained and described to the five participants as paper mock-ups, they did not draw much attention. However in the TAP1 sessions, participants had dwell time to consider appropriate menu options to complete the given task. In most cases the participants sought the "find patient" option to commence the next task on the same patient data even if it created more work for them. The 'logout' option was not overlooked while closing the software at the end of every session. Participants suggestions with regard to the prototype reflected on the systems used in the clinic which they were familiar with.

> Participant 4
> Sometimes for our bookings for … ultra sound say, so we have got one screen then next another screen, we click next and it is self-explanatory.

8.6.2 Button

Apart from menu options, buttons were also used to navigate to different operations on an interface. Participants were unsure of the order of the button options to complete a particular task. The button option to 'import data' from external sources (data from mobile apps) was one of the two main functionalities of Prototype Version 1. Functionality RP1 involved selecting the right mobile app from the list of mobile apps, selecting the patient file and then clicking the button 'Preview Data' and then 'Import Data'. The two buttons on the screen at the same time were confusing. Participants requested to display 'Preview Data' and once the data was displayed on the screen the option to 'Import Data' was suggested.

8.6.3 Scrolling

The combined report of BG reading, insulin dosage, FD and exercise was more than one screen-full and the user had to scroll across and down the screen to view the complete report. Although it was annoying at times, the pdf option showed one screen-full of data at a time and had the print option.

8.7 Theme 2 - Interface Design

The interface was designed to display the required information in the right position on the screen following as far as possible, universal patterns of website design for a computer screen or tablet. Most consultations took place at the clinic where clinicians had access to their work computer. The interface was designed to be tablet friendly and flexible to accommodate other venues. Clinicians agreed that to display two weeks of data on small screens such as mobile phones was not ideal. Hence the interface was not designed for mobile phone screens.

8.7.1 Content Placement

Task 1 required the participants to 'find' a specific patient and view the combined report for specific dates. There were three steps on one particular screen interface: select the specific dates; select the right search option (from exercise, BG, FD, insulin dosage and combined data) from the dropdown menu and preview the data on screen. The participants were eager to press 'preview data' without changing the default dates and type of search options. As the prototype had limited test data and the GDM monitoring data is captured for only the few months of pregnancy until the women delivers the baby, not all date ranges had values for display. The participants discovered this once

they were presented with an error message on screen. They then went back to alter the dates as directed in the task sheet. As in most cases the important report was the combined report about exercise, BG, insulin and FD. This should therefore be made the default option.

8.7.2 Columns of Text

Food diaries had details of food consumed extracted from selected mobile apps. As compared to other readings such as BG readings and insulin, food diaries were verbose and lengthy. The columns in the report by the hour were narrow and text would break into multiple lines. As people do not have a fixed meal break and BG readings are taken with respect to meal times, the report had to be flexible to consider a broad range of meal times. The meal time could not be fixed for each patient as meals could be had over a broad time range. Moreover BG readings had to taken two hours before and after a meal to be of relevance. Various options were discussed by participants: (a) display the full text when a mouse is hovered over it or (b) increase the column width.

Option (a) would allow the data to be viewed one piece at a time and would not allow a comparison with other data pieces. Option (b) appeared to be more practical. The hour columns displayed BG. Five meal timing columns were designed to display food diaries adjacent to the BG readings. The BG readings were crucial at breakfast as a pre-prandial and postprandial time of two hours was maintained. Women working night shifts, early morning shifts or waking up late had varied breakfast timings. A 24-hour column was therefore followed although there was minimal food consumption during late night hours. Each meal would fit into the hourly columns. Participants acknowledged that food diaries can be detailed if each and every ingredient is specified, which is challenging to display in the columns by the hour. For example: a chicken sandwich was described as two brown bread slices, 25 grams chicken, 1 tablespoon mayonnaise sauce, 1 tablespoon mustard sauce, rocket leaves, 2 slices of tomato, 2 tablespoon of mashed avocado. It was discussed that mobile apps which had a built in food database were useful. Users choose the food item that best describes the food consumed. The overall ingredients and nutrients are stored in the food database in the mobile app. MyFitnessPal has a food database to cater to different countries including separate databases for Australia and New Zealand. Identifying the right apps was crucial for the clinicians to advise their patients. Thus data interoperability and data integration were part of the prototype design.

> Participant 3
> Challenging if all details are entered, difficult to fit in narrow columns.

Participants who were dieticians wanted all the details from the FD. Other participants were contented with a summary or the usual food habits of the women.

> Participant 1
> I want to know everything they are eating.

Although the data was visually difficult to read, the participants were optimistic that the different pieces of data from various sources such as mobile apps and BG meters came together in one place. The issue of columns of text spread over multiple lines could be resolved through revised interface design.

> Participant 2
> Visually hard to read at the moment. It is somewhere to start from and drag that information to one place.

8.7.3 Text Colour

Abnormal (hyper and hypo) BG readings were asked to be displayed in red or purple coloured text by Participant 4. Other participants suggested a red coloured text to highlight them when seeing a report for a range of dates. However the interface was designed for clinicians and not the patients. Patients may perceive a negative connotation for data in red.

8.7.4 Background

Light background with dark text was recommended. Some of the data when fetched from the database followed the default datagrid format with dark blue text over a light blue background. Black text on a white background was preferred by the clinicians.

8.7.5 Date/Calendar Format

The default date format was American, which was pointed out by all the participants. This was noted and changed to suit the working environment of the clinicians (dd/mm/yyyy). The selection of dates was an issue with four of the five participants. The foremost issue was accepting the default dates shown on screen. After checking the task list they would get the day and month correct, however forget to change the year. As the sample data was a year old the clinicians had to scroll through the calendar to feed in the correct dates. However in practice if the prototype was used the wellness data would be current and the dates would only be a week or two old. It would not be difficult to change this in the calendar.

8.8 Theme 3 – Feedback

Participants had a trial and error learning process to complete the given two tasks. Post TAP1 sessions suggested appropriate error messages for invalid data input.

8.8.1 Error Message

Users did not have much difficulty understanding the error messages. The error messages aided in continuing with the task.

> Participant 1
> Not too bad, if you do something wrong the prompt tells.

Meaningful error message such as “No data for this date range”, “Invalid patient ID” were self-explanatory to minimise errors. These were realised at each and every step where a user could go wrong in the completion of a task. Various error scenarios were examined to provide the right error message in order to avoid frustration.

8.8.2 Acknowledgement

Similar to error messages which were flagged only when something went wrong, other issues such as completion of an operation or process were acknowledged with a message on screen. Example: 30 records copied.

8.9 Theme 4 – Terminology

Participants found the interface easy to use as it was related to their work and they had the domain expertise. However some of the terminologies used were confusing to them.

8.9.1 Purpose of Button

The clinicians made suggestions about the names of the button as it was confusing for them. The button ‘Back’ referred to the previous screen after completing the current task. However it was confusing for them as they were going forward after completing a task.

> Participant 4
> I might have little problem in the beginning about navigation. How to move forward when the button on screen says 'Back'?

‘Export’ and ‘Import data’ as buttons on the screen too were confusing. The participants did not realise the true meaning before undertaking the task. The ‘Import’ data button name was retained as it was meant to import data from external devices into the system. The ‘Export’ button option was suggested to be renamed ‘Report’ as the clinicians viewed the data imported from external wellness data files from mobile apps as a report.

8.10 Design Enhancements for Prototype Version 2

The five TAP1 sessions with the clinicians helped in identifying usability issues. The usability issues identified and numbered from the TAP1 sessions are illustrated in Table 8.4 to be resolved in Prototype Version 2. Prototype Version 2 was built and went through a final evaluation through TAP2 sessions and semi-structured interviews INT3 discussed in Chapter 10 Evaluation Think Aloud Protocol TAP2.

Table 8.4: Usability Design Consideration through TAP1

Usability issue #	Usability issues raised	Prototype design enhancement consideration
UI1	Combined report on screen had narrow columns of data, text breaking into different lines. The pdf file generated was easy to read.	Use a different form of report generation tool, combine columns of food entries showing three main meals and three snacks per day. To be considered in Prototype Version 2.
UI2	Navigation of moving to next and previous screen was confusing	'Back' button to move to next screen was confusing. Recommended to name it as 'Next'.
UI3	Interface buttons import and export data were confusing	Button to be renamed as 'import' to fetch data from external device. 'Preview' button to display on screen.
UI4	Selecting date range was not easy. The default American date calendar from the software was not desirable.	Display date as dd/mm/yyyy format on screen once the date is picked from calendar.
UI5	Colour text was desired to differentiate normal and abnormal BG readings.	Red or purple was suggested for abnormal glucose readings.
UI6	Steps in importing data were not clear.	Options to pick the mobile device and data file were across the screen and the final action to preview data was below. If any step was missed then the error message would prompt for the correct selection on screen.
UI7	Error messages	Suitable error messages planned.

8.11 Summary

The first set of TA protocol sessions identified usability issues in four themes. The codes for each of these themes differed for the ecosystem. These codes are helpful to extend the ecosystem or to build a similar ecosystem to serve a similar purpose.

Support from the clinicians having sufficient domain knowledge helped improve the functionality and usefulness of the prototype by resolving usability issues. Usability issues were addressed by altering the format of the information presented in the

combined report which enabled the clinicians to make better informed decisions. Usability issues addressed the functionality of the prototype and were not directed towards the aesthetics of the prototype interface.

9 Design of Prototype Version 2

Functional requirements numbered from RP1 to RP6 as indicated in Chapter 5 Requirements Analysis were for most part satisfied in Prototype Version 1. The remaining three requirements RP7 to RP9 were considered in Prototype Version 2.

9.1 Prototype Version 2 User Requirements

Although the prototype database had the provision to capture main food nutrients such as carbohydrates and calcium as part of RP4, it had no values from the selected mobile apps. Hence the interface was designed to have provision for clinicians to select these nutrients from the New Zealand Food Composition Table. Most common foods consumed in New Zealand including ethnic food of major ethnic groups are available in this database. Main nutrition values such as iron and calcium which are important for pregnancy and carbohydrates which are important in relation to GDM are considered.

Other requirements such as RP7 were considered to indicate whether a BG reading is a fasting or post-meal reading. LOINC codes were used to indicate a fasting (pre-prandial) or post-meal (postprandial) reading to save these values in the prototype database. Pre-prandial or postprandial BG readings were decided to be coded using LOINC which was not familiar to the clinicians. The clinicians were allowed to add comments on the data captured by patients which also included indicating if the BG was pre-prandial or postprandial. Previously the interface had a menu option named 'LOINC' which purpose was not clear to the clinicians. The menu option was therefore removed and the functionality RP7 was fulfilled through clinicians adding comments on the wellness data. Part of the comments were to describe whether the BG readings were fasting or post-meal. When either of these options were selected, the LOINC code was assigned in the prototype improving the semantic meaning of the captured data.

Health and wellness data captured in the prototype had to be in a format recognisable by other clinical systems (RP8). Therefore clinical terminologies such as SNOMED CT and LOINC were incorporated into the prototype. SNOMED CT codes from the dietary substance were assigned to the food consumed so it could allocate clinical codes to identify the food. Data collected in the database should also be compatible with health information standards such as FHIR which will be further investigated in Section 9.5.2.

Participants also requested mobile apps with minimal data entry (RP9). More apps with

an internal food database were considered which is discussed in the next Section 9.3. The apps which had an internal food database were My Meal Mate, MyFitnessPal and Easy Diet Diary.

9.1.1 Clinical Terminologies for Food Entries

The most common food consumed in New Zealand including the ethnic food of major ethnic groups is available in the New Zealand Food Composition Table. Main nutrition values such as iron and calcium which are important for pregnancy and carbohydrates which are important in relation to GDM were considered.

Clinicians were able to improve the quality of food entries made by patients by selecting the relevant food from the New Zealand Food Composition Table. They were also able to relate the food entries to SNOMED CT terminology. The prototype had the provision to match the food from various mobile apps to the New Zealand Food Composition Table and SNOMED CT terminologies. Although the match was made manually by clinicians selecting the relevant option from a dropdown menu as depicted in Figure 9.1, there is need for further research to map food databases to an ontology for easy identification and usage across various systems.

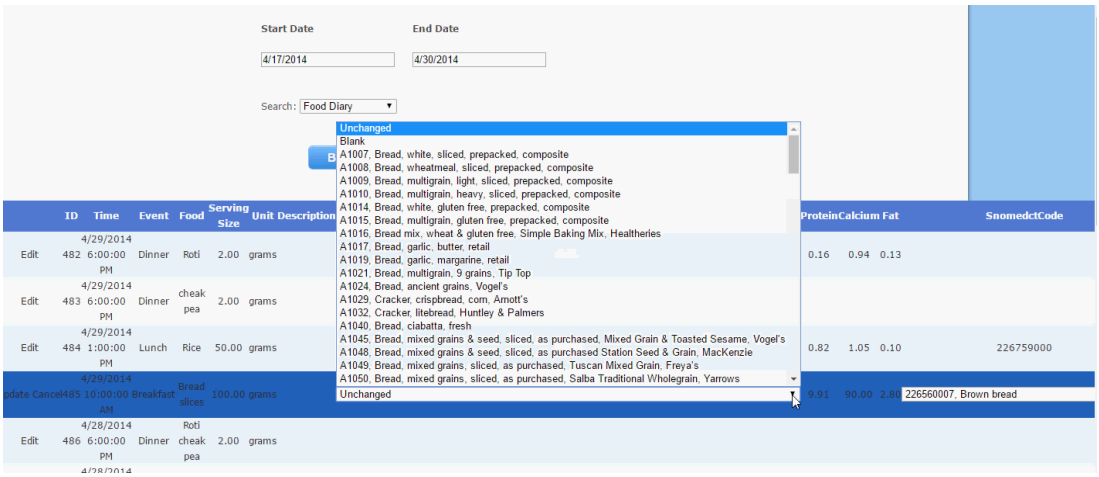


Figure 9.1: Prototype Version 2: Clinicians edit Food Entries from New Zealand Food Composition Table and Adding SNOMED CT Terminologies

9.2 Design Enhancements from TAP1

Usability issues highlighted through TAP1 sessions were improved in Prototype Version 2 as depicted in Table 9.1 and further explained in the sections below.

Table 9.1: Usability Design Consideration through TAP1

Usability issue #	Solution
UI1	New report generation tool worked with improved performance and better alignment of text.
UI2	Back button removed and user allowed to 'Preview' and then 'OK' button to go back to menu options.
UI3	Minimum buttons displayed to navigate user to options in succession.
UI4	Date format was added in webconfig file.
UI5	Red coloured text used to highlight abnormal readings.
UI6	Option buttons on screen were aligned left to right and appropriate error messages were displayed if the right option was not selected.
UI7	Appropriate error messages were designed in the prototype.

9.2.1 Combined Report

The combined report was one of the main functionalities assigned as RP2 in the research project. It displayed data from various sources into one useful report where clinicians were able to compare BG readings with FD, exercise and insulin dosage.

It was challenging to display all food details in narrow columns as a combined report on screen. The meal times for all day and for all women could not be fixed as it varied. The broken text was not easy to read and it was suggested to improve readability in Version 2. The combined report in Version 2 was developed using Visual Studio 2013 Report Viewer. The data on screen was not wholly visible and had to be scrolled across which was annoying. However the report as a pdf file was able to be fitted into one whole screen.

To avoid text breaking across lines, the 24-hour time slots were split as five areas:

Breakfast before 11:00 AM;

Morning tea 11:00AM to 12:00 PM;

Lunch 12:00 PM to 3:00 PM;

After tea 3:00 PM to 5:00 PM; and

Dinner 5:00 PM to midnight.

Even if the food was consumed outside these time slots it would be recorded against the nearest time slot noting the exact time. Other changes made in the report were to improve readability of high BG readings. These readings were displayed in red. Midwives confirmed it could not be generalised for all women. Hence data attributes in

the database will have to be redesigned to set a low and high range for each woman.

It was noticed that the reports written as GridView in Prototype Version 1 were fast in rendering data from the database. However the combined report written as Report Viewer tool in Prototype Version 2 took a longer time to generate. A sample combined report on screen is illustrated in Figure 9.3. The report in pdf format was generated immediately in both cases. A sample pdf report is illustrated in Figure 9.2.

The issue about poor performance in generating the combined report using Report Viewer was investigated in online forums such as Stackoverflow.com and social.msdn.microsoft.com. The solution discussed in these forums worked when the code <trust legacyCasModel="true" level="Full"/> was added to web.config file. The report definition in rdlc in local mode was running slow sometimes taking nearly 2-3 minutes to show data on screen or as a pdf file. With the introduction of the legacy code access (CAS) as true value (default value is false) the report performance was improved.

However this change was made later in Prototype Version 2 and participants witnessing the delay in the generation of the combined report was discussed in the prototype reviews through interviews and TA protocol. They were confident it was a technical glitch which could be fixed.

		Breakfast										Morning tea	Lunch			After tea		Dinner			
		00:00	01:00	02:00	03:00	04:00	05:00	06:00	07:00	08:00	09:00	10:00	11:00	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00
03/10/2017	Exercise								Walking - 1.0 qty		Walking - 0.0 qty				Walking - 1.0 qty					Walking - 0.0 qty		
	FoodDiary								50.00 - carbs		0.00 - carbs				150.00 - carbs					150.00 - carbs		
	GlucoseReading								5.00 - mmol/l		6.50 - mmol/l				5.50 - mmol/l					6.00 - mmol/l		
04/10/2017	Exercise								Walking - 5.0 qty		Walking - 0.0 qty				Walking - 2.0 qty					Walking - 5.0 qty		
	FoodDiary								50.00 - carbs		0.00 - carbs				100.00 - carbs					150.00 - carbs		
	GlucoseReading								6.00 - mmol/l		6.00 - mmol/l				5.50 - mmol/l					6.60 - mmol/l		
05/10/2017	Exercise								Walking - 50.0 qty		Walking - 1.0 qty				Walking - 1.0 qty					Walking - 0.0 qty		
	FoodDiary								50.00 - carbs		0.00 - carbs				100.00 - carbs					0.00 - carbs		
	GlucoseReading								6.60 - mmol/l		6.00 - mmol/l				6.50 - mmol/l					0.00 - mmol/l		

Figure 9.2: Prototype Version 2 Combined Report as pdf File

9.2.2 Interface Navigation and Buttons

Usability issues UI2 and UI3 were related to navigation and completion of tasks. Limited buttons were displayed to proceed with tasks. The labels of the buttons were amended to provide meaningful directions to undertake the given tasks.

In Prototype Version 2 minimal buttons were displayed in the initial screen – ‘Preview Data’. Clicking ‘Preview Data’ would display the data on screen; another event button

‘Import Data’ was then shown on the interface for the user to complete the act of transferring the data from the mobile app to the prototype. The ‘Back’ button was renamed ‘OK’ when displaying reports in various forms such as combined, FD as illustrated in Figure 9.3.

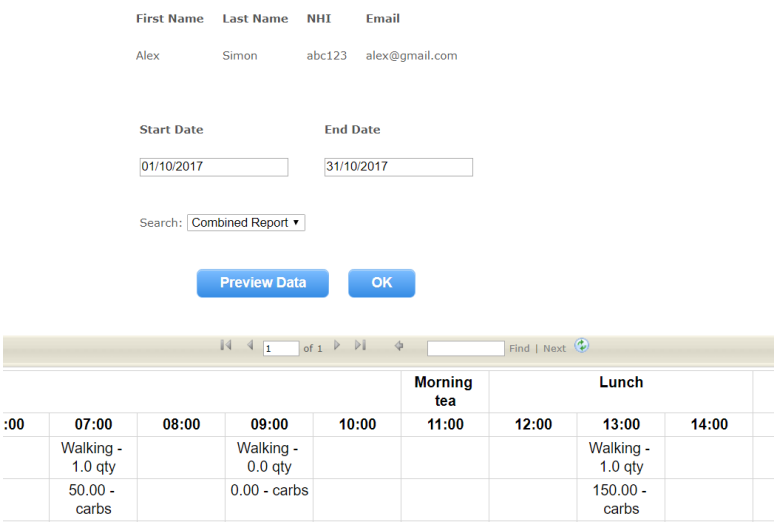


Figure 9.3: Prototype Version 2 Minimum Buttons used for Navigation

9.2.3 Date Format

The default date format was American and was not changed when the prototype was designed and evaluated as Version 1. All participants pointed out that the date format was not suitable and mistook it for the New Zealand format (dd/mm/yyyy) which they were used to when completing the tasks. Although the date was an input in various screen interfaces the amendment to change the format was required in only one file. The web.config file was edited to include a line of code:

<globalization culture="en-GB" uiCulture="en-GB" />

With the date configuration set up, the date format was changed to dd/mm/yyyy in all interfaces.

9.2.4 Abnormal Readings Text Colour

Abnormal readings were retained in red coloured text as the interface was designed for clinicians and it would be conspicuous when compared with other readings.

9.2.5 Error Messages

Meaningful error messages were included which prompted the user for the correct input or action. Most of these error messages were improved with the TAP1 sessions. TAP1 sessions allowed improvements in design so other users do not face dwell time in completing the tasks.

9.3 Extending Ecosystem with Additional Mobile Apps

As Prototype Version 1 was reviewed and modified to improve interface design, other mobile apps suitable for inclusion in the ecosystem were explored. Four mobile apps were of interest: My Meal Mate, Easy Diet, MyFitnessPal and mySugr.

9.3.1 My Meal Mate

My Meal Mate is an app available in Android and iOS. It has a built-in food database depicted in Figure 9.4 which reduces user entries when selecting food consumed. The app did not have the functionality of sharing the FD or exercise data. However when the phone with the app installed was connected to a computer the database with all the food and exercise entries were able to be downloaded into the computer. Although this is not desirable from a non-technical user's viewpoint, it was useful to demonstrate that patient managed health and wellness data stored in apps is available for sharing with clinicians.

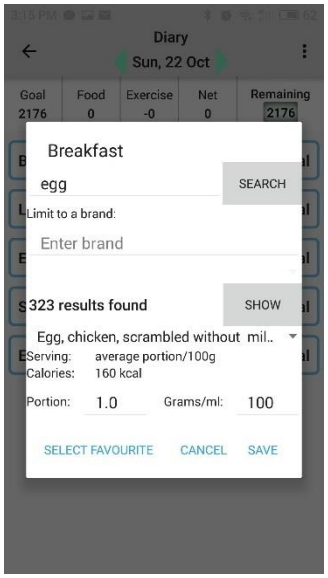


Figure 9.4: My Meal Mate App Allowing Food Entries from Food Database

The database MyMealMateDB.db was downloaded and saved in SQLite. The add-on plugin available in Mozilla Firefox facilitated storing the database as SQLite. Through the SQLite database the records from each table were generated as CSV files acceptable in Microsoft SQL Server database in the prototype. Food details were stored in FoodEntry and exercise details were stored in ExerciseEntry as shown in Figure 9.5.

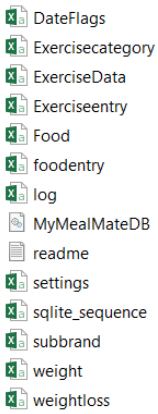


Figure 9.5: Data Files as CSV Files from My Meal Mate SQLite Database

The data from 'FoodEntry' had the necessary attributes about meal types and food items. The data was organised as a relational database concept. The data file about 'FoodEntry' as an individual file had no corresponding values for the food items and had to be referenced in the 'Food' file for its full description. Hence if the 'FoodEntry' file was emailed to clinicians as shown in Table 9.2 it had limited data about the food description and meal time. Thus the whole database had to be imported into the prototype.

Table 9.2: Food Entry Data Files as CSV files from My Meal Mate

Id	Date	MealSlot	FoodItem	Amount	Calories	Photo	CreatedOn	Deleted	NeedUpload
1	1.40651E+12	1	3012814	1	168.75	(BLOB)	1.40651E+12		1
2	1.40651E+12	2	3016289	1	66.6399994		1.40653E+12		1
3	1.40651E+12	3	101267456	1	41.7999992		1.40653E+12		1
4	1.40651E+12	4	65679	1	57.8100014		1.40653E+12		1
5	1.40997E+12	1	218353440	1	59		1.41059E+12		1
6	1.40997E+12	4	5187437	10	2220		1.41059E+12		1
7	1.40997E+12	3	1080877918	1	408.480011		1.41059E+12		1
8	1.40997E+12	2	1296178293	1.000948	654.720032		1.41059E+12		1
9	1.41005E+12	1	2000268394	1	234.899994		1.41059E+12		1
10	1.41005E+12	2	2000338329	1	295.099976		1.41059E+12		1
11	1.41005E+12	3	2000316848	1	388		1.41059E+12		1
12	1.41005E+12	4	202225453	1	331.5		1.41059E+12		1

The 'FoodItem' was the foreign key linked to 'Food' file to fetch more details about the food as highlighted in the Figure 9.6. Similarly the 'ExerciseEntry' file had links to 'ExerciseData' and 'ExerciseCategory'.

	A	B	C	D	E	F	G	H
1	foodid	desc	brandid	subbrandic	serving	size	cals	liquid
5588	3012305	Sauce Mix, White, Made Up with Ski	0	0	1oz/28g	28	59	0
5589	3012807	Eggs, Dried, Whole, Average	0	0	1oz/28g	28	568	0
5590	3012814	Eggs, Duck, Boiled & Salted, Average	0	0	1 Egg/75g	75	225	0
5591	3012819	Fu Yung, Egg, Average	0	0	1oz/28g	28	239	0

Figure 9.6: Data Files as CSV Files from My Meal Mate

A sample FD captured from My Meal Mate and imported into the prototype is shown in Figure 9.7. It is observed that food details are explained in detail in the internal food database. It allows data entries to be of the same style and standard with the food description, portion size and nutrient component.

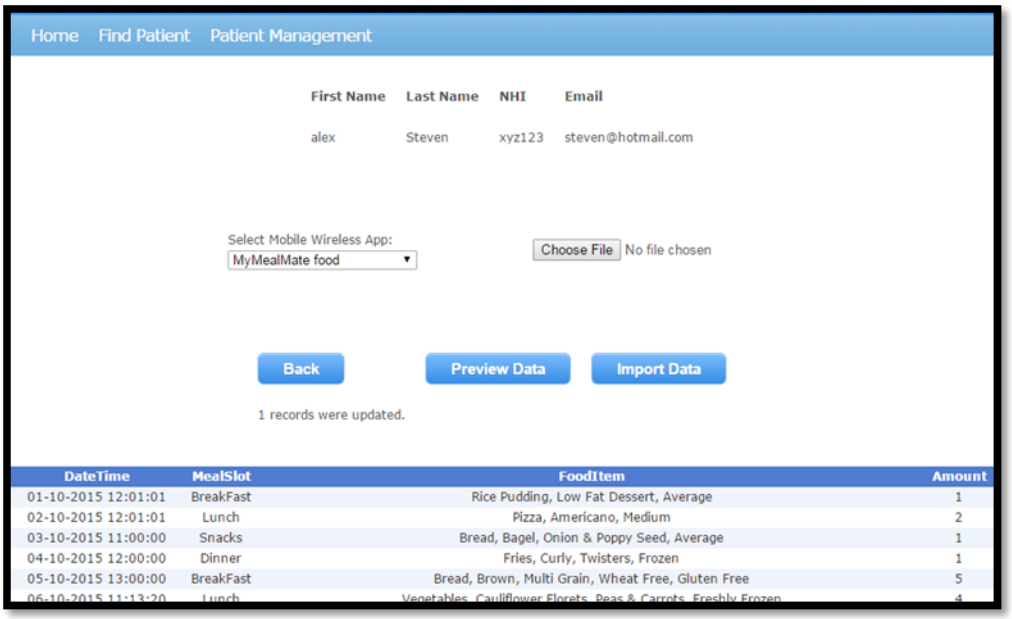


Figure 9.7: FD from My Meal Mate in the Prototype

9.3.2 Easy Diet Diary

Easy Diet Diary is a free app from Apple app store. It is linked to the Australian food database and is developed by FoodWorks® nutrient analysis. It keeps track of calories and major nutrients. Most food items in the app can be selected from the existing food database. It also allows the user to scan a barcode of the food item to obtain details of the food along with nutrient content. It can share data with clinicians through Foodworks database. However FoodWorks is a licensed software and the clinic needs to purchase the software at a cost to access it.

For trialling this app and extracting data into FoodWorks, the 14 day trial version of FoodWorks was used. Data from Foodworks was opened as a database file in Microsoft Access and a CSV file was generated to map the data from Easy Diet Diary into the prototype.

Table 9.3 illustrates the data from Easy Diet Diary which was mapped to the prototype database schema. It was noticed that the food description is taken from the food database having a standard description. Portion size is measured in grams or by cup. The measurement in terms of cups is useful and acceptable by clinicians as people find it hard to measure quantity in grams for food cooked or processed at home.

A sample screen from the prototype is displayed in Figure 9.8 which demonstrates that Easy Diet Diary can be programmed for use in the ecosystem.

Table 9.3: Sample Easy Diet Diary Data

	SeqNo	FoodID	FoodDSId	FoodDSRevision	Weight	Day	Meal	FoodName	Qty
5.68E+08	8	36037	35	150		Friday, 2 October 2015	Dinner	Leggo Pizza Sauce With Garlic, Onion & Herbs	60.00 g
5.68E+08	57	68993	35	150		Friday, 6 November 2015	Other	Ocean Royale Beer Battered Fish Fillets	5.00 fish finger
1.11E+09	47	6.6E+08	42	58		Friday, 6 November 2015	Breakfast	Apple,Fresh,Royal Gala,Peeled	1.00 cup (sliced)
1.11E+09	48	26950266	42	58		Friday, 6 November 2015	Breakfast	Pudding,bread & butter,butter	2.00 cup
1.11E+09	51	6.05E+08	42	58		Friday, 6 November 2015	Lunch	Burger,vegetable,with cheese & salad	2.00 made with sliced bread burger
1.11E+09	54	1.29E+09	42	58		Friday, 6 November 2015	Dinner	Cabanossi	7.00 piece

There were some drawbacks with the use of My Meal Mate and Easy Diet Diary. Although both these apps had an internal food database which reduced data entry for users, it was not suitable as the database was not related to the country (New Zealand) where it was used. Thus even when apps with minimal data entry were investigated to satisfy requirement RP9, it was not entirely suitable for use in New Zealand with different branded food items. On the other hand FoodWorks database being Australian was more closely related. Thus while FoodWorks being licensed comes at a cost to the clinic, the women can use Easy Diet Diary which is a free app.

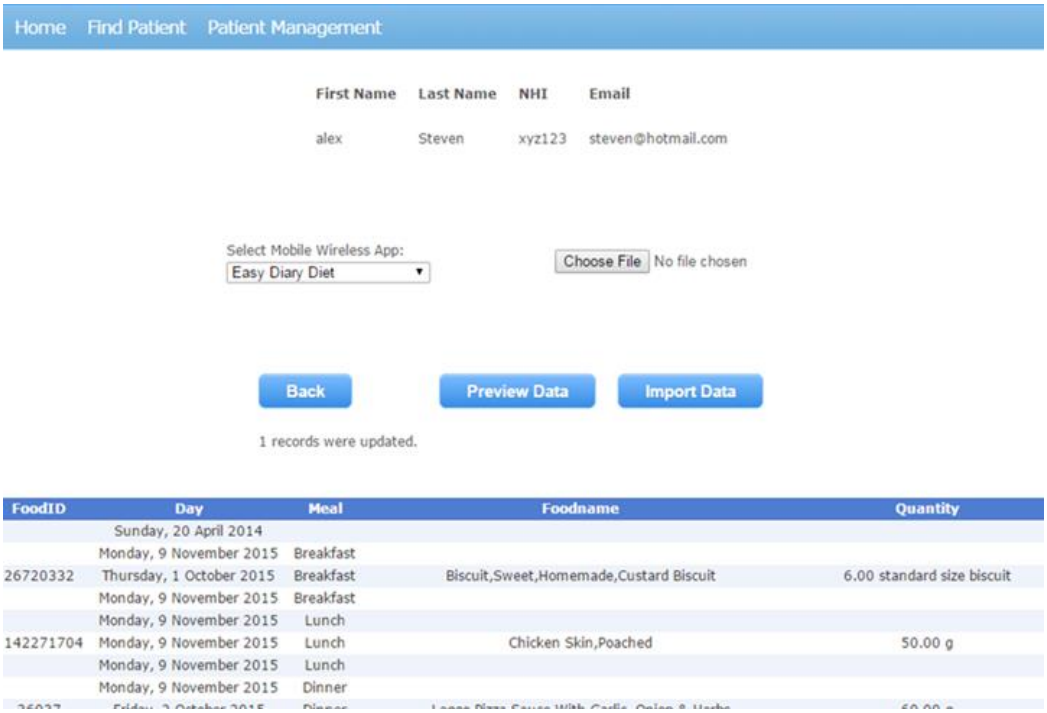


Figure 9.8: FD from Easy Diet Diary in the Prototype

9.3.3 MyFitnessPal

MyFitnessPal (MFP) has a drop down menu for food details for recording FD. It has food databases for New Zealand and a separate database for Australia. This allows the user to select the correct food type from the list as illustrated in Figure 9.9. The app has also the option to scan the barcode on the food item. A report is generated giving details about calories, carbohydrates, protein, fat, sugar and sodium, which can be shared through an individual account. However MFP has no option to download user data as a file, although a pdf report file can be downloaded. Only a premium account has the option to share the file as a data file but this comes at a cost to users and was thus not desirable for inclusion in the current research project.

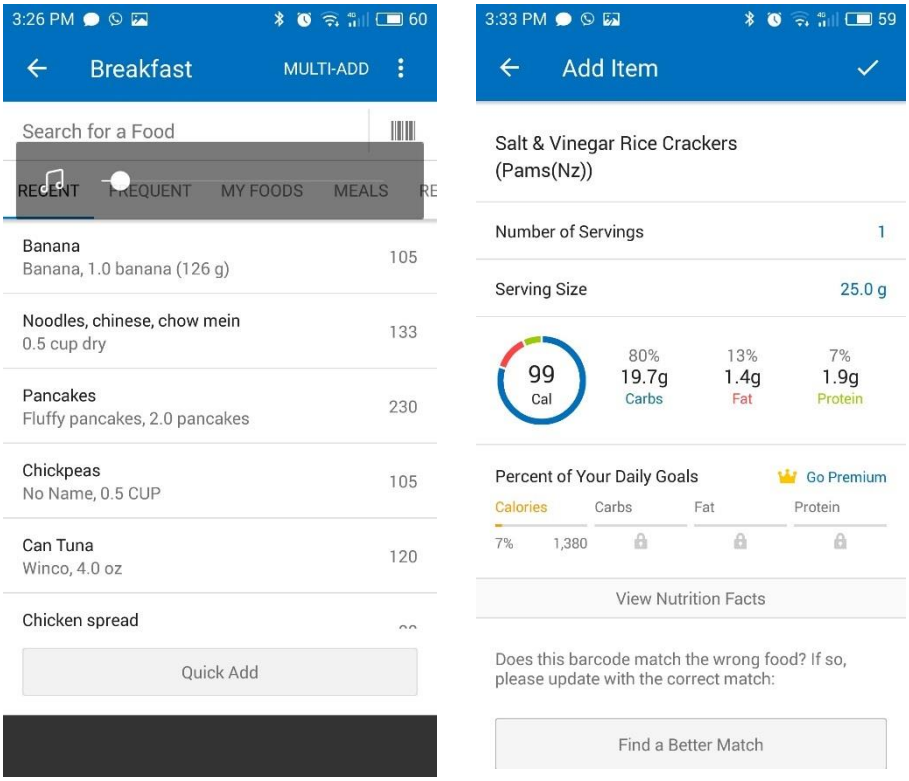


Figure 9.9: MyFitnessPal Data Entry Options through Food Database and Food Barcode

A developer's account on MFP restricts sharing the API for downloading user's data. The API is privately shared upon request with business partners. MFP integrates devices such as Fitbit, JawBone UP, Withings, Wahoo, WIFI scale. The API available from a developer's account can allow users to integrate data from partner devices into MFP. Users want to download their food and exercise data. It is evident in the numerous requests by individuals it is important to be able to download their wellness data as a file[32].

9.3.4 mySugr

mySugr is an app used in the Diabetes Clinic by Type 1 patients to record their BG readings, FD and physical activities as illustrated in Figure 9.10. Although the app is US based, the units of measurement for BG can be customised for New Zealand. Food and exercise details can be logged into the app and shared as a CSV file. The file is suitable to map its data into the prototype database.

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32 http://community.myfitnesspal.com/en/search?adv=&search=download+food+data&title=&author=&cat=all&tags=&discussion_d=1&comment_c=1&group_group=1&within=1+day&date=

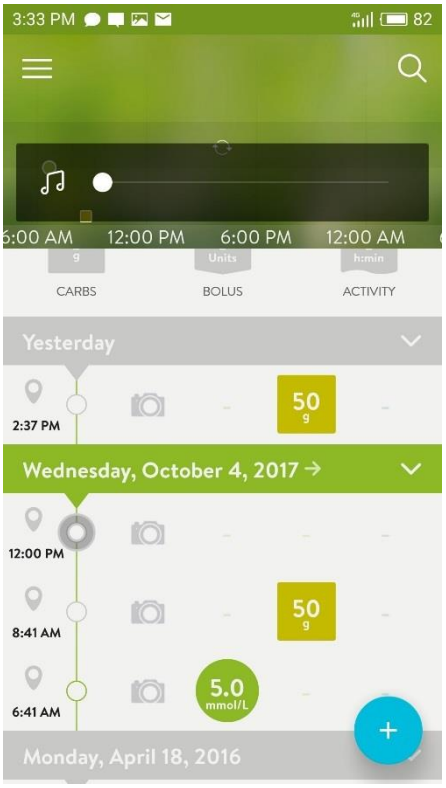

Figure 9.10: mySugr App

Table 9.4: Sample mySugr Data

Date	Time	Tags	Blood Glucose Measurement (mmol/L)	Insulin Injection Units (Pen)	Basal Injection Units	Insulin Injection Units (pump)	Insulin (Meal)	Insulin (Correction)	Temporary Basal Percentage	Temporary Basal Duration (Minutes)	Meal Carbohydrates (Grams, Factor 1)	Meal Descriptions	Activity Duration (Minutes)	Activity Intensity (1: Cosy, 2: Ordinary, 3: Demanding)	Activity Description	Steps	Note	Location	Blood pressure	Body weight (kg)	HbA1c (Percent)	Ketones	Food type	Medication
Apr 12, 2016	7:48:59 PM										75	noodles chicken											Meat,Whole grain	
Apr 13, 2016	8:48:59 PM										50	rice											Lamb	

9.4 Framework for Evaluation of Mobile Wellness Apps

The data integration prototype was a proof of concept to demonstrate an ecosystem capable of integrating data from suitable mobile apps. To start with, wellness data from two mobile apps OnTrack and Glucose Buddy were included in the ecosystem Prototype Version 1. Later other mobile apps such as My Meal Mate, Easy Diet, MyFitnessPal and mySugr were investigated and included in Prototype Version 2. The inclusion of additional mobile apps was subject to certain satisfying criteria acceptable by clinicians. This led to the concept of building a framework that was capable of including more mobile apps in the ecosystem in future.

Patients as consumers have abundant choices of wellness apps in different phone platforms. Users own different smart phones and have access to various apps. Some apps are not available in all platforms. Clinicians are unable to guide their patients as there is no particular app recommend by the clinic or hospital. App reviews may suit patients as a user, but not necessarily be acceptable by clinicians. Finally to include a suite of mobile apps in the ecosystem, the data from mobile apps should be technically viable. Thus while planning a framework perspectives from all stakeholders were considered. The feedback from clinicians and patients guided the structure of the framework.

Reviews of apps are published in websites[33] linked to hospitals and clinics. These reviews are constantly changing as new apps come into existence. Most reviews guide users on the platform, cost, main functionality and communication. When this research study was first commenced in 2013, a review of mobile apps from Princess Alexandra Hospital, Australia was available as attached in Appendix H. MyFitnessPal and Easy Diet Dairy were apps reviewed in this list. At that time MyFitnessPal had the option to share FD data as a pdf file which was not easy to save into the data integration prototype. Various other similar free apps were reviewed over time as discussed in Chapter 6 Section 6.1 and Chapter 9 Section 9.3, which were acceptable by clinicians to be part of the prototype ecosystem.

Literature around downloadable mobile apps was also reviewed which helped in selecting mobile apps for the ecosystem and to later plan the framework to extend the ecosystem with additional apps in future.

[33] https://www.healthnavigator.org.nz/app-library/d/diabetes-apps/

9.4.1 Mobile App Review

In the recent past there have been reviews of commercial downloadable mobile apps available in iOS and Android platform (Tran, Tran, & White, 2012). These reviews are in the interest of consumers (users). 33% of the apps in iOS have the functionality to track BG, insulin dosage, carbohydrates; 8% of the apps have a built in food database (Eng & Lee, 2013). In most cases the data entry was manual. Apps which came with a cost to download were of a superior quality to the free ones (West et al., 2012). However for the research study only free apps were reviewed to avoid costs to patients and the clinic.

Wicks and Chiauzzi (2015) discussed areas of improvement for providing quality mobile apps to consumers. Some of the measures suggested were initiatives from the medical technology community to boost the awareness of good apps, building a safe app consortium monitored by app developers, medical practitioners and researchers, with a review of the apps by a third party to ensure transparency and understanding of its internal working. A medical review should be made available in app stores. Overall Government bodies should regulate the safety and quality of such apps. Although these suggestions are relevant they impair innovation, are expensive and slow the process to introduce new apps. Chavez et al. (2017) evaluated apps for consumer use on the basis of managing diabetes, aesthetics, engagement and quality information. Not all apps were of the quality to complement clinical care. Patients should consult their clinicians regarding the use of a specific app for better-informed decisions at consultation.

After reviewing various literature on identifying good mobile wellness apps, a framework for evaluation of mobile apps was sought in five key areas which are discussed in detail in the Table 9.5. The various literature on each of the criteria is discussed to support the framework presented. These guidelines in the framework assist consumers (patients), clinicians and the technology community to choose the appropriate app to extend the ecosystem.

Table 9.5: Framework for Evaluation of Mobile Wellness Apps

Criteria	Description
Functionality	Main functionalities covered, usefulness

Architecture and open standards	Support for hardware devices and software apps, data interoperability
Policy	Security and privacy of patient data, cloud storage
Usability	Easy intuitive interface
Adherence	Behavioural change, user engagement

9.4.2 Functionality

Wearable devices track physical activities such as steps, calorie count and sleep activity. These tracking devices can synchronize data to a mobile app. Patients with chronic diseases can also use mobile wellness apps to record BG readings, keep track of food and carbohydrate counts and calculate insulin dosage. Most apps allow manual entry of data. Mobile phones and apps which can automate the process of downloading readings from a glucose meter need FDA certification in the US. There are an increasing number of wearables devices which can measure physical activity such as step counters. These devices can then download the data to a mobile app and share it with their clinicians. Patients are unaware if the app functionalities are adequate and correct when monitoring their health and wellness data. Hence clinician input is required to guide patients in their choice of apps and continuous monitoring of their self-management programme is necessary to achieve better health outcomes. Increased communication between patient and clinician through apps is a desirable requirement (Wu et al., 2017) in which case when a patient uploads or reports an adverse BG reading the clinician is available for advice.

9.4.3 Architecture and Open Standards

Data interoperability has been an issue in clinical systems and will continue to be so when integrating data from PHR systems, mobile apps and medical devices to monitor health and wellness. Mobile apps developed using open standards will have better acceptance with third party vendors and other systems. Hence a standard for such shared health data needs to be adopted in the open architecture with software programs such as API written to support most medical devices and mobile apps. Collaboration with participating industry partners is essential for long-term sustainability.

Google and iOS have introduced health and wellness tracking platforms namely Google Fit and Healthkit to integrate data from various devices and mobile apps of participating industry partners. Consumers have to choose the platform that best suits their mobile devices to share data. Open platforms such Bluemix, mHealth, Dossia as discussed in

Chapter 3 Literature Review Section 3.7 are other ways to build an ecosystem.

9.4.4 Policy

There is a global drive for open health data. Commercial downloadable mobile apps save users data in their servers or in cloud based storage. Users are concerned about privacy and security issues of their personal data (Chiauzzi et al., 2015). Each country has their own regulations regarding patients' data and storage from EHR systems. Consumer health and wellness data from mobile apps is still not well defined and is left to the user's choice of accepting apps and its storage. In New Zealand, a HISO 10029:2015 Health Information Security Framework has been drafted to protect patient health information when storing and sharing data in different health systems. National Health IT Board projects encourage different health systems to share clinical data safely and securely for the benefit of individuals to improve health outcomes.

9.4.5 Usability

Usability issues in mobile apps have been identified for their small screen and data entry (D. Zhang & Adipat, 2005) as compared to accessing traditional websites on a computer with monitor and keyboard. Apps should be easy to learn and take less time to complete a task (Nayebi, Desharnais, & Abran, 2012). Most downloadable app reviews are based on usability and include aesthetics, ease of use and ability to interact (Chavez et al., 2017).

9.4.6 Adherence

The effectiveness of mobile apps is also through consumer satisfaction, which aids in promoting adherence to combat health conditions. Consumers should continue its usage to realise the benefits. Good app design should consider behavioural theories.

Behavioural Change:

Short Message Service (SMS) has been used to remind users about food logs, increase exercise and motivate them to eat a balanced diet with fruit and vegetables (Dayer, Heldenbrand, Anderson, Gubbins, & Martin, 2013). Useful educational tips on nutrition, portion size and meal recipes are also part of helping users to make life style changes. SMS are sometimes annoying to users if they are sent in continuous succession. It would be useful to send a reminder once if a user misses a day, a week or a fortnight of entries. Thereafter it is best to stop as the user may have stopped using the app.

User Engagement:

Apps have features to keep users engaged for longer periods. Some of these features

include facilitating social network support and status, goal setting and the calories countdown status for each day. The analysis reports and charts promote adherence to check progress over time. Self-monitoring and tracking progress features were found in 74.8 % of the 550 iPhone apps in a study (Sama, Eapen, Weinfurt, Shah, & Schulman, 2014). Points and rewards through gamification are a growing trend in maintaining adherence levels.

9.4.7 Apps Certification

Organisations such as Happtique had set up digital platforms to build a system of certified apps that were safe and reliable for users (Boulos, Brewer, Karimkhani, Buller, & Dellavalle, 2014) and which could be recommended by medical staff. However the certified apps by Happtique were exposed to patient data privacy and security issues and the organisation consequently ceased to operate (Dolan, 2014). DocGuide (*Docguide*) has a catalogue of iPhone and iPad medical apps suitable for recommendation by health professionals. A similar catalogue is not available for other types of phones such as Android. iMedicalApps, an online publication has a medical team to review iPhone and Android mobile apps and publish their findings on its website. App store has such medical reviews for every app released. Medical devices connected to smart phones need FDA certification as it is a high risk advising medication dosage depending on readings from the device. Similar standards are in place from other organisations worldwide, for example the European Medicines Agency (EMA). To improve the quality of medical apps such as an insulin dosage calculator, app developers should maintain transparency about the development and medical calculators built into the app. The apps development should have comprehensive documentation about its internal algorithm used in dosage calculation.

9.5 Extending Ecosystem with Other Clinical Systems

Two separate projects were undertaken to investigate the possibility of storing wellness data into clinical systems outside the wellness data integration prototype. The first project involved storing the data into an existing EHR system and the other involved using the emerging healthcare information exchange standard FHIR.

9.5.1 Wellness Data in OpenEMR

The storage of wellness data into an existing EHR was investigated (Pais & Xu, 2016). OpenMRS was identified as being suitable among other existing open source EHR systems. Wellness data is generally not stored in EHR systems. The architecture of OpenEMR was studied and Class Observation had the potential to store patient's

wellness data. However the path to store such data was through a Class Visit and Class Encounter. Wellness data in CSV format was written into the OpenMRS database by a new programming code written in Java. The project demonstrated that wellness data can be written into an existing EHR system if required to be part of the HIS.

9.5.2 Wellness Data Exchange using FHIR

The data elements from FHIR resources were considered in the wellness data integration prototype as it can allow the semantic interoperability of sharing data from the prototype with any clinical system. The exchange of wellness data from the wellness data integration prototype to a FHIR server was investigated as a separate project (Pais, Parry, & Huang, 2017).

FHIR has resources for most clinical data such as Patient, Observation and CarePlan among others[34]. The data elements in Observation are designed for laboratory test data such as BG. It can record diagnosis and monitor progress. Wellness data from mobile apps and glucose meter is not designed as an FHIR resource by default. If an official resource on wellness is published in FHIR then the data from mobile apps can be integrated from the wellness data integration prototype into an EHR system. In the absence of such a resource, an existing resource called Observation was considered. It was possible to add new data elements in a resource by defining it as an *extension*. In order to explore the possibility of including wellness data in Observation, BG readings from a glucose meter were defined as an extension. The related LOINC codes were assigned to distinguish these from laboratory results. A resource cannot contain multiple values which lead to a large number of individual values. As these resources are used to exchange health data, it ends up having multiple transactions from the prototype to the FHIR server. To avoid this, the 'Bundle'[35] feature of FHIR was used to pack a collection of resources and transfer it as a single instance to the server. Several FHIR servers were investigated[36]. Hapi FHIR server[37] had an open source project in Github which had support for most resources of FHIR and its operations. The query builder UI facilitated the testing of BG readings.

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[34] https://www.hl7.org/fhir/resourcelist.html
[35] https://www.hl7.org/fhir/bundle.html

[36] http://wiki.hl7.org/index.php?title=Publicly_Available_FHIR_Servers_for_testing

[37] http://fhirtest.uhn.ca/

FHIR is an emerging standard and hence limited similar FHIR projects are available in literature. There is worldwide support for the standard.

9.5.3 Similar FHIR Projects

A vendor application has successfully integrated patients' laboratory results into an EHR system using FHIR resources (Mandel, Kreda, Mandl, Kohane, & Ramoni, 2016). Meaningful Use Stage 2[38] was adopted to allow patients access to their health data. In another project (Franz, Schuler, & Kraus, 2015), the architecture had the facility to collect weight from a weighing scale and integrate that data using FHIR resources - Device and Observation. Hong, Morris, and Seo (2017) have built an ecosystem to store patient health data from HIS to a PHR system. The PHR system based on IoT module can communicate using FHIR to share wellness data.

9.6 Summary

The wellness data integration prototype built in the current body of work has demonstrated the potential of integrating wellness data from a wide range of mobile apps and glucose meter device into an ecosystem. The choice of mobile apps included in the ecosystem was determined in consultation with clinicians who had similar wellness data requirements. The clinicians also guided the design of the prototype and through INT2 and TAP1 sessions a set of usability issues were identified and resolved in Prototype Version 2. The use of existing health informatics standards improved the semantic meaning of the wellness data. LOINC and SNOMED CT codes were included as part of the wellness data. The technology and architecture of using existing open source systems and data exchange standards were investigated through mini-projects using OpenMRS and FHIR. These mini-projects validated the ability of patient wellness data to be represented in EHR systems.

[38] https://www.healthit.gov/providers-professionals/step-5-achieve-meaningful-use-stage-2

10 Evaluation of Think Aloud Protocol TAP2 - Prototype Version 2

Prototype Version 2 was an improved version of Prototype Version 1. Usability issues identified in TAP1 were resolved in Prototype Version 2. TAP2 sessions as part of the evaluation are presented in this chapter.

10.1 TAP2: Set Up

TAP2 was applied as part of the ex post evaluation of Prototype Version 2 to confirm to the participants that the design and usability issues raised in TAP1 were considered ad remedied. Tap2 introduced additional participants including clinicians and women with GDM.

TAP2 sessions were similar to TAP1. User manual and prototype demonstration videos were emailed in advance to the participants. There was a short introduction of the prototype to new participants before the TAP2 session. Participants were then given the task list illustrated in Section 10.2. TAP2 session concluded with discussions on questions related to INT3. In some cases these discussions took place along with TAP2 sessions.

Table 10.1: Ex post Prototype Evaluation Measures

DS Evaluation Type	Method	Objectives	Techniques
Ex post	TAP2	Effectiveness Efficiency	Usability
Ex post	INT3	Effectiveness PU PEOU BI	TAM Usability

10.1.1 TAP2: Participants' Profile

The core team of five clinicians whose profiles are described in Chapter 4 Research Methodology Section 4.5 were involved in the ex ante evaluations of INT1, INT2 and TAP1. These participants further evaluated Prototype Version 2 through TAP2 and INT3 sessions as part of the ex post evaluation. Five other clinicians and five women with GDM were recruited to evaluate Prototype Version 2 through TAP2 and INT3 sessions.

10.2 TAP2: Tasks

Prototype Version 2 had the updates of the design specifications and user requirements requested in Table 9.1 of Chapter 8 Evaluation Think Aloud TAP1. Details of the design updates are described in Chapter 9 Design Prototype Version 2 under Section 9.2.

The semantic meaning of the data was improved by including clinical standards such as LOINC and SNOMED CT. Food diaries from mobile apps lacked data on important nutrients such as carbohydrates, iron and calcium required for women with GDM. The New Zealand Food Composition Table provided the missing data pieces and calculated the nutrient value based on the food portion size. SNOMED CT from the dietary substance added value to identify the food and retain its semantic value if required to integrate with other systems. The glucose meter readings taken by women at home had a different LOINC code to the one tested in the laboratory. The LOINC code also differentiated the fasting and postprandial BG readings. The unit of measurement used in New Zealand was also identified in the LOINC code. The LOINC code for the fasting BG reading from a glucose meter is 14770-2 for mmol/L unit of measurement. Similarly the LOINC code for a non-fasting BG reading is 14743-9.

The ex post evaluation was used to evaluate the prototype for acceptance and satisfaction. Fifteen participants - Ten clinicians and five women with GDM participated. Participants 1 to 5 had also participated in the first round of TAP1 sessions. There were five tasks planned in TAP2. The first two tasks were the same as the ex ante TAP1 sessions. Most participants took part in the first two tasks. Task 3 was related to pre-prandial and postprandial BG readings. Tasks 4 and 5 were designed for dieticians to include nutrient details. Although patient access was not envisaged for the prototype, the women with GDM were given a demonstration of Prototype Version 2.

The tasks 3 - 5 are illustrated below. A detailed task scenario handed to participants is attached in Appendix F.

Task 3: Identify fasting (preprandial) and non-fasting (postprandial) readings and assign LOINC codes

Task 3.1: Find patient

Task 3.2: View BG readings for a range of dates

Task 3.3: Identify whether fasting or non-fasting

Task 4: Assign SNOMED CT code for food item

Task 4.1: Find patient

Task 4.2: View FD for a range of dates

Task 4.3: Assign SNOMED CT code

Task 5: Assign nutrients value

Task 5.1: Find patient

Task 5.2: View FD for a range of dates

Task 5.3: Select food item to get calculated nutrients value

In most TAP2 sessions, the participants were exposed to routine tasks such as finding a patient and generating the combined report. The participants could scroll across the combined report and print a copy if required. The time taken to complete the tasks was not relevant as the participants undertaking the task verbalised their actions and analysed the wellness data presented on the screen. Participants were not merely interested in completing the task but wanted to understand the process and analyse the output generated on screen. Some feedback about the perceived usefulness and perceived ease of use of the prototype aimed for INT3 came through the TAP2 process.

Tasks 1 to 3 were applicable to all participants. Tasks 4 and 5 were related to nutrition and were of interest to dieticians. Although the interface was built for clinicians, patient participants were required to complete tasks 1 to 3 and their feedback gave an insight into their willingness to adopt new technologies such as mobile apps for self-management of their GDM condition and sharing their wellness data with clinicians.

Task 3 to 5 were not available in Prototype 1 and were included in Prototype Version 2. Task 3 was included as BG readings were not distinguishable whether they were fasting or postprandial. Although the glucose meter had the option to set readings as post-meal, if the user (women with GDM) is not aware of these advance settings or does not remember to set it at the time of recording BG, it can be corrected in Prototype Version 2. LOINC codes were included to add semantic value to the fasting and postprandial readings when integrated and used in the clinical environment.

Task 4 included SNOMED CT codes from the category Substance which included dietary and further branched out to food items. These codes had been used to identify food which caused allergies and dietary intolerance. The same codes were used for FD and when integrated in clinical systems would provide semantic meaning for those foods. A direct mapping was not possible as sufficient data was not captured at the time of data entry into mobile apps. For example if a user entered rice in the mobile app, the type of rice: brown, white, jasmine could not be automatically assigned. Hence clinicians had to go through these data and discuss them with their patients to improve clarity of the food type. A dropdown option was assigned to match the food best indicated by the user. The clinician would then select the right food along with SNOMED CT code in consultation with their patients.

Task 5 assigned important nutrients namely carbohydrates, iron, calcium, fat, protein from the New Zealand Food Composition Table and calculated nutrient values to the portion size consumed. Carbohydrates were essential for managing BG levels while other nutrients were essential for the pregnancy.

All participants had no issues logging into the system and finding the correct patient. Participants easily found options on screen to complete the tasks. In the beginning they were not quite sure about how to perform the task, verbalise their actions and keystrokes at the same time. With some initial prompting from the researcher they eventually managed to do both. Some of the tasks were repetitive in Task 1-3, and by the end of Task 3 they were reasonably proficient.

10.3 Interface Design

All design issues from Prototype Version 1 identified through TAP1 sessions were resolved in Prototype Version 2. New design issues were identified which were not difficult to fix as depicted in Table 10.2.

Table 10.2: Usability Design Consideration Through TAP2

Usability issues raised	Prototype design enhancement consideration
All BG readings above 6 were colour coded to red. Fasting and after meal BG have different normal parameters.	The BG readings from the glucometer should be clearly identified as fasting or non-fasting. In case it is not identified through the device, clinicians have the option to describe it as fasting or non-fasting with the LOINC code

	assigned through the interface design. Thereafter the colour coding of the readings can be changed through programming logic.
Date Range for viewing data	Current date is displayed as end date. Start date is two weeks prior, user can edit these dates. It was also suggested it goes to the period automatically when the woman first started maintaining the data.
Data across the screen	Scrolling across the screen was not convenient. File generated as a pdf file was viewed as one screenful.
BG reading and insulin dosage	BG reading displayed after insulin dosage to show cause and effect.
Background and text colours	Change default colours available in the software IDE to display black text over white background.
Terminology	Avoid clinical terminologies on the interface.

10.3.1 Date Range

As limited test data was loaded in the prototype dates for the test data was over a year old and most participants found it challenging changing the year, month and day in the calendar. In most cases the participant did not feed in the correct year merely as an oversight error and got no output displayed on the screen. It was annoying for them to go back and edit these simple data pieces. It was suggested that the prototype automatically load the start date when a patient is identified. This issue was mainly because of the limited test data used and the test data was old. However in a live situation when women visit the clinic they bringing with them the latest data from the last two weeks and hence it would not be difficult to select the correct date range.

10.3.2 Wellness Data Display

The first five participants appreciated the improved report format of the combined wellness data. Breakfast was allocated from 1:00 to 10:00 (1:00 AM to 10:00 AM), morning tea from 10:00 to 12:00 (10:00 AM to 12:00 PM), lunch from 12:00 to 15:00 (12:00 PM to 3:00 PM), afternoon tea from 15:00 to 17:00 (3:00 PM to 5:00 PM) and dinner from 17:00 to 24:00 (5:00 PM to midnight). Exercise data was also put in the same columns. The pdf file was easy to scale on the screen and view all data for the day across the screen.

> Participant 1
> (Viewing the pdf) This is much nicer to look at. You can see what exactly the readings were, when the readings were taken and what has been eaten with different meals on different days. It is much easier to see in pdf than the first report that was generated (on screen).

Participants who did not take part in the first round of evaluation of Prototype Version 1 found it difficult to read across the screen. Participants who had evaluated both prototypes saw the improvements in the Prototype Version 2. The amount of verbose text written under FD varied from simple words to detailed descriptions. The column size could vary with these data and it was challenging to fit all of it in a screenful of data. The printed pdf version was easier to read.

One clinician was unhappy with the order of data display. She wanted the insulin dosage before the BG reading as it reflects cause and effect.

> Participant 9
> For me this screen is very hard to read because it is the wrong way because I want the insulin before the BG.

10.3.3 Terminology

Participants did not know the importance of LOINC codes. They however proceeded with the task and later appreciated the additional comments included for fasting and non-fasting readings with LOINC code. The terminology on the interface needs to be clear to the user for undertaking the tasks. Clinicians were not used to relating data in medical terminologies although most HIS have data stored in medical terminologies.

> Participant 3
> I have clicked one reading and not sure what LOINC readings are?
> I go edit and use drop down menu to select one code fasting and non-fasting.

10.3.4 Background and Text Colour

The additional tasks were designed as new interfaces but the design plan omitted some of the review feedback from TAP1. Similar usability issues identified earlier in the Prototype Version 1 were omitted in the design of new functionalities RP7 and RP8. Participants could not easily locate *Edit* and then *Update/Cancel* options in tasks 4 and 5. The background and text colour were taken from the default template available in the IDE.

> Participant 3
> Hard to read the update on the blue background.

10.4 Missing Data

Participants 1 to 5 had reviewed Prototype Version 1 and could relate to the revised version of the prototype. The combined report about wellness data: BG readings, FD,

insulin and exercise was able be viewed in one place, which was useful to clinicians. However the participants raised concerns that it would be impractical to go through each day's FD with the women and fetch additional information about nutrient values from food databases. They could educate them by going through a few days and then the women could self-manage in their own time if the prototype had an interface for the women.

> Participant 1
> It is nice that it incorporates with food database, so it could be of some value. But the amount of time we get to be with the women there is probably not much time.

The FD may not be complete. It does not mean the women were not eating; it could be they did not enter the details because they either thought their blood sugars are normal or simply forgot to update. Clinicians need to analyse the data case by case and make notes if any exceptional data is observed.

> Participant 7
> Because they got GD they don't have to write down what they have been eating. They only need to write down only if they have been eating only for that time what they have had high blood sugars. If their sugars are normal we don't ask them to write down.
> Lot of them I do see, they send me their full FD. But they don't have to do that.

10.4.1 Comments

Comments were useful for clinicians to make notes alongside the data readings. Some of the comments would reflect the activity, food intake or insulin dosage.

> Participant 7
> I might write a comment saying if I know she forget her insulin, she did more exercise than usual, or she had a big slice of cake (baby shower), maybe that kind of things I might write.

10.5 Educating about Carbohydrates and Insulin Dosage

Women with GDM have to learn how to manage gestational diabetes in a short timeframe. Mobile apps along with glucose meter readings can bring these data together in the clinical system. Although women with GDM are not taught to count carbohydrates as long term Type 1 patients, the carbohydrate content in the food is useful to them to adjust the insulin dosage as required. Women had to learn to manage their food quantity, BG and insulin dosage and it was not required to record food in grams as it was difficult to guess the right quantity. It was sufficient to record in cups or other measures.

> Participant 7
> I know my patients would find it helpful to know how many carbohydrates. It may help quantify how much insulin to take or adjust to. If they know they are having less amount of many grams of carbohydrates, then they need x amount of insulin. Moreover, they do not need to record in grams, it is sufficient for them to say 2 slices brown bread, ½ cup rice.

10.6 Patient Feedback

Women with GDM found the prototype system useful as it collates all data about BG and FD in one report. They were willing to use mobile apps which could allow them to keep track of their diet and BG. Women were familiar with using mobile apps to monitor their steps and diet even before their pregnancy and onset of GDM. However the clinic had a template on which they were asked to share their details as a physical diary or through the spreadsheet template.

10.6.1 Patient Willingness

Women expressed that their midwives were not aware of appropriate apps for recommendation. They assumed that their midwives being older would be slow in adopting new technologies such as mobile apps. The clinic had young and older midwives and some were willing to try mobile apps. They saw the potential of logging FD anytime anywhere, which could help with food recall and feed in accurate data.

Women had regular consultations with their midwives at the diabetes clinic with only a few appointments with a dietician during their pregnancy. For some women this was insufficient as they were not able to manage their BG. Dieticians made changes to the women's diet on a case-by-case basis. Exercises and reduced intake of carbohydrates at dinner were recommended.

Three of the participants were willing to use mobile apps to log FD as they preferred electronic logging and saw the potential benefits of the wellness data integration prototype. They were unaware of mobile apps suitable for the self-management of GDM. Through the prototype review and discussions, they realised the functionalities of different apps available for consumers and were keen to use them.

> Participant 11
> *(I would) absolutely use it and comfortable to share the data with clinician if suitable apps are available.*

Two participants (Participants 14, 15) had kept a paper diary and were happy to continue it even in their second pregnancy. They said it worked for them with their midwives expecting the same. For one participant (Participant 14), the condition was

well managed and she did not have adverse BG readings during her second pregnancy. For the other participant (Participant 15), it was not as good as she had put on 10 kilograms more weight than in her previous pregnancy. Electronic logging would be useful to women who cannot manage their condition and need their midwife's advice to change diet or insulin dosage.

Four of the five patient participants were of South Asian ethnicity. There was one New Zealand European (pakeha) participant. There were other Asian women (Chinese) at the clinic who were unwilling to participate. Most of these women were generally not obese. At the time of recruiting there was one lady from the Middle East who could not participate as she could not communicate in English. All the participants owned a smart phone including those who declined to participate. Many of these women had used mobile apps for weight loss, fitness and educating themselves about pregnancy care. There was only one woman of Maori ethnicity who did not own a smart phone. The clinicians too had expressed that most of the women owned a smart phone; in some cases the partner had one. The clinic is located in Auckland Central which has a high migrant population; however the demographics may not be representative of other clinics in the region or country.

Most women had a busy life as they were either working and/or had younger children to care for, which left little time to maintain FD and for exercise. However most women kept the BG readings and had to recall their FD retrospectively to complete a paper FD at consultation time.

10.6.2 Patient Prototype Review

Women had reviewed the Prototype Version 2 and did not have much feedback to offer about the interface and design. They thought it would be useful to their clinicians as the prototype would be able to put all information together in one place. Most women were able to complete the first three tasks without difficulty compared to the clinicians as they were familiar with computers and smart phones.

10.7 Summary

This chapter discussed the TAP2 sessions and the themes derived for improving the prototype. A higher level of automation to upload the wellness data into the prototype was expected by a few . A recommendation to display insulin dosage before BG readings was made by one participant midwife late in the TAP2 sessions. Health informatics standards such as LOINC and SNOMED CT were not known to the

clinicians. The purpose of using standards for improving the semantics was demonstrated through the prototype menu. The clinical terminologies were internally coded and saved in the database of the prototype. Participants saw the benefits of improving semantics thereby adding value. However only dietitians and some midwives completed Task 4 and 5.

Women with GDM completed Tasks 1 to 3 and found it not difficult to complete the tasks as they had experience using mobile phones, apps and computers. They were willing to use apps if it was beneficial to them.

11 Discussion

The current body of work defined the research process in various chapters from Chapter 1 Introduction and leading into the background, knowledge and literature about building the ecosystem of integrating data from mobile wellness apps for the self-management of GDM. The DSRM guided through UCD principles built the wellness data integration prototype and evaluated it for acceptance through TAM. Usability issues were evaluated through TA protocol. The research process addressed the research questions which are further discussed in the current chapter.

There were three key questions

- How can data from various mobile wellness apps be combined to help and support lifestyle change and clinical decision making in the management of GDM?
- How can this combination be supported and built based on semantic interoperability using lexical database and/or ontologies like health standards, food and nutrition?
- Are clinicians and women with GDM ready to use such approaches?

11.1 Wellness Data Integration

The devices and software support to collate wellness data suitable for the self-management of GDM were reviewed in the literature. There were no studies specifically related to GDM, however relevant studies for self-management of chronic diseases such as diabetes were identified (Jian et al., 2011; Marceglia et al., 2015; Plastiras et al., 2014; Puustjärvi & Puustjärvi, 2011; Reilent et al., 2011) and have been discussed in the literature review. Of late, there have been clinical trials (Garnweidner-Holme et al., 2015; Mackillop et al., 2016) involving the use of technology, such as mobile apps for pregnancy outcomes for women with GDM. However, in all these cases, the wellness data from a mobile app or PHR system integrated into the clinical system was pre-determined. The mobile app was designed as part of the research study. In the current body of work, existing downloadable apps from Android and iOS platforms are considered for possible data integration. Many women with GDM have used mobile apps for lifestyle change and fitness. These apps are relevant to support food, diet and

exercise during pregnancy and under conditions such as GDM. Consumers will want to continue using apps of their choice for clinical consultations. The possible solutions for integrating data into an ecosystem are discussed in the sub-sections below.

11.1.1 Data Integration Tools

The current body of work reviewed the data integration literature for solutions to integrate wellness data from a range of mobile apps thus allowing a choice for different mobile users on different platforms. Two tools, namely MOMIS and Talend, were utilised. Both tools had GUI interface to drag and drop schema mappings from source to a target. Clinicians as users required training to use these tools. Although the tools had the facility to generate a global schema allowing semantic interoperability using built-in lexical databases such as Wordnet, neither of the tools could be used on an adhoc basis. Firstly, the source schema of all existing mobile apps to be integrated into the system had to be re-considered each time new app data was required to be integrated. The introduction of a new app would change the existing global schema requiring the data schema in the database to be changed. Talend was easy to relate to as the mapping of source to target was shown as in relational database SQL statements. Talend was therefore more appropriate in consultations with clinicians regarding the choice of various mobile apps and the relevant data pieces to be included in the prototype database. Once the target schema was fixed, it was not difficult to manually map new app data to the existing global schema. Although the data schema varied in different mobile apps, it was designed to store similar wellness data elements. Date and time format varied in different apps and had to be combined as a date type in the prototype.

11.1.2 Semantic Interoperability

Clinical terminologies and standards improved the semantic meaning of wellness data. Fasting and post-meal BG readings were flagged as a Boolean datatype in the software supporting the Caresens glucose meter. This was programmatically changed in the prototype to include the LOINC code for fasting or post-meal. If the status was missing as many women did not know how to include this while using the glucose meter, there was provision in the prototype for the clinician to correct and update the status. From the end user perspective including clinicians, clinical standards such as LOINC and SNOMED CT were not known to them. On the prototype interface, the menu choice for editing BG was specified as fasting or post-meal; however internally, it was stored with a LOINC code. This would improve the semantic meaning of the data when transmitting to other systems.

SNOMED CT terminologies used to denote food mainly for allergies were used to identify food if required in the prototype. This was done if the clinicians especially dietitians thought that some food needed to be clinically represented if it was required for transmitting to clinical systems.

Wellness data is not sufficiently represented in clinical systems and mobile wellness apps. With a data-driven strategy employed in public and private sectors and the popularity of mobile apps for wellness, life style change and to manage chronic diseases, these data elements have potential to be defined as medical terminologies. Through this body of work, it was possible to use existing data elements or define new wellness data in health exchange standards such as FHIR. Such approaches are also undertaken by other researchers (Franz et al., 2015; Hong et al., 2017). The limitation with such an approach, is that different vendors will define their own wellness data.

11.1.3 Missing Data

It was evident that women did not maintain their FD on a regular basis and were asked for this only if their BG readings were unusually high or low. Hence missing data did not mean there was no food consumed on those days. It just meant that they had a regular diet as on other days or had merely forgotten to update their FD. Hence the data collected had to be analysed in discussion with the women to complete the gaps. Clinicians had provision to include comments as additional information and for record keeping.

11.1.4 Ecosystem Extension

Although the prototype had a fixed number of mobile apps to begin with, it was flexible to include additional mobile apps in future. Currently Android or iOS platforms have APIs to connect to different devices and integrate data. A similar approach would be helpful to achieve building an ecosystem of connecting mobile apps through APIs in which case the source and target schema are known in advance to map the data.

11.2 Prototype Acceptance

The iterative nature of the prototype development with UCD principles helped achieve a deeper understanding of the GDM consultation context and design requirements. Clinicians as users helped in identifying the main requirements and improving the report combining wellness data from various sources. Women used glucose meter, mobile apps for FD and exercise to keep track of their BG, FD and exercise. Clinicians had various requirements regarding the visual display of the report data on the screen.

The wellness data, insulin dosage and BG readings had to be displayed in a particular fashion for easy comparison of these values at consultation time. Insulin dosage values were required to be displayed before BG readings to show the '*cause and effect*'.

11.2.1 Clinicians' and Women with GDM Perceptions

Clinicians were involved from inception right up to the final stages of the research study. Although the research study would benefit women, the clinicians had a vested interest to improve the consultations at the clinic. Clinicians were able to guide the design of the prototype as they had the domain knowledge of the requirements for the self-management of GDM. Although the main requirements were clear in the first interviews (INT1) and clearly defined in the Chapter 5 Requirements Analysis, the iterative cycles of developing the prototype over two iterations fulfilled the related sub-requirements and usability issues. The review of Prototype Version 1 highlighted usability issues in the interview sessions (INT2) and TA protocol sessions (TAP1) which were resolved along with other usability issues identified through TAP2 in Prototype Version 2.

Clinicians wanted to upload the BG readings and FD data themselves into the prototype. Some found it an additional workload to do so. The accuracy of the data was questioned and the clinicians wanted to review the data before uploading it into the prototype. An element of trust is required for clinicians to accept patient managed health data as this is not the same data captured by clinicians in a HIS. However there is evidence of better health outcomes (Holtz & Lauckner, 2012) (Free et al., 2013) when patients have involved themselves in the self-management of their own diseases and thus there is a case for trusting patients to upload their own wellness data into the prototype accurately.

The women with GDM reviewed Prototype Version 2 and were agreeable to logging wellness data electronically using their smart phone mobile apps and sharing it with clinicians. They found the prototype easy to use but did not have much input about its functionality and interface design. The prototype was designed for clinicians to use. In future, when clinicians gain confidence that their patients are able to enter accurate wellness data, the prototype can be upgraded to include patients as users.

Overall, the perceptions differed between clinicians and the women as outlined in Table 11.1. It was important to include women in the evaluation to determine their acceptance to using mobile apps and sharing electronic files as input to the prototype.

Table 11.1: Summary of Clinicians and Women with GDM Perceptions

Clinicians	Women with GDM
Found it useful to find all information regarding FD, insulin, BG, exercise in one place for comparison	Useful if there are recommended apps to enter this information with less effort
Usability issues identified at Prototype Version 1 and 2 about the combined report. They were expecting to see the required information suitable for GDM in the right format.	Found the interface was easy to use.
Midwives anticipated additional workload in uploading patient data. The older midwives were not good using new technologies and accepted they would have teething issues in the beginning and eventually learn it through repetition.	Many were used to electronic logging of fitness data and food and were acceptable to the new concept of using mobile apps and sharing with their midwives. Some older midwives liked reading handwritten notes at consultation time rather than reading their emails and FD attachments.

Although very few women with GDM participated in the complete evaluation of the prototype, many women at the clinic were aware and willing to use mobile apps. They thought apps were a convenient way of keeping track of their diet instead of using paper-based booklets provided by the centre. Hence it is observed that the change to digital health data is a patient driven movement. Clinicians expressed their inability to recommend apps to their patients due to lack of knowledge about appropriate apps available.

11.2.2 Others' Perceptions

Clinicians were concerned about the women not having sufficient clinical understanding to feed correct data into the apps and interpret it. Not all women owned a smart phone or had internet connection in their home. Women of Pacific and Maori ethnicity from lower socio-economic background were not equipped with technological gadgets to move into the electronic space of logging their FD and BG. As the study was conducted in Auckland, the migrant population including Chinese and South Asians, had high incidence of GDM. These communities had the gadgets but were not well versed in the

English language. It was difficult to conduct interviews with them due to the language barrier and they were not willing to participate in the research. Some women of Middle Eastern ethnicity had interpreters at consultation time at the clinic.

Women with Type 1 diabetes were recommended to use mySugr app, however there was no such recommendation for women with GDM. Older midwives have not kept pace with new technologies such as apps suitable for pregnancy (Hendricks, Ireson, & Pinch, 2016). A similar trend was observed in the clinic by women with GDM. Although the midwives saw potential in mobile apps, not all were confident of using them.

11.3 Achievements and Contributions

The process of building the wellness data integration prototype contributed to various areas of research such as mobile apps suitable for health and wellness, integration of patient-managed health and wellness data into clinical systems, acceptance of mobile app data for clinical consultations and patients' perception of using technology related interventions for self-management of their condition. The intervention was specific to GDM which is a short term condition which has higher lifelong risk for a mother (Bellamy, Casas, Hingorani, & Williams, 2009) and child (Clausen et al., 2008).

The major contributions from the current body of work are discussed as follows:

1. **Proof of concept and acceptability of the artefact (prototype):** The artefact successfully demonstrated the proof of concept and its acceptability through various methodological concepts of UCD, TA protocol and TAM in the DSRM process. These concepts can be guidelines to develop new information systems related to health and wellness applications. Technological advancement of using public APIs, cloud and 5G wireless can further refine the prototype.

2. **Inductive themes from the TAM theory:** Inductive themes emerged from the TAM theory based on PU, PEOU and BI. Clinicians recognised the PU of the ecosystem as they could see a working prototype being built. Feedback from clinicians on PEOU improved usability of the prototype. The themes are useful in designing a similar ecosystem where patient's health and wellness data is collected for clinical consultations. The themes identified through qualitative analysis are useful to develop a survey instrument to evaluate the ecosystem or a similar system on a quantitative basis.

3. **Usability guidelines:** The two sets of TA protocol helped in improving the usability of the prototype which can be applied to health and wellness data representation in various devices and applications. The presentation of data suitable for the self-management of GDM is not ideal in most consumer mobile apps. Clinicians feedback was useful to change the order and amount of data shown as information. Thus, usability guidelines emerged through using UCD and TA protocol. These guidelines will help to build new and relevant information systems related to health and wellness applications both from consumer and clinician point of view.

4. **Semantic data integration:** The body of work also researched other similar systems built to integrate data from patient managed devices and apps into the hospital systems. In most cases medical terminologies and health information exchange standards were used. Evolving health exchange standards such as FHIR were also proved to be able to integrate wellness data in clinical systems. Wellness data from mobile apps lack medical terminologies; however, using mobile apps with built-in food database have greater potential for semantic integration. Data integration techniques and tools are other ways to achieve mapping of source data to target schema.

5. **A framework for evaluation of mobile wellness apps:** The search for suitable mobile apps for the ecosystem contributed to a framework to include additional mobile apps. The range of mobile apps is constantly changing, and newer apps are being introduced which are efficient, effective and easy to use. The framework will guide software developers, clinicians and patients to adopt mobile apps suitable for the self-management of GDM and clinical consultations.

6. **Base platform to manage other chronic conditions:** The ecosystem developed from this research study included provision to accommodate food diary and exercise which are key requirements for the self-management of other chronic diseases such as Type 1 and 2 diabetes, blood pressure, certain types of cancer et cetera.

11.4 Limitations

The wellness data integration protocol was a proof of concept of integrating suitable consumer mobile apps. Data from some apps was not readily acceptable into the

prototype and hence had to be manually cleaned through programming scripts. The prototype was evaluated by clinicians which allowed revisions in iterations to an acceptable level. However it was not ready for clinical trials. The design and evaluation of the prototype took much time. There were limited evaluations of Prototype Version 2 by the women (patients).

With high penetration of mobile apps, awareness of apps to support the self-management of GDM and the drive for data driven ecosystems, research in this area will advance to allow easy sharing of data between devices and systems. The concept of open standards and APIs to share data will help in building the ecosystem in the future.

Although free apps and those that could be trialled for a limited time for free were researched, the cost factor was not considered. A separate feasibility study needs to be undertaken in the clinic considering the set up and ongoing cost for both patients and clinic.

11.5 Comparison to Other Systems

Similar research on integrating patient managed wellness data from PHRs, medical devices and mobile apps have been undertaken. However, their adoption has been limited due to several reasons such as interoperability, inaccurate data from patients, information overload (Witry, Doucette, Daly, Levy, & Chrischilles, 2010) and trust and privacy issues (H. Li, Gupta, Zhang, & Sarathy, 2014). Integrating patient managed data from PHRs and devices such as mobile apps has the potential to improve communication between patients and their clinicians (Harris et al., 2010). Research studies have demonstrated improved health outcomes when patients are actively engaged in their own health care (Hibbard & Greene, 2013). In one such study (Darkins et al., 2008) use of telehealth care for self-management of chronic diseases has shown significant improvements in health outcomes and efficacy.

Studies related to GDM and the use of mobile apps are currently underway but have not yet been published. These studies (Choi et al., 2016; Clifton et al., 2016) are related to physical activity and maintaining weight gain during pregnancy. The use of mobile apps for FD and BG reading are however not part of these studies.

11.6 Future Directions

There has been interest from various parties to share user wellness data through mobile apps and sensor technologies. APIs have been recommended to share proprietary data from various vendors. However, although technical interoperability is achieved, semantic interoperability remains an issue.

11.6.1 Technology Advancement

In anticipation of building a system to allow semantic interoperability, a Wellness Warehouse Engine (W2E) allowed interfaces to various data sources through REST API (Saaranen, Parak, Honko, Aaltonen, & Korhonen, 2014). The engine in the system transformed the incoming data into generic re-usable output parameters. Mostly activity tracking devices such as Fitbit Zip, Withings Pulse and Jawbone UP were trialled to demonstrate the proof-of-concept of the W2E system (Honko et al., 2016). The incoming data was related to sleep, exercise and blood pressure. FD was not part of the data. The architecture needs significant work to accept verbose data such as FD.

Sensor devices to track temperature, pulse and BG readings through Internet of Things (IoT) is an evolving approach to monitor patients (Fernandes & de Lucena, 2015). The sensor devices are connected to a Cloud based solution through REST API web service. Real time health and wellness data collected at the Cloud database has an interface to analyse these data for clinicians. FD is still a challenge with details of food entered being verbose and not universally uniform.

In the wake of the current situation of using existing mobile wellness apps on different platforms, data from apps was available as CSV, XML and HTML. Accessibility to proprietary API was not public as in the case of MyFitnessPal for the current research study. However in the future, with more public APIs available for mobile wellness apps and vendors sharing their device or app data, it will be possible to access data directly from the cloud-based database with user permission.

11.6.2 Clinical Trials

The design and evaluation of the prototype as part of the ecosystem is a proof-of-concept approach to building such an ecosystem for clinical trials. The current body of work has a framework to select the right apps in the ecosystem and integrate the wellness data for improved communication between patients and clinicians. The usefulness and ease of use of the ecosystem can be fully realised through clinical trials.

There is also potential to undertake quantitative research studies in the future.

11.6.3 Other Health Conditions

The current body of work was on the self-management of a health condition and was related to a particular type of patient. The routine for monitoring BG or any other health conditions such as blood pressure or weight is similar although the frequency may differ. Similar wellness data types are required to track these conditions. Hence the proof-of-concept ecosystem can be adapted for other chronic diseases such as stress relief and its management. The semantic meaning of the data can be improved through related existing clinical terminologies and health exchange standards. Mobile apps have the capacity of a computer processor and together with wireless, mobile and cloud computing technologies, it is possible to track and manage wellness data on the go.

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Appendices

Appendix A – Ethics Approvals

AUTEC

SECRETARIAT

15 June 2015

Dave Parry

Faculty of Design and Creative Technologies

Dear Dave

Re Ethics Application: **15/156 User interface for clinicians to integrate data from mobile wellness apps for self-management of gestational diabetes mellitus (GDM)**

Thank you for providing evidence as requested, which satisfies the points raised by the Auckland University of Technology Ethics Committee (AUTEC).

Your ethics application has been approved for three years until 1 June 2018.

As part of the ethics approval process, you are required to submit the following to AUTEC:

- A brief annual progress report using form EA2, which is available online through http://www.aut.ac.nz/researchethics. When necessary this form may also be used to request an extension of the approval at least one month prior to its expiry on 1 June 2018;
- A brief report on the status of the project using form EA3, which is available online through http://www.aut.ac.nz/researchethics. This report is to be submitted either when the approval expires on 1 June 2018 or on completion of the project.

It is a condition of approval that AUTEC is notified of any adverse events or if the research does not commence. AUTEC approval needs to be sought for any alteration to the research, including any alteration of or addition to any documents that are provided to participants. You are responsible for ensuring that research undertaken under this approval occurs within the parameters outlined in the approved application.

AUTEC grants ethical approval only. If you require management approval from an institution or organisation for your research, then you will need to obtain this. If your research is undertaken within a jurisdiction outside New Zealand, you will need to make the arrangements necessary to meet the legal and ethical requirements that apply

there.

To enable us to provide you with efficient service, please use the application number and study title in all correspondence with us. If you have any enquiries about this application, or anything else, please do contact us at ethics@aut.ac.nz.

All the very best with your research,

Kate O'Connor

Executive Secretary

Auckland University of Technology Ethics Committee

Cc: Sarita Pais sarita.pais@aut.ac.nz

2 June 2016

Dave Parry

Faculty of Design and Creative Technologies

Dear Dave

Re: Ethics Application: **15/156 User interface for clinicians to integrate data from mobile wellness apps for self-management of gestational diabetes mellitus (GDM)**

Thank you for your request for approval of an amendment to your ethics application.

I have approved the minor amendment to your ethics application allowing an extension of the inclusion criteria.

I remind you that as part of the ethics approval process, you are required to submit the following to the Auckland University of Technology Ethics Committee (AUTEC):

- A brief annual progress report using form EA2, which is available online through http://www.aut.ac.nz/researchethics. When necessary this form may also be used to request an extension of the approval at least one month prior to its expiry on 1 June 2018;
- A brief report on the status of the project using form EA3, which is available online through http://www.aut.ac.nz/researchethics. This report is to be submitted either when the approval expires on 1 June 2018 or on completion of the project.

It is a condition of approval that AUTEC is notified of any adverse events or if the research does not commence. AUTEC approval needs to be sought for any alteration to the research, including any alteration of or addition to any documents that are provided to participants. You are responsible for ensuring that research undertaken under this approval occurs within the parameters outlined in the approved application.

AUTEC grants ethical approval only. If you require management approval from an institution or organisation for your research, then you will need to obtain this.

To enable us to provide you with efficient service, please use the application number and study title in all correspondence with us. If you have any enquiries about this application, or anything else, please do contact us at ethics@aut.ac.nz.

All the very best with your research,

Kate O'Connor

Executive Secretary

Auckland University of Technology Ethics Committee

Cc: sarita.pais@aut.ac.nz

Appendix B – Participation Information

Participant Information Sheet

Software System (Prototypes Version 1 and Version 2) Evaluation by Clinicians

Date Information Sheet Produced:

28 March 2015

Project Title

User Interface for Clinicians to Integrate Data from Mobile Wellness Apps for Self-management of Gestational Diabetes Mellitus (GDM)

An Invitation

I am a PhD student at Auckland University of Technology (AUT). I have completed my Masters in Computer and Information Sciences at AUT with First Class Honours. My PhD research involves Health Informatics, data integration and building user interface. I am undertaking a research study to construct a user interface (prototype) for clinicians to support the management of Gestational Diabetes Mellitus (GDM) of their patients. The prototype will capture heterogeneous data from various mobile wellness apps about food diary, exercise and glucose readings to help/support lifestyle change and clinical decision making in the management of GDM.

You are invited to take part in this research study. Your participation in this study is voluntary and you may withdraw at any time, without being disadvantaged in any way.

The data collected through interviews, 'think aloud' protocol and a questionnaire will be used for analysis in my doctoral study. It is important for you to understand the background and aim of this research study before you can commit to participate in this study.

What is the purpose of this research?

The aim of this research study is to identify the current clinician consultation procedure for women with GDM and how a new software system (prototype) can improve the consultation procedure for clinicians. The research study will contribute to my PhD qualification and I may be able to publish in academic journals and present at conferences.

You will be required to evaluate a software system (prototype) built for clinicians to support the self-management of GDM. Please remember that it is the prototype being evaluated and not you.

How was I identified and why am I being invited to participate in this research?

You are being invited to participate in this research because you have responded to the advertisement displayed in the staff room at ADHB Maternity/Pregnancy Care, Diabetic Centre. You have been randomly chosen among others, as you indicated your interest in participating in this research study.

What will happen in this research?

You will be asked to evaluate the software system (Prototype Version 1 and Version 2) through semi-structured interview questions, 'think aloud' protocol and a questionnaire. The feedback will improve the prototype through interactive cycles. I will be conducting a qualitative analysis of the feedback collected as part of the evaluation of each version of the prototype.

The 'think aloud' protocol is a usability evaluation tool. You will be verbalising your actions while using the prototype. A specific task (case scenario) will be set. A video recording of the screen and your voice will be captured, which will help in coding the video at a later stage.

Appropriate and realistic hypothetical data will be entered into mobile wellness apps. The prototype will receive input from data extracted from these wellness apps and will generate suitable reports.

The set of datasets captured from the mobile wellness apps will be discussed with you to confirm their appropriateness, correctness and suitability (validated). No actual patients or their personal data or information will be involved in this study.

You are required to evaluate Prototypes Version 1 and Version 2.

What are the discomforts and risks?

You may be embarrassed if you find it difficult to complete the tasks during the 'think aloud' evaluation of each version of the prototype.

You may not be comfortable in going through the interview or the 'think aloud' procedure.

You may feel obliged to participate because of your team leader (lead physician for a team).

How will these discomforts and risks be alleviated?

Video tutorials and a user manual will be provided at the beginning to familiarise you with all the tasks. If you have difficulties in using the prototype this will be of interest to my research. You should remember it is the prototype and not you who is being evaluated.

The recording will be strictly confidential and you will not be identified. Recordings of your voice and the computer screen will be captured in the 'think aloud' protocol. Interview recordings only involve audio (your voice) and note taking by me.

You can stop taking part at any time.

What are the benefits?

The outcome of the research will enable the integration of mobile wellness data and support clinicians to help their patients in managing lifestyle change and clinical decision making. It will help in health interventions for treatment and management of GDM.

The research is part of my doctoral study and hence will be of benefit to me in gaining the PhD qualification.

How will my privacy be protected?

Individual participants will not be identified in the data analysis, thesis report or in any publications from this research study. No participants' personal information is collected. All notes and recordings taken during interviews and the 'think aloud' protocol will be securely stored in a locked cabinet.

What are the costs of participating in this research?

Participants required to evaluate Prototypes Version 1 and Version 2 will need to be available for a total of five hours in three sittings (1 hour, 2 hours and 2 hours). As a token of thanks you will be offered a gift voucher (koha), which I acknowledge does not match the rate of your professional service.

What opportunity do I have to consider this invitation?

I would appreciate your confirmation of participation within a week of receiving this participation information sheet.

How do I agree to participate in this research?

You need to contact the researcher (Sarita Pais). Contact details are given below. You will need to sign a written consent form to agree to participate in this research study.

Will I receive feedback on the results of this research?

A summary of research findings will be emailed to participants.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Associate Professor Dave Parry, dave.parry@aut.ac.nz, +64 9 921 9999 xtn 8918.

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, Kate O'Connor, *ethics@aut.ac.nz* , 921 9999 ext 6038.

Whom do I contact for further information about this research?

Researcher Contact Details:

Sarita Pais, Doctoral Research student, Sarita.pais@aut.ac.nz, 021 0379273

Project Supervisor Contact Details:

Supervisor, Associate Professor Dave Parry, dave.parry@aut.ac.nz, +64 9 921 9999 xtn 8918.

Approved by the Auckland University of Technology Ethics Committee on 15 June 2015, AUTEC Reference number 15/156.

Participant Information Sheet

Prototype Version 2 Evaluation by Clinicians

Date Information Sheet Produced:

28 March 2015

Project Title

User Interface for Clinicians to Integrate Data from Mobile Wellness Apps for Self-management of Gestational Diabetes Mellitus (GDM)

An Invitation

I am a PhD student at Auckland University of Technology (AUT). I have completed my Masters in Computer and Information Sciences at AUT with First Class Honours. My PhD research involves Health Informatics, data integration and building user interface. I am undertaking a research study to construct a user interface (prototype) for clinicians to support the management of Gestational Diabetes Mellitus (GDM) of their patients. The prototype will capture heterogeneous data from various mobile wellness apps about food diary, exercise and glucose readings to help/support lifestyle change and clinical decision making in the management of GDM.

You are invited to take part in this research study. Your participation in this study is voluntary and you may withdraw at any time, without being disadvantaged in any way.

The data collected through 'think aloud' protocol and a questionnaire will be used for analysis in my doctoral study. It is important for you to understand the background and aim of this research study before you can commit to participate in this study.

What is the purpose of this research?

The aim of this research study is to identify the current clinician consultation procedure for women with GDM and how a new software system (prototype) can improve the consultation procedure for clinicians. The research study will contribute to my PhD qualification and I may be able to publish in academic journals and present at conferences.

You will be required to evaluate a software system (prototype) build for clinicians to support the self-management of GDM. Please remember that it is the prototype being evaluated and not you.

How was I identified and why am I being invited to participate in this research?

You are being invited to participate in this research because you have responded to the advertisement displayed in the staff room at ADHB Maternity/Pregnancy Care, Diabetic Centre. You have been randomly chosen among others, as you indicated your interest in participating in this research study.

What will happen in this research?

You will be asked to evaluate the software system (Prototype Version 2) through the 'think aloud' protocol and a questionnaire. The feedback will improve the prototype through interactive cycles. I will be conducting a qualitative analysis of the feedback collected as part of the evaluation of the prototype.

'Think aloud' protocol is a usability evaluation tool. You will be verbalising your actions while using the prototype. A specific task (case scenario) will be set. A video recording of the screen and your voice will be captured, which will help in coding the video at a later stage.

Appropriate and realistic hypothetical data will be entered into mobile wellness apps. The prototype will receive input from data extracted from these wellness apps and will generate suitable reports.

The set of datasets captured from mobile wellness apps were discussed in Prototype Version 1 evaluation to confirm appropriateness, correctness and suitability (validated). No actual patients or their personal data or information will be involved in this study.

You are required to evaluate Prototype Version 2.

What are the discomforts and risks?

You may be embarrassed if you find it difficult to complete the tasks in the 'think aloud' evaluation of the prototype.

You may not be comfortable in going through the interview or the 'think aloud' procedure.

You may feel obliged to participate because of your team leader (lead physician for a team).

How will these discomforts and risks be alleviated?

Video tutorials and user manual will be provided in the beginning to familiarise with the tasks. If you have difficulties in using the prototype this will be of interest to my research. You should remember it is the prototype and not you who is being evaluated.

The recording will be strictly confidential and you will not be identified. Recordings of your voice and computer screen is captured in the think aloud protocol. Interview recordings are strictly by voice and note taking by me.

You can stop taking part at any time.

What are the benefits?

The outcome of the research will enable the integration of mobile wellness data and support clinicians to help their patients in managing lifestyle change and clinical decision making. It will help in health interventions for treatment and self-management of GDM.

The research is part of my doctoral study and hence be of benefit to me in gaining the PhD qualification.

How will my privacy be protected?

Individual participants will not be identified in the data analysis, thesis report and any publications from this research study. No participants' information is collected. All notes and recordings taken at 'think aloud' protocol will be securely stored in a locked cabinet.

What are the costs of participating in this research?

Participants required to evaluate Prototype Version 2 will need to be available for 2 hours. As a token of thanks you will be offered a gift (koha), which I acknowledge does not match the rate of your professional service.

What opportunity do I have to consider this invitation?

I would appreciate your confirmation of participation within a week of receiving this participation information sheet.

How do I agree to participate in this research?

You need to contact the researcher (Sarita). Contact details given below. You need to sign a written consent form to agree to participate in this research study.

Will I receive feedback on the results of this research?

The summary of research findings will be emailed to participants.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Associate Professor Dave Parry, dave.parry@aut.ac.nz, +64 9 921 9999 xtn 8918.

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Researcher Contact Details:

Sarita Pais, Doctoral Research student, Sarita.pais@aut.ac.nz, 021 0379273

Project Supervisor Contact Details:

Supervisor, Associate Professor Dave Parry, dave.parry@aut.ac.nz, +64 9 921 9999 xtn 8918.

Approved by the Auckland University of Technology Ethics Committee on 15 June 2015, AUTEC Reference number 15/156.

Participant Information Sheet

Prototype Version 2 Evaluation by women with GDM

Date Information Sheet Produced:

28 March 2015

Project Title

Data Integration of Mobile Wellness Apps for Self-management of Gestational Diabetes Mellitus (GDM)

An Invitation

I am a PhD student at Auckland University of Technology (AUT). I have completed my Masters in Computer and Information Sciences at AUT with First Class Honours. My PhD research involves Health Informatics, data integration and building user interface. I am undertaking a research study to construct a user interface (prototype) for clinicians to support the management of Gestational Diabetes Mellitus (GDM) of their patients. The prototype will capture heterogeneous data from various mobile wellness apps about food diary, exercise and glucose readings to help/support lifestyle change and clinical decision making in the management of GDM.

You are invited to take part in this research study. Your participation in this study is voluntary and you may withdraw at any time, without being disadvantaged in any way.

The data collected through 'think aloud' protocol and a questionnaire will be used for analysis in my doctoral study. It is important for you to understand the background and aim of this research study before you can commit to participate in this study.

What is the purpose of this research?

The aim of this research study is to identify the current clinician consultation procedure for women with GDM and how a new software system (prototype) can improve the consultation procedure for clinicians. The research study will contribute to my PhD qualification and I may be able to publish in academic journals and present at conferences.

You will be required to evaluate a software system (prototype) build for clinicians to support the self-management of GDM. Please remember that it is the prototype being evaluated and not you.

How was I identified and why am I being invited to participate in this research?

You are being invited to participate in this research because you have responded to the advertisement handed out at ADHB Maternity/Pregnancy Care, Diabetic Centre. You have been randomly chosen among others, as you indicated your interest in participating in this research study.

What will happen in this research?

You will be asked to evaluate the software system (Prototype Version 2) through the 'think aloud' protocol and a questionnaire. The feedback will improve the prototype through interactive cycles. I will be conducting a qualitative analysis of the feedback collected as part of the evaluation of the prototype.

'Think aloud' protocol is a usability evaluation tool. You will be verbalising your actions while using the prototype. A specific task (case scenario) will be set. A video recording of the screen and your voice will be captured, which will help in coding the video at a later stage.

Appropriate and realistic hypothetical data will be entered into mobile wellness apps. The prototype will receive input from data extracted from these wellness apps and will generate suitable reports.

The set of datasets captured from mobile wellness apps were discussed in Prototype Version 1 evaluation to confirm appropriateness, correctness and suitability (validated). No actual patients or their personal data or information will be involved in this study.

You are required to evaluate Prototype Version 2.

What are the discomforts and risks?

You may be embarrassed if you find it difficult to complete the tasks in the 'think aloud' evaluation of the prototype.

You may not be comfortable in going through the interview or the 'think aloud' procedure.

You may feel obliged to participate because of your team leader (lead physician for a team).

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The recording will be strictly confidential and you will not be identified. Recordings of your voice and computer screen is captured in the think aloud protocol. Interview recordings are strictly by voice and note taking by me.

You can stop taking part at any time.

What are the benefits?

The outcome of the research will enable the integration of mobile wellness data and support clinicians to help their patients in managing lifestyle change and clinical decision making. It will help in health interventions for treatment and self-management of GDM.

The research is part of my doctoral study and hence be of benefit to me in gaining the PhD qualification.

How will my privacy be protected?

Individual participants will not be identified in the data analysis, thesis report and any publications from this research study. No participants' information is collected. All notes and recordings taken at 'think aloud' protocol will be securely stored in a locked cabinet.

What are the costs of participating in this research?

Participants required to evaluate Prototype Version 2 will need to be available for 2 hours. As a token of thanks you will be offered a gift (koha), which I acknowledge does not match the rate of your professional service.

What opportunity do I have to consider this invitation?

I would appreciate your confirmation of participation within a week of receiving this participation information sheet.

How do I agree to participate in this research?

You need to contact the researcher (Sarita). Contact details given below. You need to sign a written consent form to agree to participate in this research study.

Will I receive feedback on the results of this research?

The summary of research findings will be emailed to participants.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Associate Professor Dave Parry, dave.parry@aut.ac.nz, +64 9 921 9999 xtn 8918.

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, Kate O'Connor, *ethics@aut.ac.nz* , 921 9999 ext 6038.

Whom do I contact for further information about this research?

Researcher Contact Details:

Sarita Pais, Doctoral Research student, Sarita.pais@aut.ac.nz, 021 0379273

Project Supervisor Contact Details:

Supervisor, Associate Professor Dave Parry, dave.parry@aut.ac.nz, +64 9 921 9999 xtn 8918.

Approved by the Auckland University of Technology Ethics Committee on 15 June 2015,

Appendix C – Interview Questions

Semi-structured interview

Prototype 1 (before building prototype) - Semi-structured interview

Five participants including physician, dietician and midwife will be interviewed.

Semi-structured interview questions on user centred design (Martin et al., 2012)

1. How are clinical consultations with women with GDM under investigation relating to wellness data like food diary and glucose readings currently performed?
2. What are the problems that clinicians currently encounter with these clinical consultations? What are the consequences for patients, and clinicians?
3. Whether there is a felt need for the proposed system?
4. What type of wellness data is required from women with GDM as input to the proposed system?
5. How should be the design of the proposed system?
6. What factors may affect the safe and effective uptake of the proposed system within the clinical environment?

Prototype 1 and 2 evaluation - Semi-structured interview

Prototype 1 will have five participants including physician, dietician and midwife.

Prototype 2 will have fifteen participants including physician, dietician and midwife.

7. How well is the data set made available for testing in the prototype appropriate and sufficient to represent wellness data from mobile apps and glucose readings?
8. How robust is the prototype to address the problems identified by clinicians in supporting their patients' self-management of GDM?
9. How well does the prototype combine heterogeneous data from various data source (wellness data)?
10. Does the prototype generate appropriate reports to clinicians from the combined data? If yes, how? If no, why?
11. What is your opinion regarding the 'perceived usefulness' of the prototype?
12. What is your opinion regarding the 'perceived ease of use' of the prototype?

References:

Martin, J. L., Clark, D. J., Morgan, S. P., Crowe, J. A. & Murphy, E. (2012). A user-centred approach to requirements elicitation in medical device development: A case study from an industry perspective, *Applied Ergonomics*, 43(1), 184-190.

Appendix D – Stakeholder Requirements Analysis Document

Prototype design stakeholder consultation (Version 7)

Scope

The main aim is to determine whether a diverse “constellation” of mobile apps can be used together to add value and robustness in a clinical application. An ecosystem will be built to integrate data from various mobile wellness apps with a software system.

Introduction

GDM self-management includes managing diet, blood glucose, nutrition and exercise. It has been clinically trialled in many studies (Crowther et al., 2005) (Landon, 2010) to determine whether self-management achieved a better pregnancy outcome. Figure 1 describes an overall requirements for the proposed GDM self-management programme. Women with GDM have higher pregnancy risks and diet, nutrition and exercise are important to control foetal weight and manage other pregnancy outcomes. A mobile wellness app can assist in the management of diet, blood glucose, insulin, weight and exercise. Clinical data maintained in the Health Information System (HIS) like laboratory reports and pregnancy outcomes are currently beyond the scope of this research project.

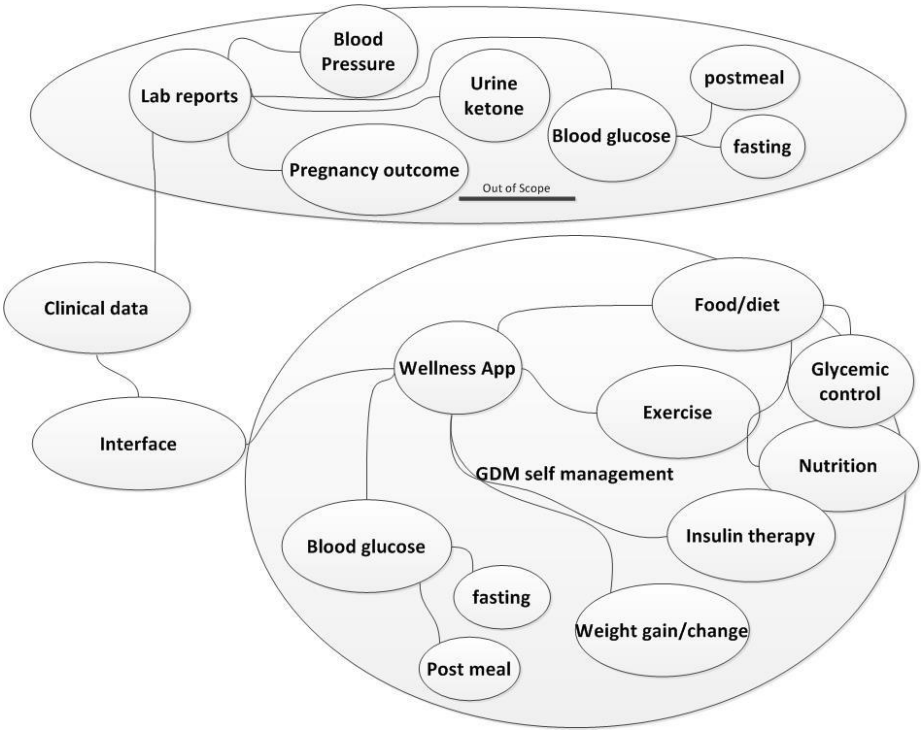


Figure 1: GDM Self-management Conceptual Model

Mobile wellness apps have potential as a dietary assessment tool. At present most mobile apps have potential to share their data. While patients can choose to use a mobile app of their choice data from such heterogeneous sources cannot be stored in one single database system available to clinicians. The aim of the proposed body of work is to develop a prototype to store such data from heterogeneous sources (apps) so as to be able to be used by clinicians more effectively and efficiently.

An ecosystem is built using existing wellness apps sending data to be received in an interface. The prototype called ‘Mobile Wellness Data Integration’ will be built to receive data from wellness apps and generate reports required by clinicians. The prototype will be developed using user centred design (Martin et al., 2012). As the prototype is built to capture mobile wellness app data, the main requirements developed in the prototype are to **import data interface** and **display data interface**. The prototype screens are demonstrated below.

Main menu (Figure 2) depicts three choices to clinician as a user. Currently the prototype is designed for a single user.

In the second stage user login interface will be built. Two type of users will be defined - ‘Admin’ and ‘Clinician’. ‘Admin’ can create new users and perform all other functionalities of ‘clinician’. ‘Clinicians’ can import new data from a known constellation of mobile apps, display the combined data about glucose readings, insulin dosage, food diary and exercise.

In the main menu:

Patient – to select a particular patient and perform operations related to the patient like import data made available from wellness mobile app. The heterogeneous data is made to match the target database of the prototype by running some scripts. Once the data is saved in the target database clinician can display the data in various ways.

Reports – The prototype can generate reports on data about all patients stored in the target database.

Help – Assist user in using the prototype.

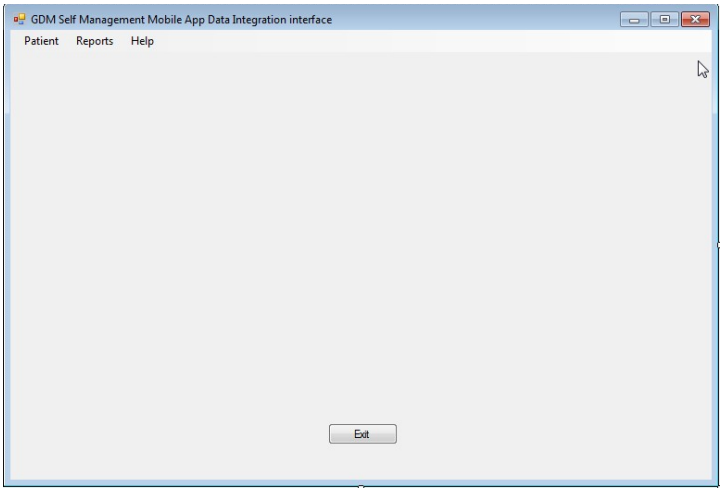


Figure 2: Main menu 'Wellness Data Integration' interface

Find patient interface (Figure 3) will search a patient through various options given to user like last name, first name, NHI, email id. In case of last name and first name many patients by the same name or part of the name will be displayed. User then needs to select the right patient.

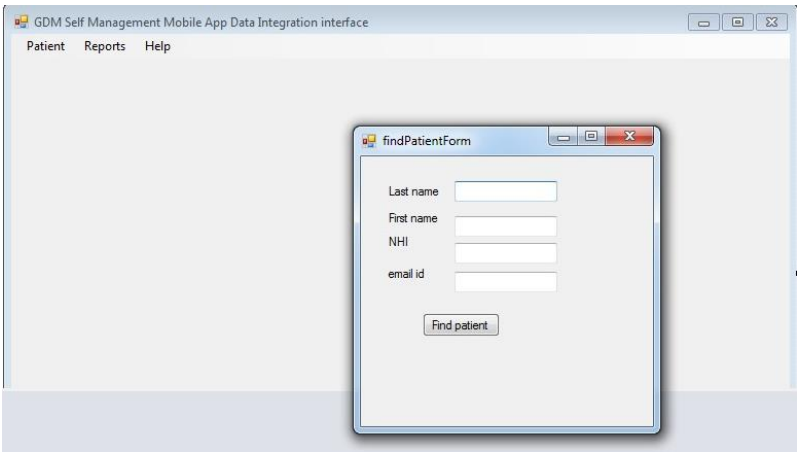


Figure 3: Find patient interface

Once a patient is selected the user is directed to another interface called patient information (Figure 4). Here patient information like personal details will be displayed. The next two options are the main functionalities undertaken as part of the research study.

Import data interface will map data from heterogeneous sources (mobile wellness apps) and map to the target database of the prototype.

Display data interface will display the data from the target database in the format as required by clinicians.

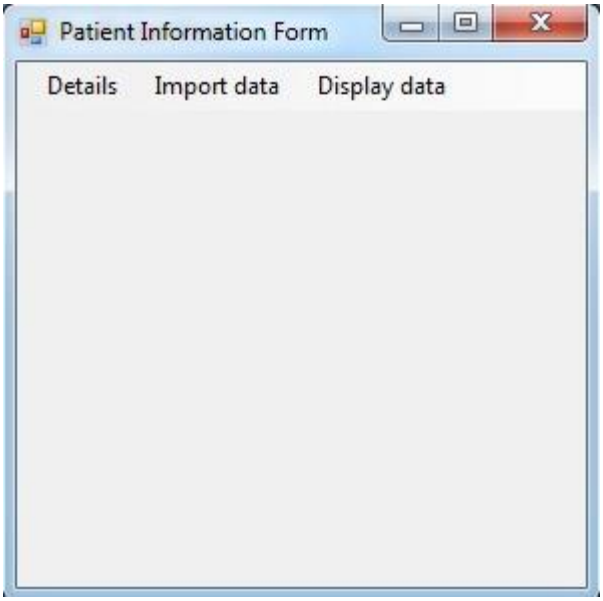


Figure 4: Patient Information interface

Import data interface (Figure 5) will show a diverse “constellation” of mobile wellness apps suitable for GDM self-management. The user will select an appropriate mobile wellness app used by patient and run the script to extract data from the selected mobile wellness app and store it in target database.

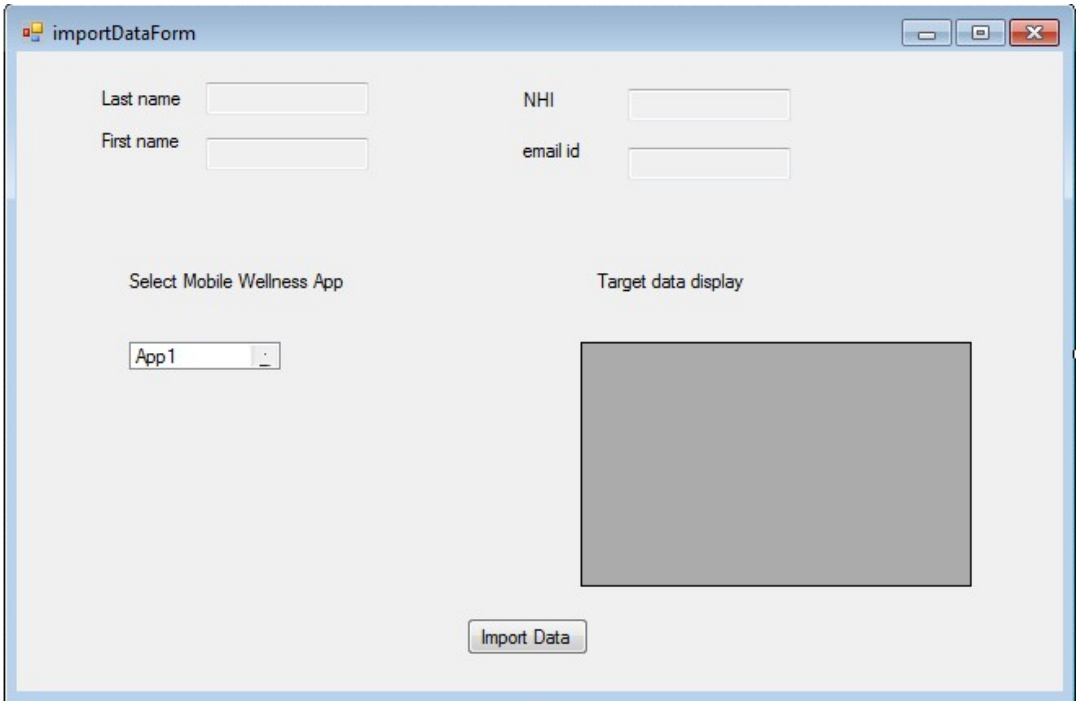


Figure 5: Import data interface

Display data interface (Figure 6) shows the details of data for a patient for a given date range. All details captured about GDM self-management can be shown on screen or export to a file. The listing can be selective by glucose readings, insulin dosage, food diary and exercise. The listing will display all details by default.

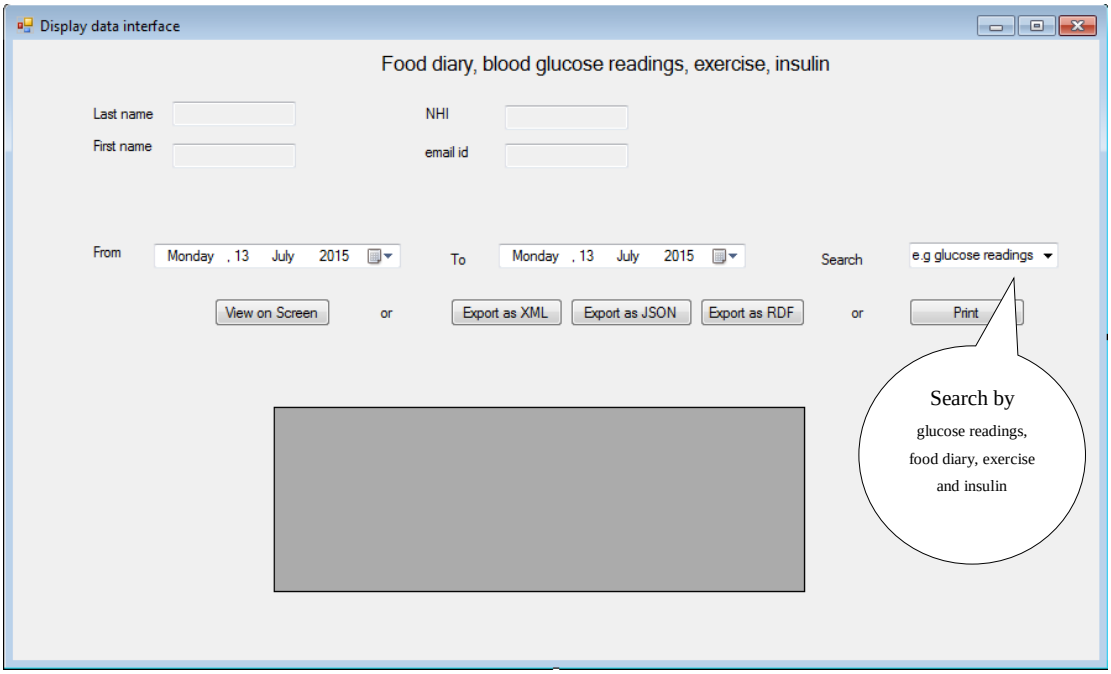


Figure 6: Display data interface

User requirements

High level requirements are realised through the prototype shown above.

Prioritisation technique called MoSCoW (Must, Should, Could, Would) is used to identify the high, medium, low level and nice to have requirements for the prototype.

MoSCoW Prioritisation technique

Must	High level, must be satisfied in the prototype	Mobile wellness data integration Combined report of wellness data about glucose reading, food diary and exercise

		Weight gain/loss chart
Should	High to Medium level, critical requirement should be satisfied	Certain patient details, Comments by clinicians to be shared in the team, login and roles
Could	Low level, desirable requirement but not necessary depending on available resources and time.	Help menu
Would (Won't)	Nice to have requirements, not implemented in the current release, considered for the future.	Non-functional requirements like data encryption for privacy reasons

Detailed requirements to be determined by stakeholders (clinicians)

R1 Extract data from mobile wellness app and save it in target database

R1.1 Select the appropriate mobile wellness app

R1.2 Run the script to extract data from mobile wellness app and save it in target database

R2 Display the combined data about wellness (glucose reading, insulin dosage, food diary, exercise) for a patient

R2.1 Display option on screen or print made available

R2.2 Display data for a specific period (start date and end date)

R2.3 Display specific or a combination of data (glucose reading, insulin dosage, food diary, exercise)

R2.4 Display weight gain/loss chart

R2.4 Export data as XML, JSON, RDF

R3 Manage patient data (Create, Read, Update and Delete)

R3.1 Create a new patient

R3.2 Read an existing patient

R3.3 Update an existing patient

R3.4 Delete an existing patient

R4 Manage comment for a patient (Create, Read, Update and Delete)

R4.1 Comment about glucose reading

R4.1.1 Add comment about glucose reading

R4.1.2 Read comment about glucose reading

R4.1.3 Edit comment about glucose reading

R4.1.4 Delete comment about glucose reading

R4.2 Comment about insulin dosage

R4.2.1 Add comment about insulin dosage

R4.2.2 Read comment about insulin dosage

R4.2.3 Edit comment about insulin dosage

R4.2.4 Delete comment about insulin dosage

R4.3 Comment about food diary

R4.3.1 Add comment about food diary

R4.3.2 Read comment about food diary

R4.3.3 Edit comment about food diary

R4.3.4 Delete comment about food diary

R4.4 Comment about exercise

R4.4.1 Add comment about exercise

R4.4.2 Read comment about exercise

R4.4.3 Edit comment about exercise

R4.4.4 Delete comment about exercise

R5 Manage user

R5.1 Create new user (admin / clinician)

R5.2 Edit user information

R5.3 Delete user

R6 Help menu

Selection of mobile wellness apps

Most mobile apps are available free on Android and iPhone.

Apps should be available on Android as a first preference as we can get cheap Android smart phones.

1. **My Meal Mate**

Data is stored in SQL Lite. All food and exercise are listed from the food database and hence only codes are shown in the Food and exercise entry.

Food entry

Id	Date	MealSlot	FoodItem	Amount	Calories	Photo	CreatedOn	Deleted	NeedUpload
1	1.41E+12	1	3012814	1	168.75	(BLOB)	1.41E+12		1
2	1.41E+12	2	3016289	1	66.64		1.41E+12		1
3	1.41E+12	3	1.01E+08	1	41.8		1.41E+12		1
4	1.41E+12	4	65679	1	57.81		1.41E+12		1
5	1.41E+12	1	2.18E+08	1	59		1.41E+12		1
6	1.41E+12	4	5187437	10	2220		1.41E+12		1
7	1.41E+12	3	1.08E+09	1	408.48		1.41E+12		1
8	1.41E+12	2	1.3E+09	1.000948	654.72		1.41E+12		1
9	1.41E+12	1	2E+09	1	234.9		1.41E+12		1
10	1.41E+12	2	2E+09	1	295.1		1.41E+12		1
11	1.41E+12	3	2E+09	1	388		1.41E+12		1
12	1.41E+12	4	2.02E+08	1	331.5		1.41E+12		1

Exercise entry

Id	Date	Code	Time	Calories	CreatedOn	Deleted	NeedUpload
1	1.41E+12	5010	30	85.8	1.41E+12		1
2	1.41E+12	1009	30	221	1.41E+12		1
3	1.41E+12	5010	30	85.8	1.41E+12		1

2. Glucose Buddy

Date	Time	Type	Event	Name	Value	Units
10/19/201	1:39	Activity	After Lunc	walking	60	mins
10/19/201	1:30	Food	Lunch	rice	200	grams

3. OnTrack

18/10/2014 14:07	Exercise	Walking		60	
18/10/2014 14:00	Food		Lunch	250	Rice

4. Microsoft HealthVault (iPhone, computer)

Date	Food	Servings	Serving si:	Energy
9/21/2014	Bread, egg, toasted	1	1	89.3025 cal

5. Doctor Diet

Date	Time	Meal	Food
6/09/2014	12:22	Lunch	whole pita bread

6. Caresens glucose readings

time	glucose value(mmol/L)	manual	cs	memo	exercise	meal	insulin_type	insulin_amount
08/May/2012 22:47:48	7		N			N	null	null

Target database will comprise of the following data tables (in progress).

Follow data types from FHIR resources.

http://www.hl7.org/fhir/resourcelist.html

Patient

NHI			
name			
address			
telecom			
gender			
Ethnicity			
Comments			Comments on patient

Food diary

NHI	Varchar		
EventDate	DateTime		
Event	Varchar		
Food	Varchar		
ServingSize	Decimal		Values like 1, 0.5,
ServingUnit	Varchar		Grams, cup, table spoon
FoodDescription	Varchar		

Carbohydrate	Decimal		
Protein	Decimal		
Calcium	Decimal		
Fat	Decimal		
Comments	Varchar		Comments on patient

Glucose reading

NHI	Varchar		Source data will be identified by email id
Date	Date		
Time			
Reading	Decimal		
Unit	Varchar		
Comments	Varchar		Comments on patient

Medication_dosage

NHI	Varchar		
Date	Date		
TypeInsulin	Varchar		
Medication	Varchar		
Time			
Event	Varchar		
UnitsGiven	Decimal		

Comments	Varchar		Comments on patient

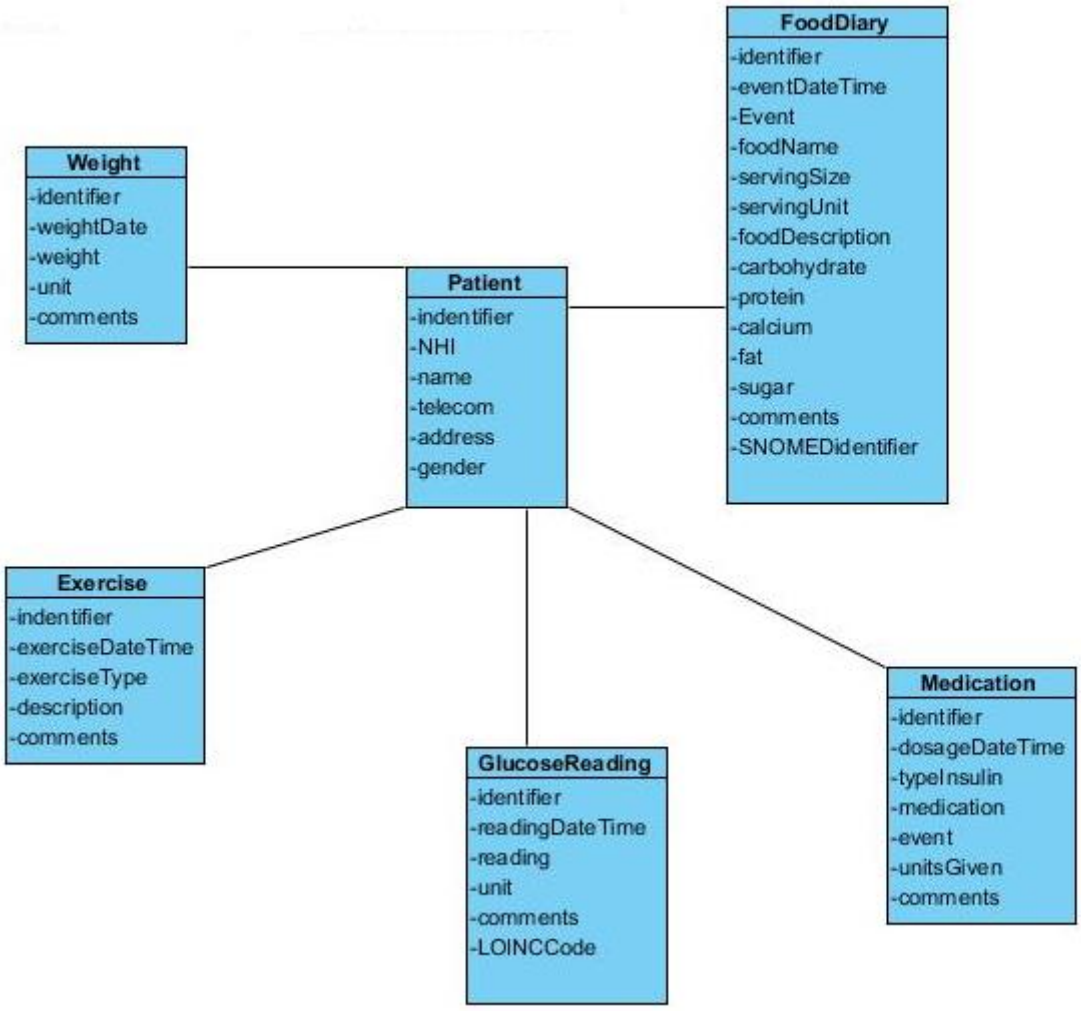
Exercise

NHI	Varchar		
Date	Date		
Time			
TypeActivity	Varchar		
Description	Varchar		
Comments	Varchar		Comments on patient

Weight Gain or Loss

NHI	Varchar		
Date	Date		
Weight	Decimal		
Unit	Varchar		Kg or pounds
Comments	Varchar		Comments on patient

Class Diagram



References:

Crowther, C. A., Hiller, J. E., Moss, J. R., McPhee, A. J., Jeffries, W. S., & Robinson, J. S. (2005). Effect of treatment of gestational diabetes mellitus on pregnancy outcomes, *The New England Journal of Medicine*, 352(24), 2477-2486.

Landon, M. B. (2010). Is there a benefit to the treatment of mild gestational diabetes mellitus?. *American Journal of Obstetrics and Gynecology*, 202(6), 649-653.

Martin, J. L., Clark, D. J., Morgan, S. P., Crowe, J. A. & Murphy, E. (2012). A

user-centred approach to requirements elicitation in medical device development: A case study from an industry perspective, Applied Ergonomics, 43(1), 184-190.

Appendix E – User Manual

Prototype Version 1
User Manual

The main aim is to determine whether a diverse "constellation" of mobile apps can be used together to add value and robustness in a clinical application. An ecosystem will be built to integrate data from various mobile wellness apps with a software system.

LOGIN PAGE: This is the login page where clinicians enter their username and password. There are two types of users: Clinician and admin.

As a 'Clinician' user you can perform most routine jobs about patient management, importing data from mobile apps and blood glucose meter.

As an 'Admin' user you can perform all the task of a clinician user. You are allowed to manage users and maintaining data about clinical codes such as LOINC, SNOMED CT and New Zealand Food database.

Figure 1: Login Page

Patient option: This page will open after the login page as a clinician. Clinician can

find patient, manage patient details.

Figure 2: Patient Option

Find Patient Page: Here clinician can find the patient by searching for their First Name, Last Name, NHI, and Email.

Figure 3: Find Patient Page

Patient Information Page: Here clinician can import new wellness data provided by

patients, run combined wellness report. The combined wellness report has data about blood glucose readings, insulin dosage, food diary and exercise generated as different lines of data for each day.

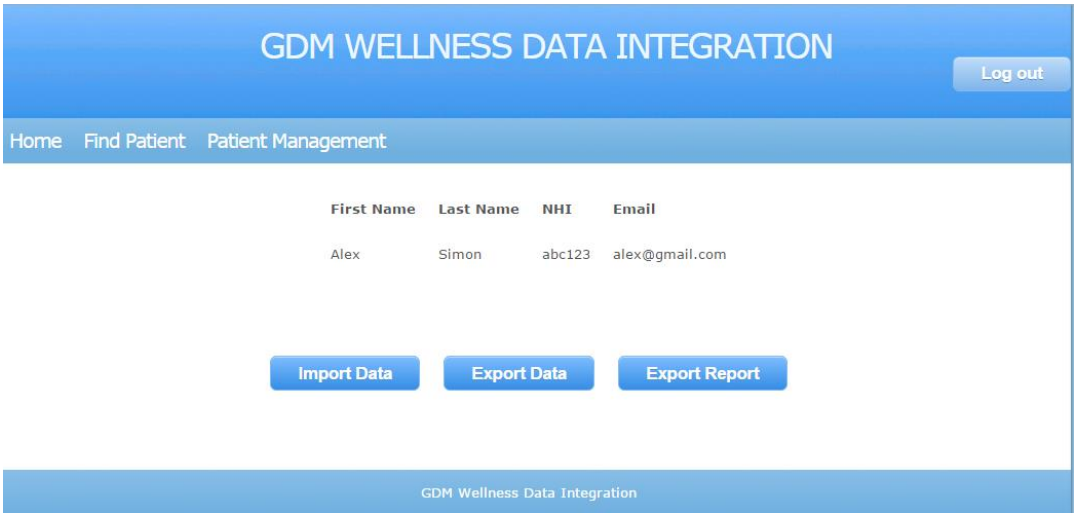


Figure 4: Patient Information Page

Import Data Page: This page will be open on clicking the import data button in PatientInformation page. Here clinician can import and patient data by selecting the wireless app and uploading the file.

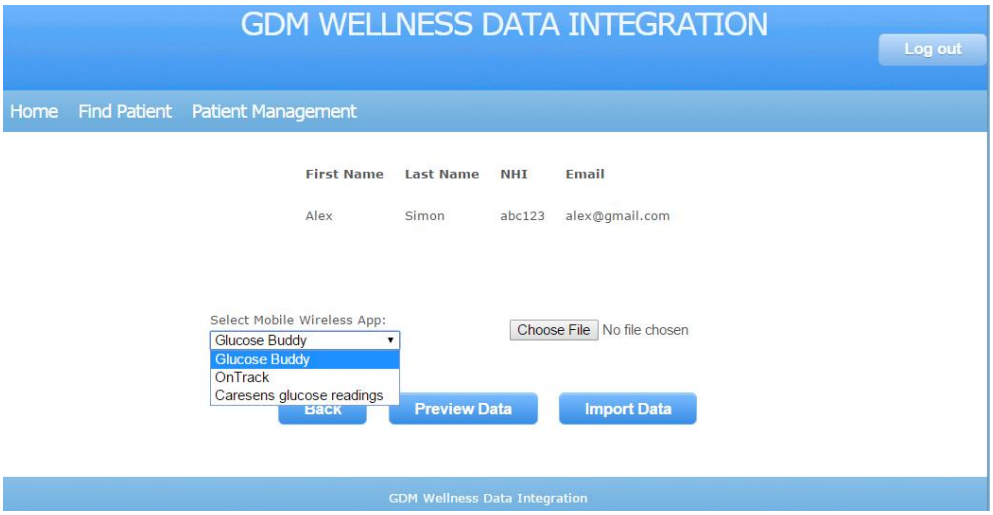


Figure 5: ImportData Page

On Clicking Preview Data Button: On clicking preview button, the patient data will be shown in list.

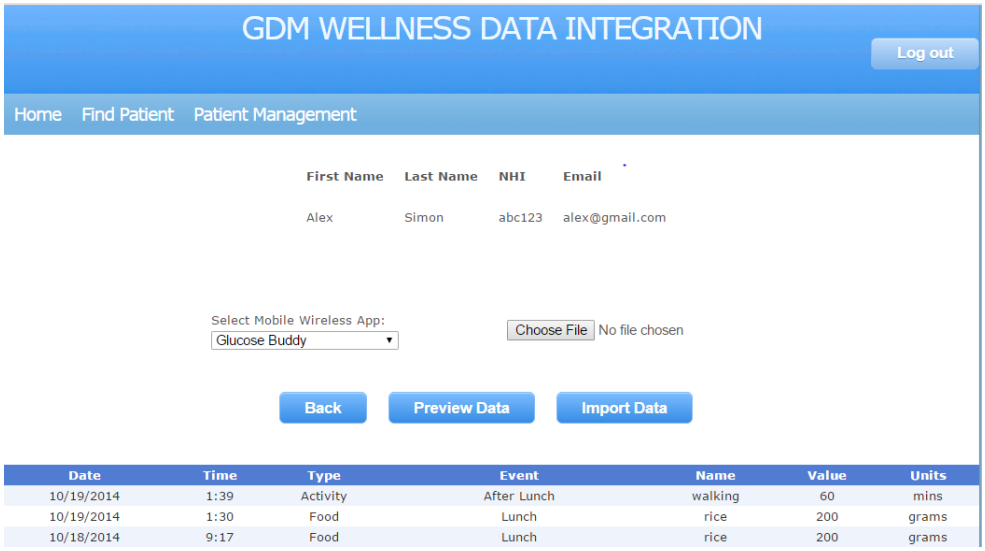


Figure 6: Preview Data

On clicking on Import Data: In this, patient data is imported from a file. A window will be show after importing the data.

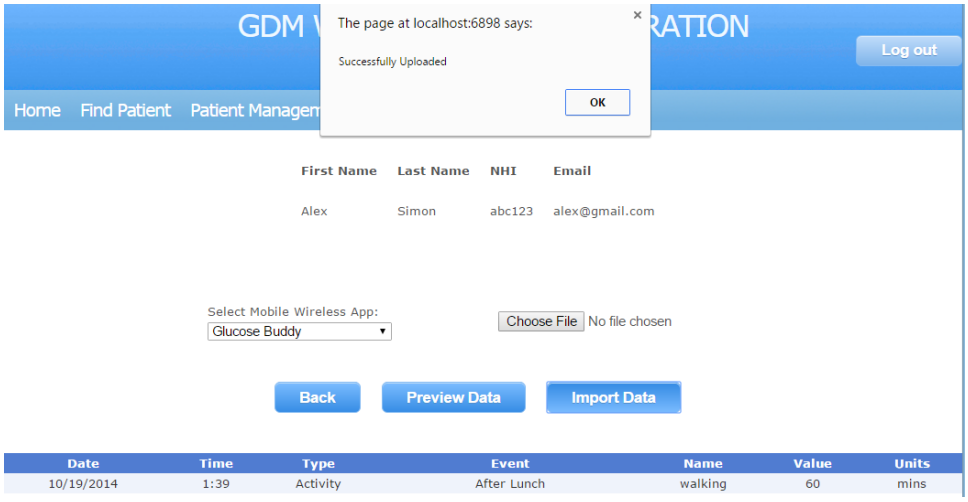


Figure 7: Importing Data

ExportData Page: If a clinician want to save the patient data regarding the exercise, food or weight. Moreover, clinician can have a combine report of the patient which have

the all of the data of the patient.

Figure 8: ExportData Page

Patient Page: On clicking the patient management ink in the menu bar, this page will open. Here Clinician can add a new patient and other information regarding the patient.

Figure 9: Patient Page

Exercise Page: Here clinician can add details about exercise of the patient.

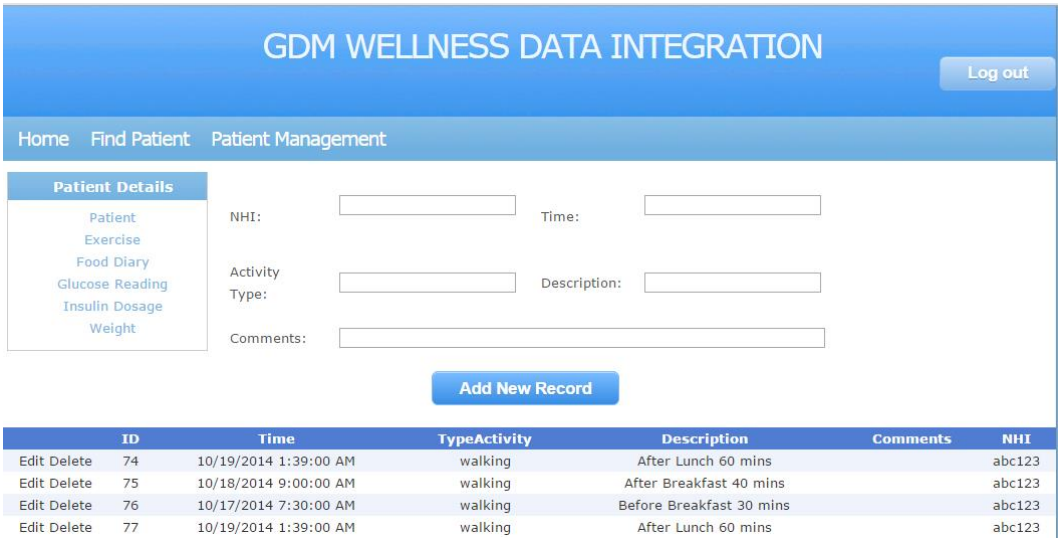


Figure 10: Exercise Page

FoodDiary Page: Here clinician can add information regarding the food of the patient.

Figure 11: FoodDiary Page

GlucoseReading Page: Here clinician can enter glucose reading of the patients.

Figure 12: GlucoseReading Page

InsulinDosage Page: Here clinician can enter the insulin dosage of the patient .

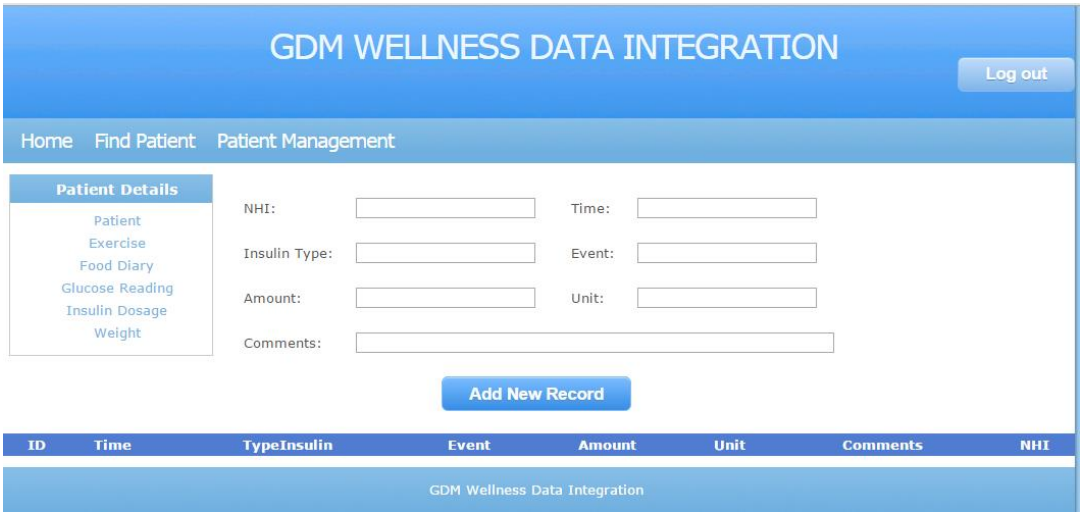


Figure 13: InsulinDosage Page

Weight Page: Here clinician can enter the weight information of the patient.

Figure 14: Weight Page

Tables Snapshots:

Exercise.dbo: This is the table which has the details of the exercise of the patient which are entered by the clinicians.

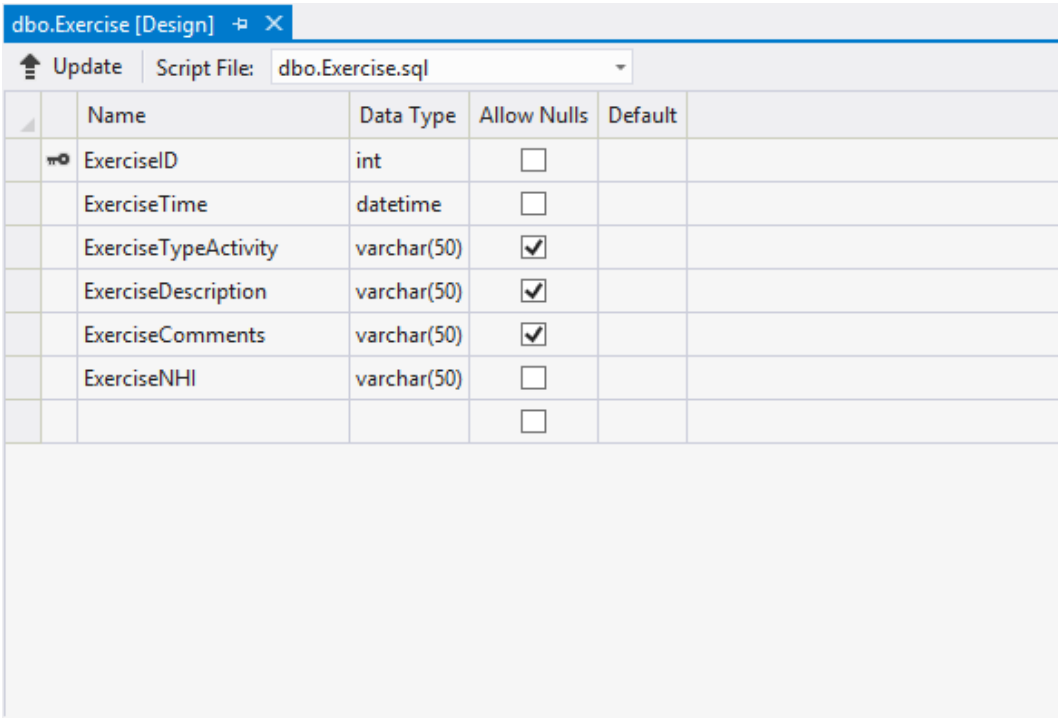


Figure 16.1: Exercise

Food Diary.dbo: This is the table which has the details of the food diary of the patient which are entered by the clinicians.

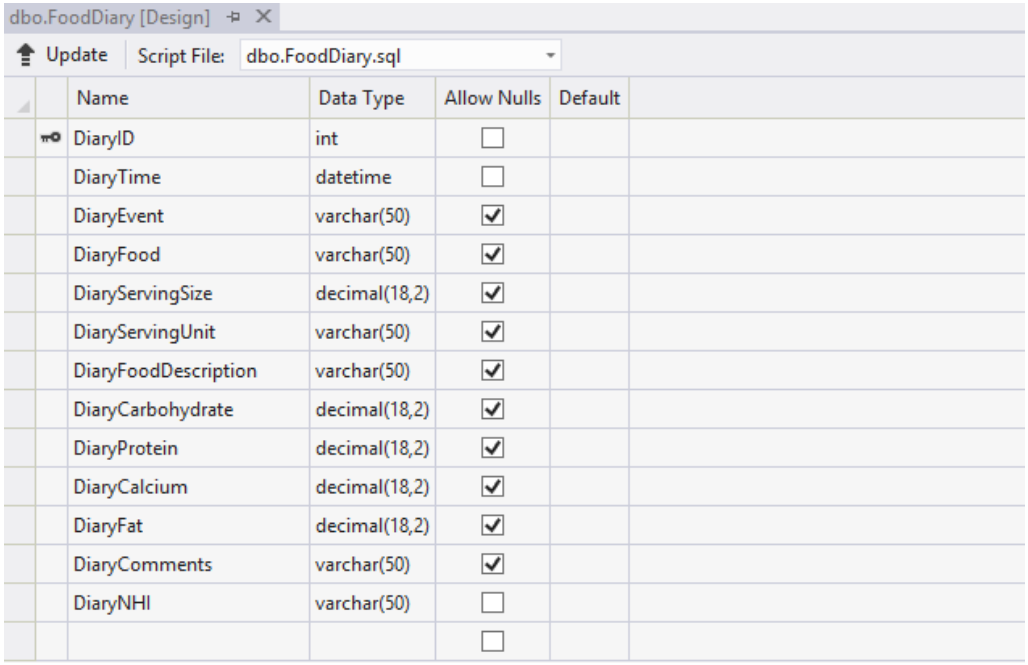


Figure 16.2: FoodDiary

GlucoseReading.dbo: This is the table which has the details of the glucose reading of the patient which are entered by the clinicians.

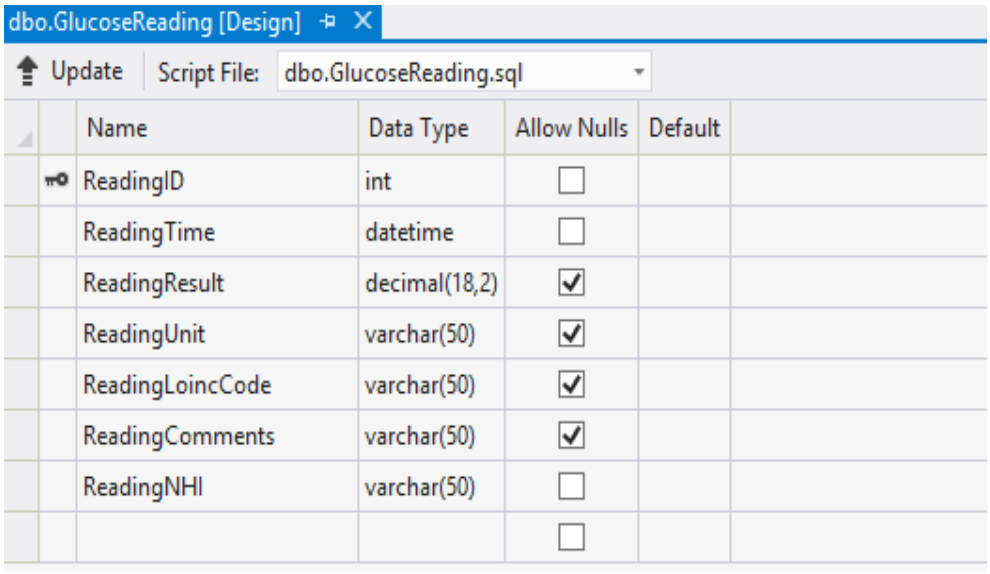


Figure 16.3: GlucoseReading

InsulinDosage.dbo: This is the table which has the details of the insulin dosage of the patient which are entered by the clinicians.

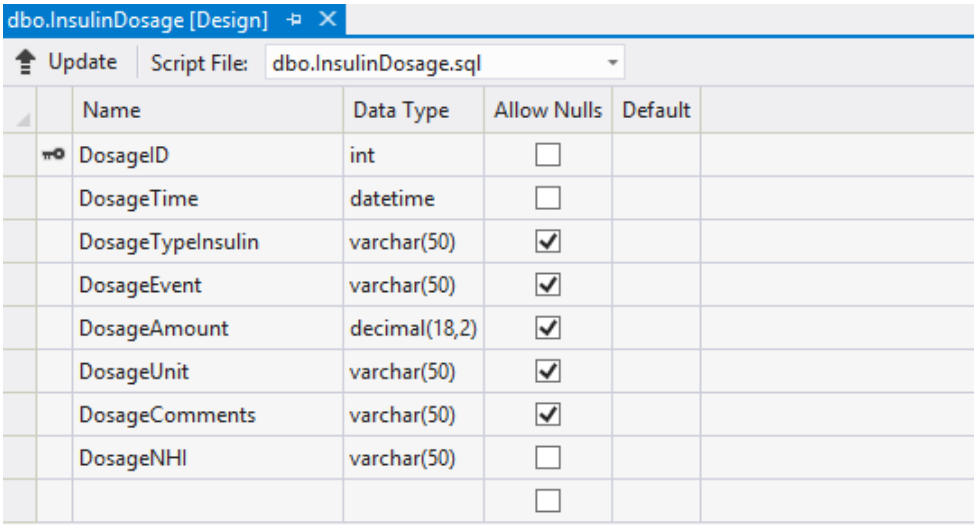


Figure 16.4: InsulinDosage

Patient.dbo: This is the table which has the details of the patient while entering the new patient in the system.

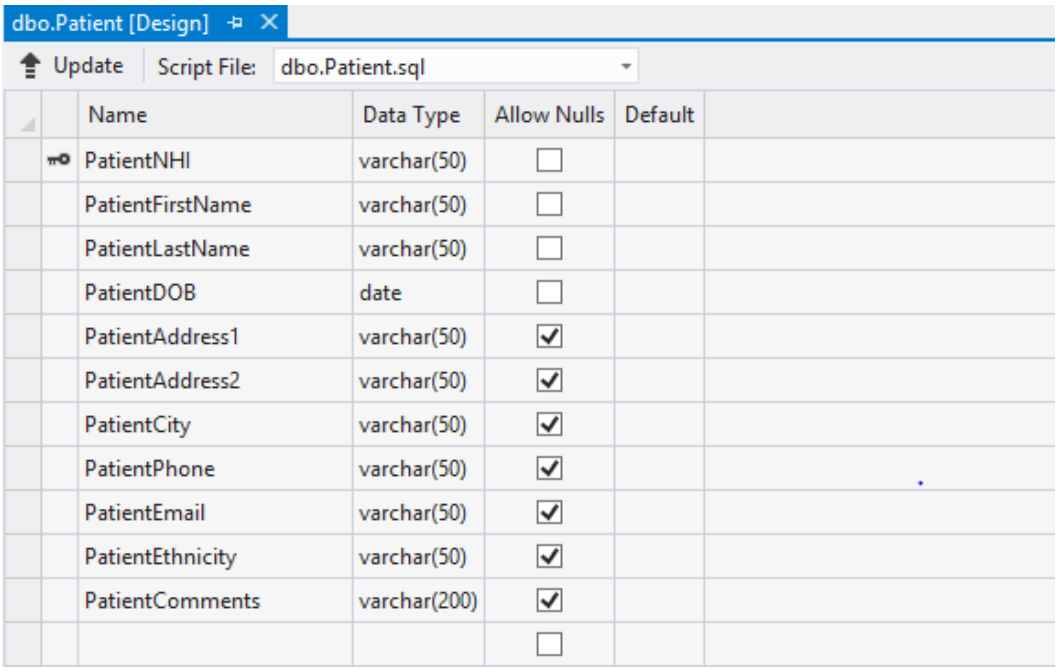


Figure16.6 Patient

User.dbo: This is the table which has the details of the users i.e. Admin and Clinicians.

dbo.User [Design]

Update | Script File: dbo.User.sql

Name	Data Type	Allow Nulls	Default
UserID	int	☐	
UserEmail	varchar(50)	☐	
UserPassword	varchar(50)	☐	
UserFirstName	varchar(50)	☑	
UserLastName	varchar(50)	☑	
UserType	varchar(50)	☐	
		☐	

Figure16.7 User

Weight.dbo: This is the table which has the details of the weight of the patient which are entered by the clinicians.

dbo.Weight [Design]

Update | Script File: dbo.Weight.sql

Name	Data Type	Allow Nulls	Default
WeightID	int	☐	
WeightTime	datetime	☐	
WeightResult	decimal(18,2)	☑	
WeightUnit	varchar(50)	☑	
WeightComments	varchar(50)	☑	
WeightNHI	varchar(50)	☐	
		☐	

Figure16.8 Weight

Prototype Version 2

User Manual

An ecosystem is developed to integrate wellness data from various mobile wellness apps and glucose meter. The main aim is to determine whether a diverse "constellation" of mobile apps can be used together to add value and robustness in a clinical application.

Login Page

This is the login page where clinicians enter their username and password. There are two types of users: Clinician and Admin.

Most routine jobs about patient management, importing data from mobile apps and blood glucose meter are performed by a user with 'Clinician' role. A clinician can view patient wellness data and add comments and additional information where required.

All administrative tasks in the system as well as all the tasks of a Clinician user can be performed by an 'Admin' user. An Admin user can manage other users and maintain codes such as LOINC, SNOMED CT and New Zealand Food database.

Figure 1: Login Page

Patient option

This page will open after the login page as a Clinician. A Clinician will have two

options: Find Patient and Manage Patient Details.

Figure 2: Patient Option

Find Patient Page

Here a Clinician can find a patient by their First Name, Last Name, NHI, or Email address.

Figure 3: Find Patient Page

Patient Information Page

Here a Clinician can import new wellness data provided by the patient and run a combined wellness report. The combined wellness report has data about blood glucose readings, insulin dosage, food diary and exercise generated as different lines of data for each day.

Figure 4: Patient Information Page

Import Data Page

Clicking on Import Data takes the user to the Patient Information page. Here the clinician can import wellness data from a suitable mobile app included in the ecosystem. Clinician need to pick the correct mobile app or glucose meter from the drop down list. The correct patient data file needs to be picked to preview the data on screen and import it into the system.

Figure 5: Import Data Page

Preview Data **Option**

On clicking Preview option, the patient wellness data will be shown as below.

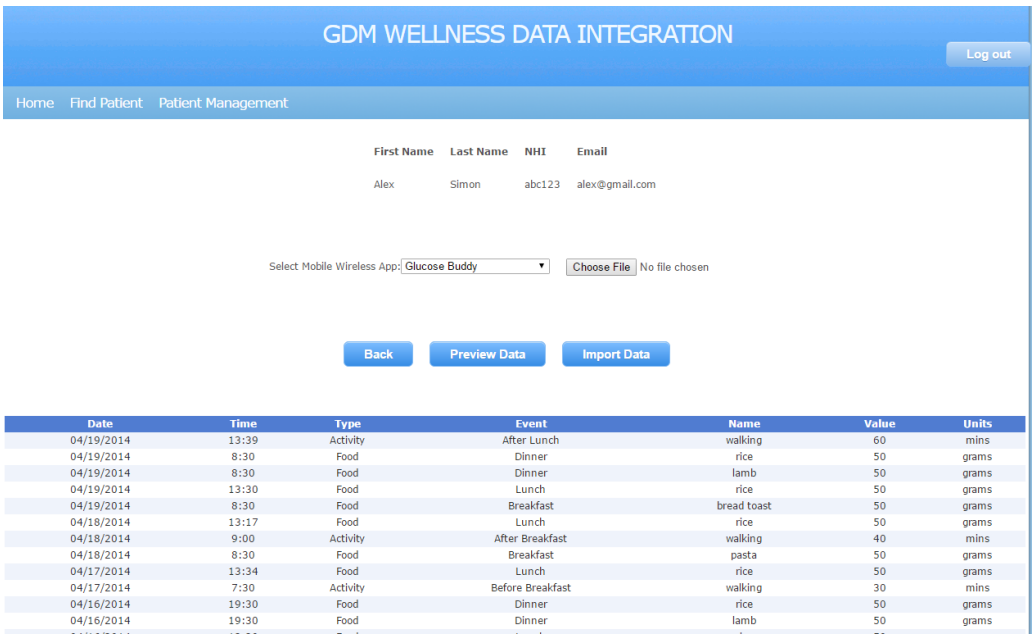


Figure 6: Preview Data

Import Data Option

On clicking 'Import Data' option Patient wellness data can be imported from the chosen mobile app and file. A message will be displayed after importing the data.

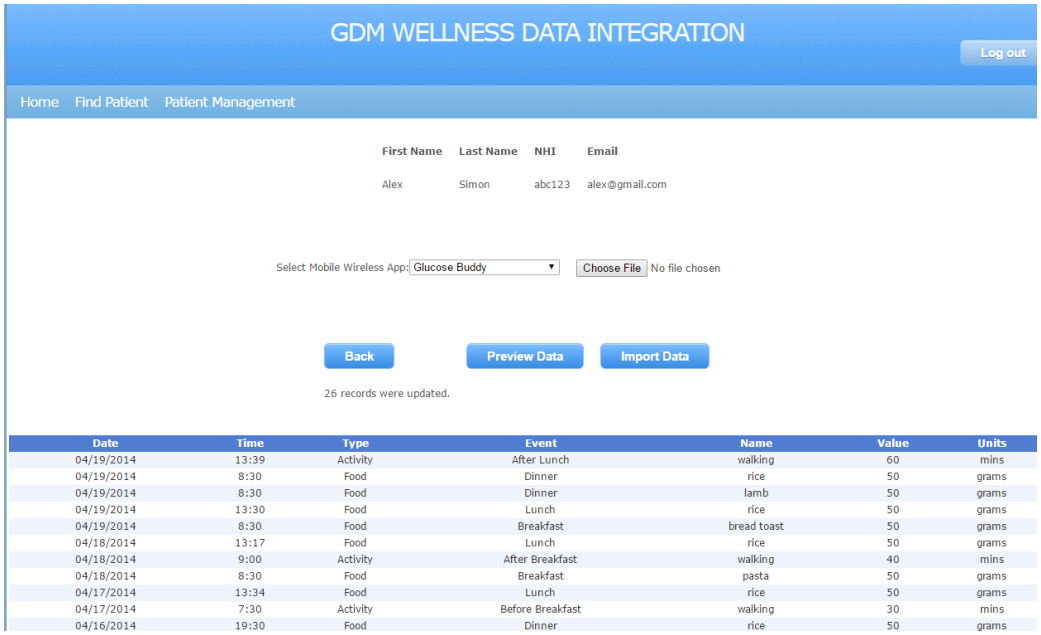


Figure 7: Import Data

Report Page

A clinician can run a combined report about blood glucose, exercise and food diary for a period between start and end date. This is a useful report to clinicians as they can view

wellness data captured in various devices. Since it is brought together in the system, it is easy to share in a team of clinicians caring for a patient.

After importing the ‘Back’ option will take to Patient Report option. Click the ‘Report’ option to take to next page.

Figure 8: Patient Report Option

The user needs to select the start and end date and range of different individual data about food diary, exercise, blood glucose and combined wellness report. Preview option will display data on screen.

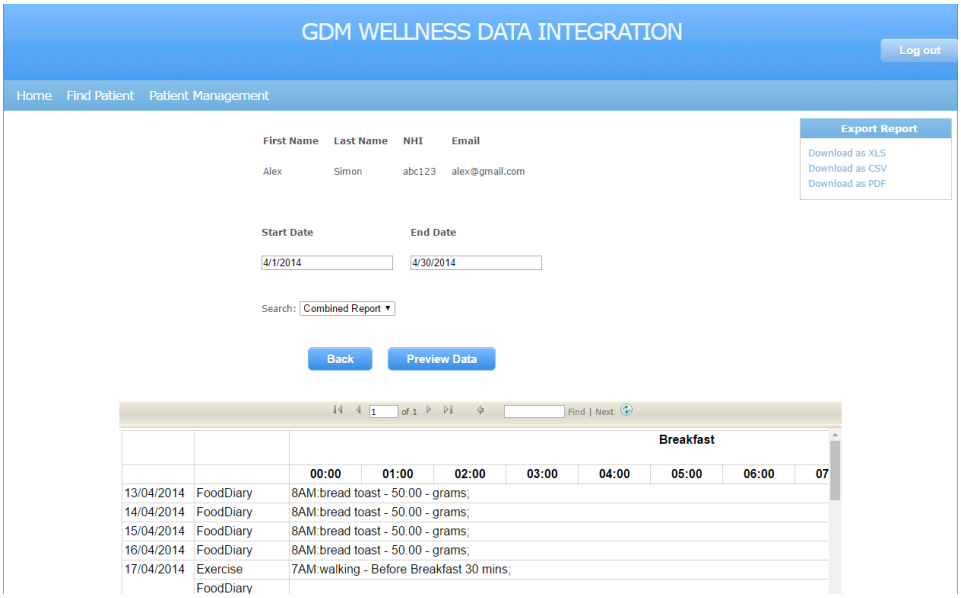


Figure 9: Combined Report on Screen

A report file as pdf can be generated if the top right option ‘Download as pdf’ is selected. Sample report as pdf displayed below.

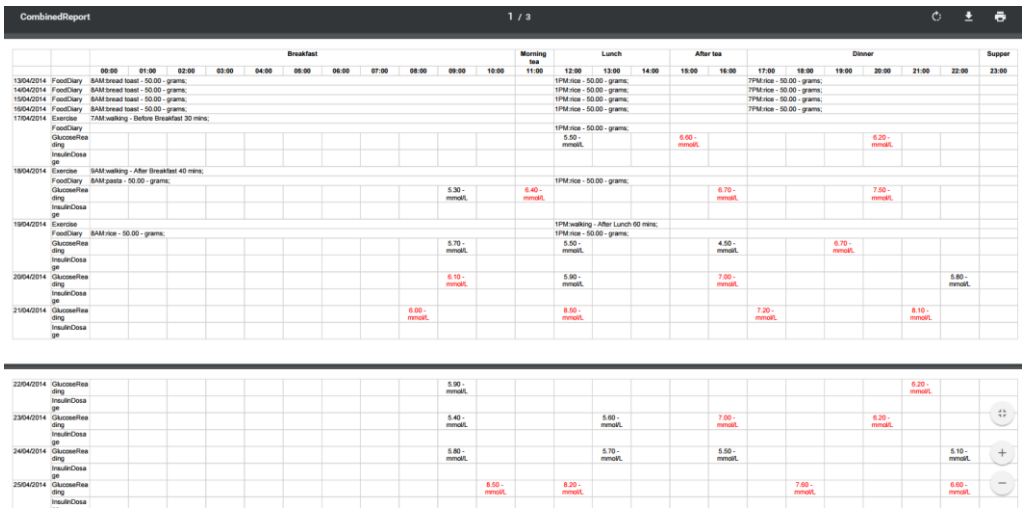


Figure 10: Combined Report as pdf

Patient Page

The Patient Management option will allow a user to add a new patient and other information regarding the patient.

Figure 11: Patient Information

LOINC code

Logical Observation Identifiers Names and Codes (LOINC) have terminologies relating to laboratory results. It has codes for glucometer with mmol/L unit.

14770-2 Fasting

14743-9 Non-fasting

A user can add these codes for a patient's glucose readings.

Edit will display drop down menu to pick the correct LOINC code and the user can add comments and check abnormal glucose readings which are shown as red colour text. Update option will complete the changes in the system.

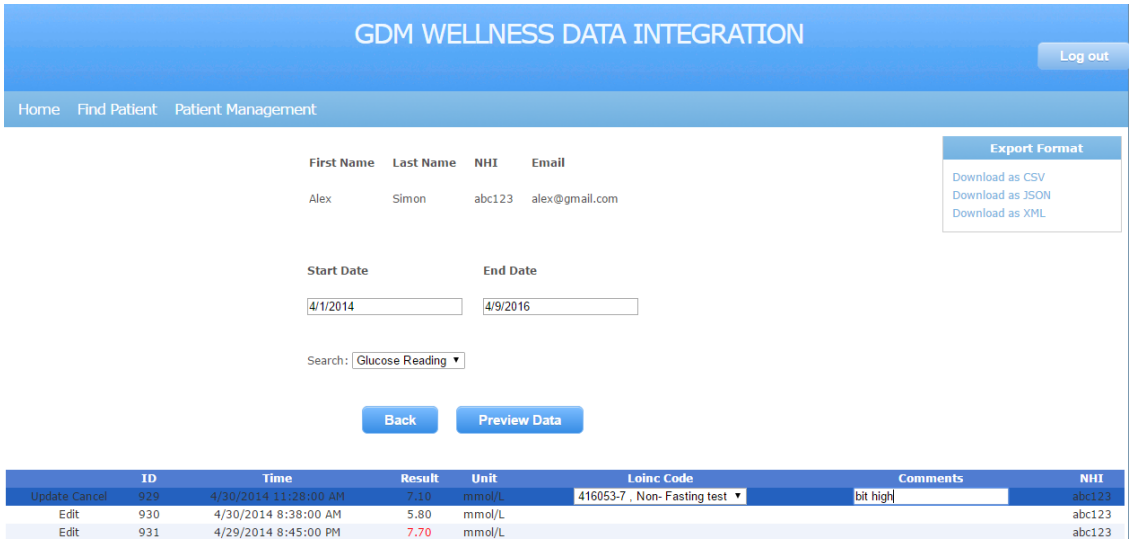


Figure 12: LOINC Code and Comments

SNOMED CT

Systematised Nomenclature of Medicine Clinical Terms (SNOMED CT) has an identification and definition for recording primary health data of a patient. It has comprehensive coverage about many items including symptoms, diagnoses and substance. It provides a consistent information interchange and allows interoperable electronic health record. The 'substance' has 'dietary' to branch out to further food items. Each food item is uniquely identified which include cooked food such as rice and raw food such as banana. These food identifiers are used to identify food allergies and dietary intolerance. The same codes are used to add semantic value to food items in the food diary.

As a user, clinician can pick the SNOMED CT code from a drop box menu and assign it to the food consumed by patient. Update option will complete the task.

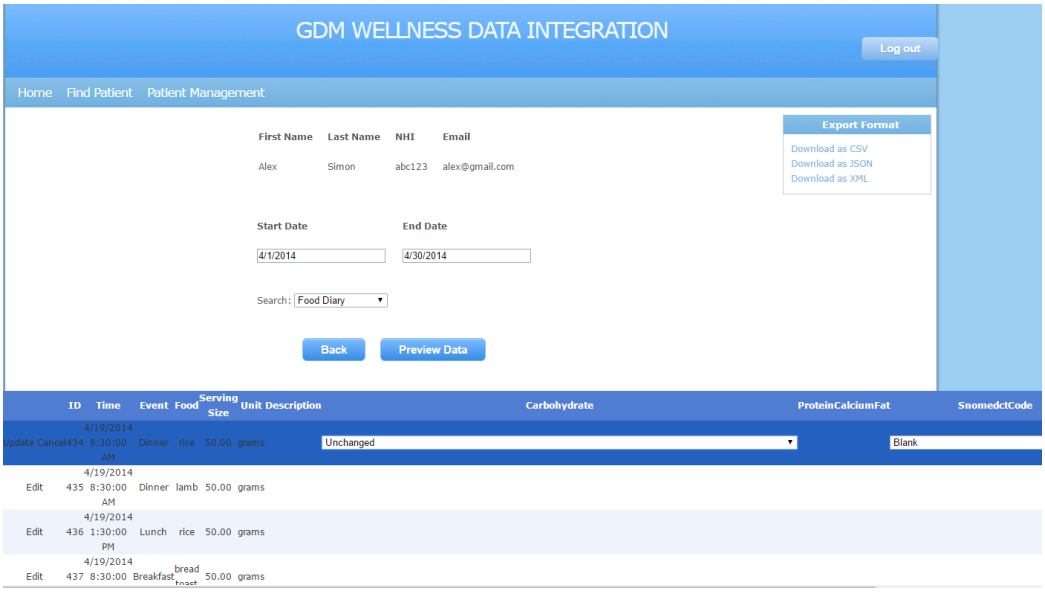


Figure 13: SNOMED CT for Food Items

New Zealand Food Composition Database

New Zealand Food Composition Database has information about many nutrients available in food. Main nutrition values such as calcium, fat and protein which are important for pregnancy and carbohydrates which are important in relation to GDM are considered.

As a user, a clinician can pick the related food items (Example rice) from a drop box menu and assign it to the food consumed by patient. Nutrient values from the composition table are assigned to the food consumed. Update option will complete the task.

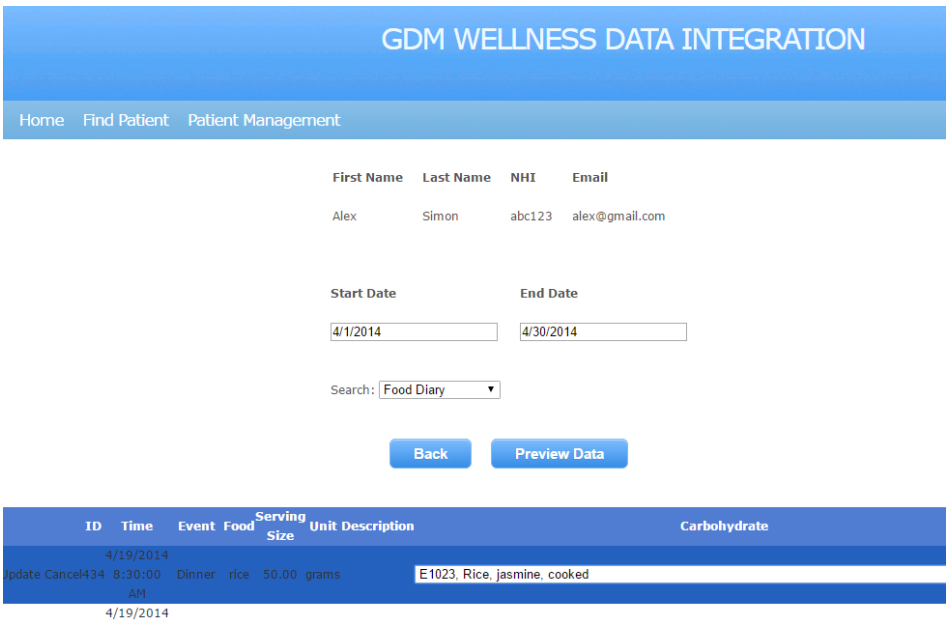


Figure 14: Nutrition from Food Composition Table

Once 'Update' is clicked the calculated values about nutrients by portion size are displayed and stored in the system.

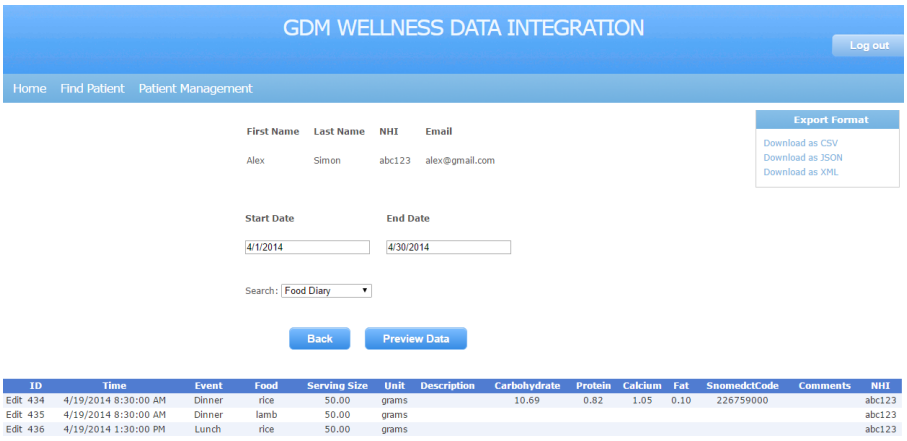


Figure 15: Calculated Nutrients and SNOMED CT Coding

Data Schema

The data schema of various entities such as patient, blood glucose, food diary, exercise, user account is presented below. The schema was designed after consulting clinicians and trialling wellness data from various mobile apps and glucose meter.

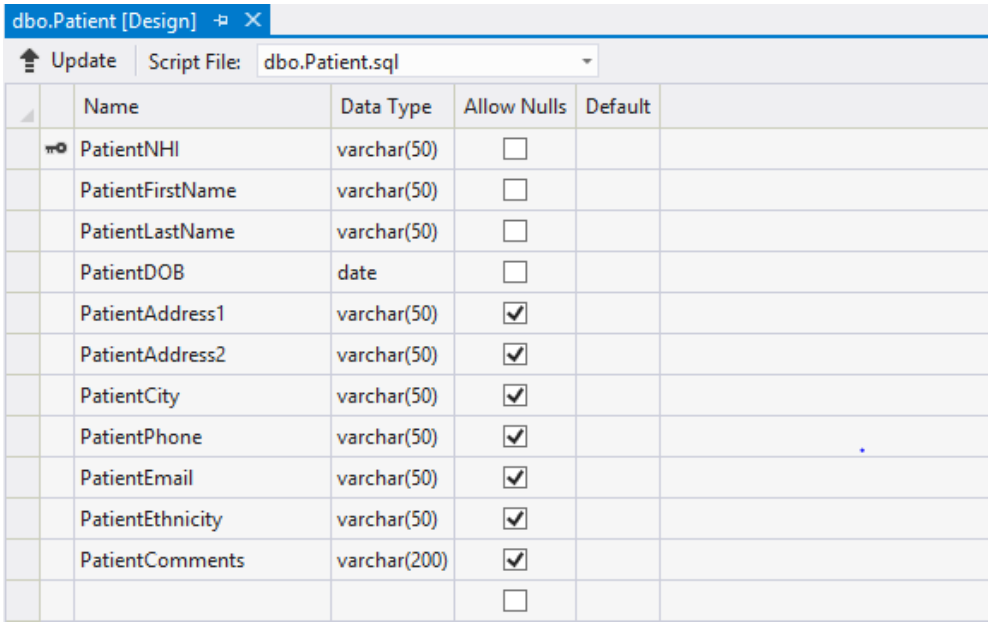


Figure 16: Patient

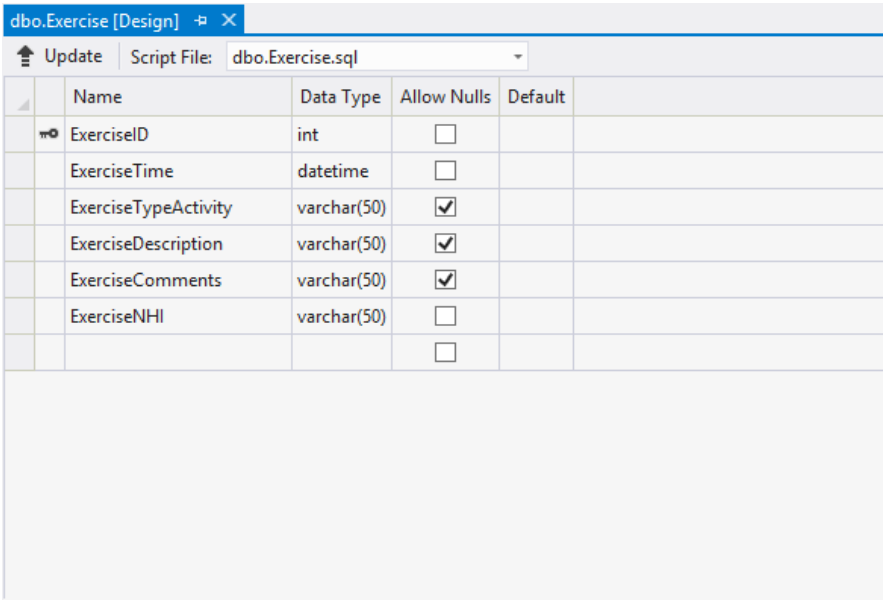


Figure 17 Exercise

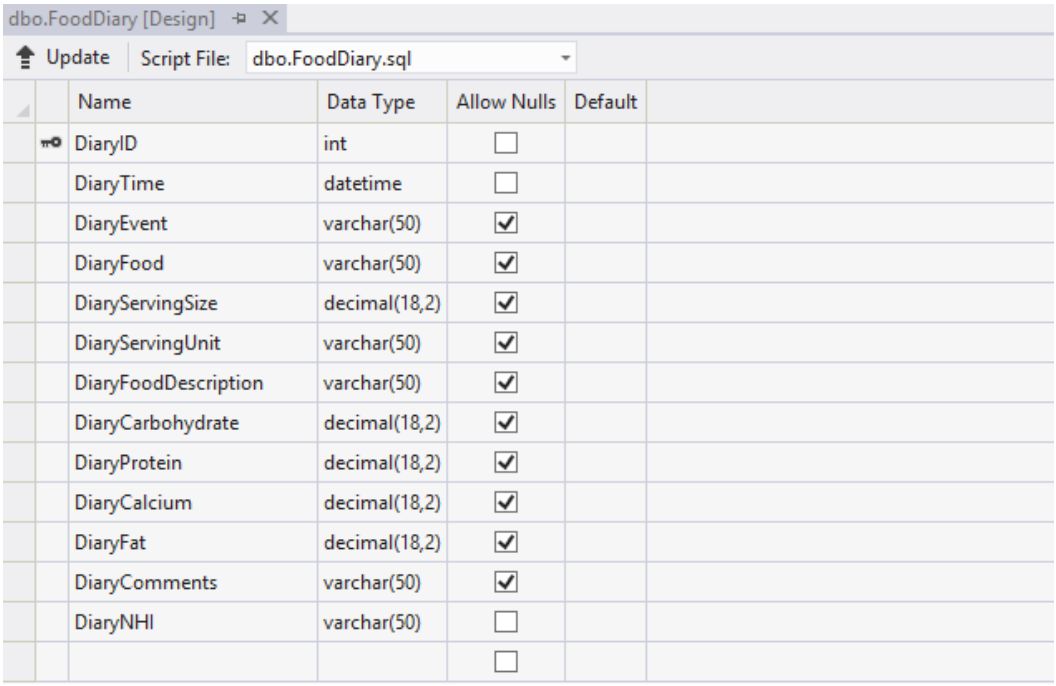


Figure 11: Food Diary

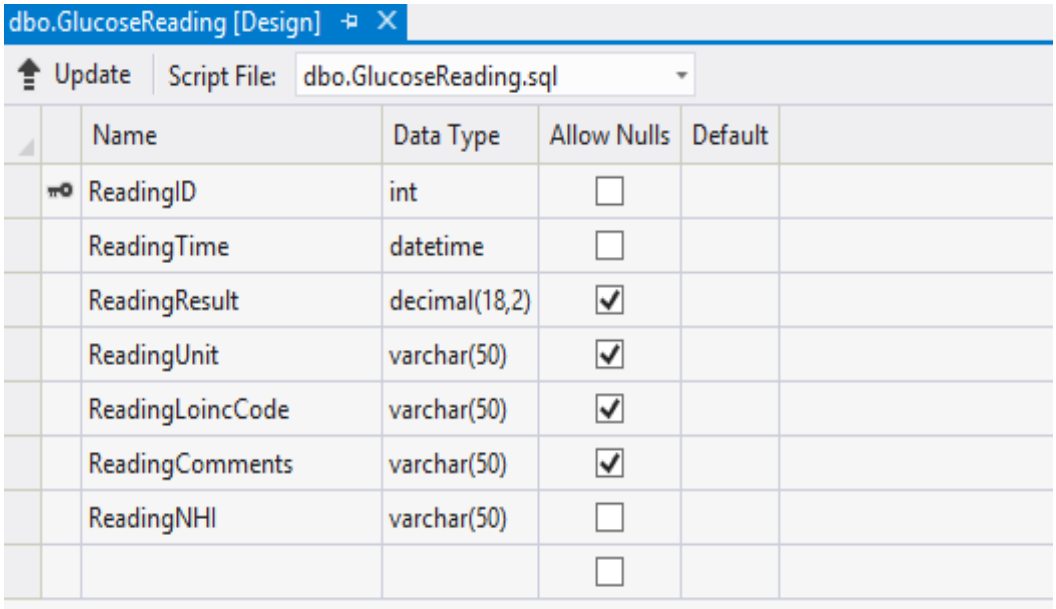


Figure 19: Glucose Readings

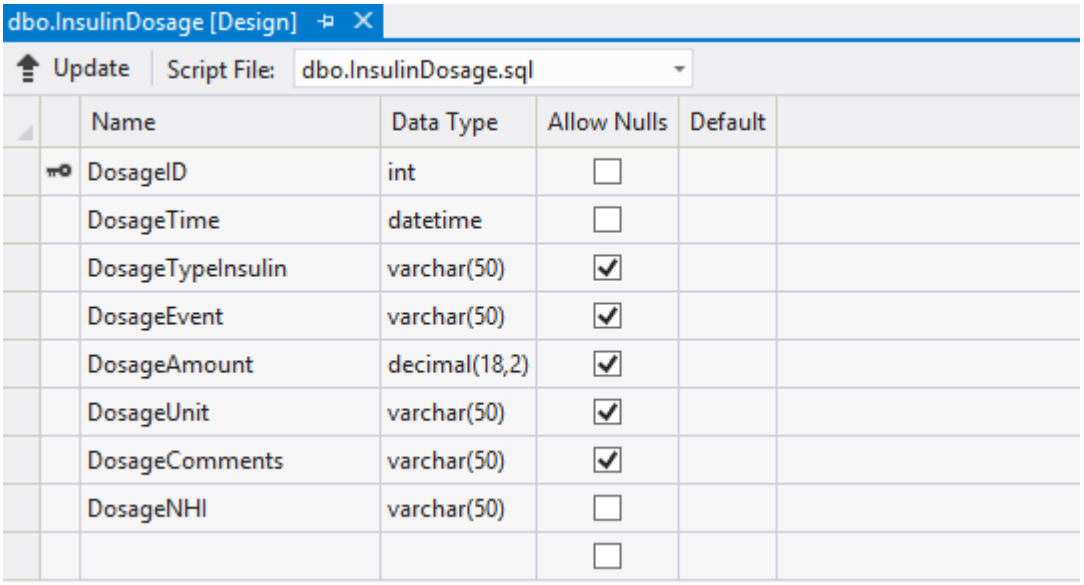


Figure 20: Insulin Dosage

dbo.User [Design]

Update | Script File: dbo.User.sql

Name	Data Type	Allow Nulls	Default
UserID	int	☐	
UserEmail	varchar(50)	☐	
UserPassword	varchar(50)	☐	
UserFirstName	varchar(50)	☑	
UserLastName	varchar(50)	☑	
UserType	varchar(50)	☐	
		☐	

Figure 21: User

dbo.Loinc [Design]

Update | Script File: dbo.Loinc.sql

Name	Data Type	Allow Nulls	Default
LoincCode	varchar(50)	☐	
LoincDescription	varchar(50)	☑	
		☐	

Figure 22: LOINC Code

dbo.Snomedct [Design]

Update | Script File: dbo.Snomedct.sql

Name	Data Type	Allow Nulls	Default
SnomedctCode	varchar(50)	☐	
SnomedctDescription	varchar(500)	☑	
		☐	

Figure 23: SNOMED CT Code

dbo.Food [Design]

Update | Script File: dbo.Food.sql

	Name	Data Type	Allow Nulls	Default
🔑	FoodID	varchar(50)	☐	
	FoodName	varchar(100)	☐	
	FoodCalcium	decimal(18,2)	☑	
	FoodCarbohydrate	decimal(18,2)	☑	
	FoodFat	decimal(18,2)	☑	
	FoodProtein	decimal(18,2)	☑	

Figure 24: Food Composition Table

Appendix F – Think Aloud Protocol Tasks

Think aloud protocol

Prototype Version 1 and Version 2 evaluation - Think aloud protocol

Prototype 1 will have five participants including physician, dietician and midwife.

Prototype 2 will have fifteen participants including physician, dietician and midwife.

A specific task will be given to the clinician. Video tutorials will be provided about the prototype and its functionalities. Participants are asked to verbalise their actions as they perform the steps in the task.

Prototype Version 1 and version 2 Task

Step 1: You are given glucose readings and wellness data (food diary and exercise) from mobile apps. You are required to upload the data for a patient into the prototype.

Step 2: You can run the report to view the combined data about glucose readings, food diary and exercise.

Step 3: You can refine the query for a specific period (start date and end date).

Step 4: You can add a comment for a specific date and combined data to be shared with in the team.

Think Aloud Protocol testing

An ecosystem is developed to integrate wellness data from various mobile wellness apps and glucose meter. The main aim is to determine whether a diverse "constellation" of mobile apps can be used together to add value and robustness in a clinical application.

Most routine jobs about patient management, importing data from mobile apps and blood glucose meter are performed by a user with 'Clinician' role. A clinician can view patient wellness data and add comments and additional information where required.

Task 1 – Combined Wellness Report

Clinician can run a combined report about blood glucose, exercise and food diary for a period between start and end date. This is a useful report to clinicians as they can view wellness data captured from various devices. Since it is brought together in the system, it is easy to share in a team of clinicians caring a patient.

Login as a clinician and view the combined wellness report for a patient.

Login as a clinician,

User Email: jason@gmail.com
User Password: 1234
User Type: Clinician

1. Find Patient
   First Name: Ruby

2. Click 'Report' option
   Start Date: 17 April 2014
   End Date: 30 April 2014
   Search: Combined Report
   Click 'Preview Data'
   (View the combined wellness data on screen)
   Generate the same report as pdf file. Click 'Download pdf'.

Task 2 – Import Wellness Data

Clinician can import wellness data from a suitable mobile app included in the ecosystem. Clinician need to pick the correct mobile app and glucose meter from the drop down list. The correct patient data file needs to be picked to preview the data on screen and import it into the system.

1. Find patient
   Patient Name: Helen

2. Import Data

   Select Mobile App: Glucose Buddy
   Choose File: GlucoseBuddyHelen
   Click ‘Preview Data’
   (View the data on screen)
   Click ‘Import Data’
   (Check message on screen n records saved in the system database)

   Select Mobile App: Caresens Glucometer
   Choose File: caresensHelen
   Click ‘Preview Data’
   (View the data on screen)
   Click ‘Import Data’
   (Check message on screen n records saved in the system database)

3. Click ‘Back’ option
   Click ‘Report’ option

   Start Date: 17 April 2015
   End Date: 30 April 2015
   Search: Combined Report
   Click ‘Preview Data’
   (View the combined wellness data on screen)

   Generate the same report as pdf file. Click ‘Download pdf’.

Task 3 – Assign LOINC code

Logical Observation Identifiers Names and Codes (LOINC) have terminologies relating to laboratory results. It has codes for glucometer with mmol/L unit.

14770-2 Fasting

14743-9 Non-fasting

Patient Helen is selected and Select Glucose Readings.

1. Find Patient
   First Name: Ruby

2. Click ‘Report’ option
   Start Date: 17 April 2014
   End Date: 30 April 2014
   Search: Glucose Readings
   View data.

3. Click ‘Edit’ to one line of record to change LOINC readings
   Select from Drop Down menu either Fasting or Non-fasting reading
   Click ‘Update’ to save changes

Task 4 – Assign SNOMED CT code

Systematised Nomenclature of Medicine Clinical Terms (SNOMED CT) has an identification and definition for recording primary health data of a patient. Each food item is uniquely identified which include cooked food such as rice and raw food such as banana. These food identifiers are used to identify food allergies and dietary intolerance. The same codes are used to add semantic value to food items in the food diary.

As a user, clinician can pick the SNOMED CT code from a drop box menu and assign it to the food consumed by patient. Update option will complete the task.

Patient Helen is selected and Select Food diary.

1. Find Patient
   First Name: Ruby

2. Click 'Report' option
   Start Date: 17 April 2014
   End Date: 30 April 2014
   Search: Food diary
   View data

3. Click 'Edit' to one line of record to change SNOMED CT
   Select from Drop Down menu the correct food item.
   System will automatically allocate the SNOMED CT code.
   Click 'Update' to save changes

Task 5 – Assign Nutrients Values

New Zealand Food Composition Database has information about many nutrients available in food. Main nutrition values such as calcium, fat and protein which are important for pregnancy and carbohydrate which is important in relation to GDM is considered.

Nutrients values are sometimes missing in the mobile wellness data.

As a user, clinician can pick the related food items (Example rice) from a drop box menu and assign it to the food consumed by patient. Nutrient values from the composition table are assigned to the food consumed. Update option will complete the task.

Patient Helen is selected and Select Food diary.

1. Find Patient
   First Name: Ruby

2. Click ‘Report’ option
   Start Date: 17 April 2014
   End Date: 30 April 2014
   Search: Food diary
   View data.

3. Click ‘Edit’ to one line of record to change Food Nutrients
   Select from Drop Down menu the correct food item.
   System will automatically assign the calculated nutrients value by portion size consumed.
   Click ‘Update’ to save changes

Appendix G: Test Data

Caresens Blood Glucose reader

name		birthday	sex	serial number	data unit	user idx	NHI_number	DATEFORMAT	
Natasha		28-Jul-80	F	A5A246B01161	mmol/L	2	abc123	DD/MMM/YYYY	
time	org_glucose value(mg/dL)	glucose value(mmol/L)	manual	cs	memo	exercise	meal	insulin_type	insulin_amount
30/04/2015 11:28	129	7.1	N	N			N	Novorapid	30
30/04/2015 8:38	106	5.8	N	N			N	Humalog	50
29/04/2015 20:45	139	7.7	N	N			N	Humalog	31
29/04/2015 15:30	108	6	N	N			N	Humalog	32
29/04/2015 11:23	101	5.6	N	N			N	Humalog	33
29/04/2015 8:15	98	5.4	N	N			N	Humalog	34
28/04/2015 20:09	126	7	N	N			N	Humalog	35
28/04/2015 20:08	136	7.5	N	N			N	Humalog	36
28/04/2015 12:34	143	7.9	N	N			N	Humalog	37
28/04/2015 12:33	136	7.5	N	N			N	Humalog	38
28/04/2015 9:27	91	5	N	N			N	Humalog	39
27/04/2015 21:43	101	5.6	N	N			N	Humalog	40
27/04/2015 12:24	122	6.7	N	N			N	Humalog	41
27/04/2015 9:56	100	5.5	N	N			N	Humalog	42
26/04/2015 21:05	114	6.3	N	N			N	Humalog	43
26/04/2015 13:47	98	5.4	N	N			N	Humalog	44
26/04/2015 9:52	99	5.5	N	N			N	Novorapid	45
25/04/2015 22:18	120	6.6	N	N			N	Novorapid	46
25/04/2015 22:17	116	6.4	N	N			N	Novorapid	47
25/04/2015 18:47	138	7.6	N	N			N	Novorapid	48
25/04/2015 18:47	133	7.3	N	N			N	Novorapid	49
25/04/2015 12:19	146	8.1	N	N			N	Novorapid	50

25/04/2015 12:15	148	8.2	N	N			N	Novorapid		
25/04/2015 12:15	145	8	N	N			N	Novorapid	31	
25/04/2015 10:13	153	8.5	N	N			N	Novorapid	32	
25/04/2015 10:12	115	6.3	N	N			N	Novorapid	33	
24/04/2015 22:28	93	5.1	N	N			N	Novorapid	34	
24/04/2015 16:52	99	5.5	N	N			N	Novorapid	35	
24/04/2015 13:28	97	5.3	N	N			N	Novorapid	36	
24/04/2015 13:28	104	5.7	N	N			N	Novorapid	37	
24/04/2015 9:21	101	5.6	N	N			N	Novorapid	38	
24/04/2015 9:20	106	5.8	N	N			N	Novorapid	39	
23/04/2015 20:42	113	6.2	N	N			N	Novorapid	40	
23/04/2015 16:54	120	6.6	N	N			N	Novorapid	41	
23/04/2015 16:54	126	7	N	N			N	Novorapid	42	
23/04/2015 13:07	102	5.6	N	N			N	Novorapid	43	
23/04/2015 9:40	98	5.4	N	N			N	Novorapid	44	
22/04/2015 21:26	113	6.2	N	N			N	Novorapid	45	
22/04/2015 9:40	107	5.9	N	N			N	Novorapid	46	
21/04/2015 21:48	147	8.1	N	N			N	Novorapid	47	
21/04/2015 17:34	130	7.2	N	N			N	Novorapid	48	
21/04/2015 17:33	129	7.1	N	N			N	Novorapid	49	
21/04/2015 12:34	154	8.5	N	N			N	Novorapid	50	
21/04/2015 12:33	138	7.6	N	N			N	Novorapid	33	
21/04/2015 12:32	142	7.8	N	N			N	Novorapid	33	
21/04/2015 8:53	102	5.6	N	N			N	Novorapid	33	
21/04/2015 8:52	109	6	N	N			N	Novorapid	33	
20/04/2015 22:15	104	5.7	N	N			N	Novorapid	33	
20/04/2015 22:14	106	5.8	N	N			N	Novorapid	33	
20/04/2015 16:49	127	7	N	N			N	Novorapid	33	

20/04/2015 12:46	104	5.7	N	N			N	Novorapid	33	
20/04/2015 12:45	107	5.9	N	N			N	Novorapid	33	
20/04/2015 9:32	110	6.1	N	N			N	Novorapid	33	
19/04/2015 19:16	122	6.7	N	N			N	Novorapid	33	
19/04/2015 16:45	82	4.5	N	N			N	Novorapid	33	
19/04/2015 12:05	100	5.5	N	N			N	Novorapid	33	
19/04/2015 9:02	103	5.7	N	N			N	Novorapid	33	
18/04/2015 20:36	135	7.5	N	N			N	Novorapid	33	
18/04/2015 16:29	121	6.7	N	N			N	Novorapid	33	
18/04/2015 11:59	116	6.4	N	N			N	Novorapid	33	
18/04/2015 9:18	96	5.3	N	N			N	Novorapid	33	
17/04/2015 20:02	112	6.2	N	N			N	Novorapid	33	
17/04/2015 15:44	119	6.6	N	N			N	Novorapid	33	
17/04/2015 12:34	99	5.5	N	N			N	Novorapid	33	

Glucose Buddy

Date	Time	Type	Event	Name	Value	Units
04/19/2015	1:39	Activity	After Lunch	walking	60	mins
04/19/2015	8:30	Food	Dinner	rice	50	grams
04/19/2015	1:30	Food	Dinner	lamb	50	grams
04/19/2015	1:30	Food	Lunch	rice	50	grams
04/19/2015	8:30	Food	Breakfast	bread toast	50	grams
04/18/2015	9:17	Food	Lunch	rice	50	grams
04/18/2015	9:00	Activity	After Breakfast	walking	40	mins
04/18/2015	8:30	Food	Breakfast	pasta	50	grams
04/17/2015	1:34	Food	Lunch	rice	50	grams
04/17/2015	7:30	Activity	Before Breakfast	walking	30	mins
04/16/2015	8:30	Food	Dinner	rice	50	grams
04/16/2015	1:30	Food	Dinner	lamb	50	grams
04/16/2015	1:30	Food	Lunch	rice	50	grams
04/16/2015	8:30	Food	Breakfast	bread toast	50	grams
04/15/2015	8:30	Food	Dinner	rice	50	grams
04/15/2015	1:30	Food	Dinner	lamb	50	grams
04/15/2015	1:30	Food	Lunch	rice	50	grams
04/15/2015	8:30	Food	Breakfast	bread toast	50	grams
04/14/2015	8:30	Food	Dinner	rice	50	grams
04/14/2015	1:30	Food	Dinner	lamb	50	grams
04/14/2015	1:30	Food	Lunch	rice	50	grams
04/14/2015	8:30	Food	Breakfast	bread toast	50	grams
04/13/2015	8:30	Food	Dinner	rice	50	grams
04/13/2015	1:30	Food	Dinner	lamb	50	grams
04/13/2015	1:30	Food	Lunch	rice	50	grams
04/13/2015	8:30	Food	Breakfast	bread toast	50	grams

OnTrack

DateTime	Type	Exercise	Event	Value	Food
30/04/2014 14:07	Exercise	Walking		45	
30/04/2014 19:06	Food		Dinner	3	Roti
30/04/2014 10:07	Exercise	Walking		60	
30/04/2014 13:00	Food		Lunch	50	Rice
29/04/2014 18:00	Food		Dinner	2	Roti
29/04/2014 18:00	Food		Dinner	2	cheak pea
29/04/2014 14:07	Exercise	Walking		30	

29/04/2014 13:00	Food		Lunch	50	Rice
29/04/2014 10:00	Food		Breakfast	100	Bread slices
28/04/2014 18:00	Food		Dinner	2	Roti cheak pea
28/04/2014 14:07	Exercise	Walking		30	
28/04/2014 13:00	Food		Lunch	50	Rice
28/04/2014 10:00	Food		Breakfast	100	Bread slices
27/04/2014 18:00	Food		Dinner	2	Roti
27/04/2014 18:00	Food		Dinner	2	cheak pea
27/04/2014 14:07	Exercise	Walking		30	
27/04/2014 13:00	Food		Lunch	50	Rice
27/04/2014 10:00	Food		Breakfast	100	Bread slices
26/04/2014 18:00	Food		Dinner	2	Roti
26/04/2014 18:00	Food		Dinner	2	Mutton
26/04/2014 14:07	Exercise	Walking		30	
26/04/2014 13:00	Food		Lunch	50	Rice
26/04/2014 10:00	Food		Breakfast	100	Bread slices
25/04/2014 18:00	Food		Dinner	2	Roti
25/04/2014 14:07	Exercise	Walking		30	
25/04/2014 13:00	Food		Lunch	50	Rice
25/04/2014 10:00	Food		Breakfast	100	Bread slices
24/04/2014 18:00	Food		Dinner	2	Roti
24/04/2014 14:07	Exercise	Walking		30	
24/04/2014 13:00	Food		Lunch	50	Rice
24/04/2014 10:00	Food		Breakfast	50	Porridge
23/04/2014 18:00	Food		Dinner	2	Roti
23/04/2014 14:07	Exercise	Walking		30	

23/04/2014 13:00	Food		Lunch	50	Rice
23/04/2014 10:00	Food		Breakfast	100	Bread slices
22/04/2014 18:00	Food		Dinner	2	Roti
22/04/2014 14:07	Exercise	Walking		30	
22/04/2014 13:00	Food		Lunch	50	Rice
22/04/2014 10:00	Food		Breakfast	100	Bread slices
21/04/2014 18:00	Food		Dinner	2	Roti
21/04/2014 14:07	Exercise	Walking		30	
21/04/2014 13:00	Food		Lunch	50	Rice
21/04/2014 10:00	Food		Breakfast	100	Bread slices
20/04/2014 18:00	Food		Dinner	2	Roti
20/04/2014 14:07	Exercise	Walking		30	
20/04/2014 13:00	Food		Lunch	50	Rice
20/04/2014 10:00	Food		Breakfast	100	Bread slices
19/04/2014 18:00	Food		Dinner	2	Roti
19/04/2014 14:07	Exercise	Walking		30	
19/04/2014 13:00	Food		Lunch	50	Rice
19/04/2014 10:00	Food		Breakfast	100	Bread slices
18/04/2014 18:00	Food		Dinner	2	Roti
18/04/2014 14:07	Exercise	Walking		30	
18/04/2014 13:00	Food		Lunch	50	Rice
18/04/2014 10:00	Food		Breakfast	100	Bread slices
17/04/2014 18:00	Food		Dinner	2	Roti
17/04/2014 14:07	Exercise	Walking		30	
17/04/2014 13:00	Food		Lunch	50	Rice
17/04/2014 10:00	Food		Breakfast	100	Bread slices

Appendix H: Mobile Apps Review

Review of Mobile Apps (Author)

18/10/20

Date 14

Index	App	cost	iPhone/Android	Data Export	Data formats	Data attributes (Activity)	Remarks	Notes	Has Exproted data
1	dbees Diabetes	free	Both	mulitiple format	CSV,PDF, xlsx	Meal,Glicemy,Pressure,Physical Activity,Weight,Note,Alarm	food, exercise,		Y
2	onTrack	free	Android	mulitiple format	HTML, XML(backup)	Glucose, Food, Exercise, Medication, Weight, Blood Pressure, Pulse, HbAlc	add/edit new categories, track blood glucose, hemoglobin A1c, food, weight		Y
3	Diabetes dieta	free	Android	-	-	-	Just a linking to other website to get ebook, article or video..		
4	Diabetes Diet	Free	Android	-	-	-	It's a recipe app that provides dozens of recipes		
5	Diabetes Info ++		did not find from both	-	-	-	-		
6	Diagnosis and management	Free	Both	-	-	-	Reference guide on the diagnosis, classification, and management of multiple sclerosis (MS), concisely presented for use at the point of care.		
7	gestational diabetes	$ 5.99 iphone $2.99 Android	Both	-	-	-	Quick Reference guide for the diagnosis and management of Gestational Diabetes		

8	Gestational Diabetes Management	$3.69 NZ	Android			Gluose, Food, exercise, calories ,fetal movements, medicines	not sure the export report format		
9	The Essential Guide to living well with diabetes	$3.99	Iphone				Its about understanding and managing Type 1 and Type 2 diabetes and the associated complications that come with them		
10	The Journals of the American Diabetes Association	Free	Iphone	-	-	-	Access to full-text articles for users with personal or institutional subscriptions to Diabetes, Diabetes Care, Diabetes Spectrum, or Clinical Diabetes.		
11	Gestational Diabetes Diet	Free	Android	-	-	-	Video, Artcles about a very fast diet.		
12	My Meal Mate	Free	Both		full databaseSQLite		Database can be opened in SQLite. A set of tables are available and need some interface built to display data		Y
13	Welldoc Diabetes Manager	free	Iphone				Available through health provider or employer, data stored securely in the cloud and can integrate with EMR		
14	Glucose Buddy	free	both		CSV		BG, carbs, insulin dosage, activities, weight	only export " Weight and Blood Pressure" data	Y
15	Diabetes Plus	free	Android	dropbox, doctor, email	PDF		BG, carbs, insulin dosage, activities, weight		Y

16	Glucose Meter	NZ$3.22	Android	data can synchronisation with Google Health			Track HbA1C, Food, Weight, Exercise, Medication, Blood Pressure, Pulse, earlier sync Google Health		
17	Diabetes Pharma	NZ3.70 Android $2.99 Iphone	Both				Type 2, insulin dosage,		Y
18	diabetes recorder	NZ$2.83	Android	make PDF	pdf	Blood Glucose, HaAlc, Weight, Blood Pressure, Insulin	manage blood glucose levels every day		
19	WaveSense Diabetes Manager	free	iPhone				Blood glucose, carbohydrate, insulin doses, activity. Graphs the data and provides ability to email reports		
20	LogFrog	free available	iPhone		Excel spreadsheet		Blood sugar, carbs, insulin, exercise, A1c		Y
21	GoMeals	Free	Both				Blood glucose, calories, carbs, activity and comes with an integrated food database	is not available in NZ	
22	Cals & Macros FREE	Free	Both		csv, html		Calculate your caloric and macronutrient requirements and track your daily food intake		Y
23	Blood Glucose	Free	Android	Multiple format	html		Basic blood sugar tracking by type of event (before breakfast, before dinner, after lunch, etc.)		Y
24	myfitnesspal	Free	Both	Synchronise data onto server	online report		Largest food database of any Android calorie counter, food and exercise entry		

25	My Diet Journal	Free	Android	Multiple format	plain text email	Exercise, meals, Diary	To keep track of what and when you eat, drink, and any supplements you take. Keep your exercise log as well as any statistics you want to track, such as your weight, BMI, Percent Body Fat, or blood pressure.		
26	Doctor Diet diary	Free	Both	Multiple format	PDF, csv	meal, symptoms	track diet and symptoms together		Y
27	A fitness pal	Free	Both	synchronize data to server		server is not working currently			
28	MynetDiary	Free, but need to register paid membership	Both	synchronize data to server			Quickest **food and exercise** tracking		
29	Food Diary	$1.25	Android		csv, xls				
30	mysymtoms Food Diary	$4.99	Android		HTML				
31	Diabetes Glucose Diary	Free	Android		csv, html				
32	onTrack	Free	Android		HTML, CSV, XML	Blood glucose, exercise, food, weight	add/edit new categories, track blood glucose, haemoglobin A1c, food, weight		Y
33	dbees Diabetes	Free			CSV, XML	food, exercise			

Review of Apps for Monitoring Food Intake and Exercise (Ingrid Hickman and Brooke Elsworthy, Princess Alexandra Hospital, November 2012.)

Monitoring healthy lifestyles

Apps to help you keep track of your food and exercise routine

App	Rating*	Exercise tracking	Food tracking	Social Networks	Compatibility	Cost	Barcode scanner**	Pros	Cons
My Fitness Pal	5/5 (376 public reviews)	✓	✓	✓	• Android • iPhone, iPad & iPod	Free	✓	• No internet connection required • Syncs with your computer	• Not available for Blackberry
My Net Diary Calorie Counter	5/5 (20 public reviews)	✓	✓	✓	• Android • Blackberry • iPhone, iPad & iPod	Free 'Pro' version $4.49 US	✓	• Gives personalised nutrition and motivation feedback daily	• Cost associated with upgrade
Livestrong Calorie Tracker	3.5/5 (6 public reviews)	✓	✓	✓	• Android • Blackberry • iPhone, iPad & iPod	Free Upgrade $2.99 US	x	• Reminds you to record if you forget	• Pounds instead of kilograms in initial configuration
Daily Burn Tracker	3.5/5 (13 public reviews)	✓	✓	✓	• Android • Blackberry • iPhone, iPad & iPod	Free	✓	• No internet connection required	• Measures height in feet and inches only
Easy Diet Diary	4.5/5 (295 public reviews)	Coming soon	✓	✓	• iPhone, iPad & iPod	Free	✓	• Can send food diary away to be analysed by a professional	• Not available for android
Fitocracy	5/5 (41 public reviews)	✓	x	✓	• Android • Blackberry • iPhone, iPad & iPod	Free	x	• Provides motivating comments	• Does not track food
Ready, Set, Run!	2.5/5 (11 public reviews)	yes	x	x	• iPhone, iPad & iPod	Free	x	• Find the best program for you by taking the running health check	• No community interaction available • Does not track food

*The rating and number of public reviews will change over time. Correct as of November 2012.

**Barcode scanner is only available with compatible devices (needs a camera)

Supporting healthy habits

Information to help you make healthier food choices and find easy exercises

App	Rating*	Exercise	Food	Social Networks	Compatibility	Cost	Pros	Cons
Food Switch	4.5/5 (29 public reviews)	x	✓	✓	• Android • iPhone, iPod & iPad	Free	• Barcode Scanner • Red / Amber / Green system to identify healthy foods	• Not available with Blackberry
Weight Watchers	3/5 (40 public reviews)	x	✓	✓	• Android • Blackberry • iPhone, iPod & iPad	Free	• ProPoints, health news • Recipes, cheat sheets • Shopping list	• Must be a current subscriber to access all the weight-loss tools
Jenny Craig - Dining Out Guide	2.5/5 (9 public reviews)	x	✓	✓	• Android • iPhone, iPod & iPad	Free	• Quizzes & tips • Animated visual portion guide • Nutrient profiles listed	• Not available with Blackberry
Calorie King	4/5 (32 public reviews)	x	✓	x	• Android • Blackberry • iPhone, iPod & iPad	Free	• Show specific nutrient profile of foods • Compare foods for healthier choices	• No community interaction available
Spark Recipes	2.5/5 (384 public reviews)	x	✓	x	• Android • Blackberry • iPhone, iPod & iPad	Free	• Accommodates dietary needs • Provides healthy recipes • Online videos from Chef	• No community interaction available
Daily Leg Workout	4.5/5 (36 public reviews)	Yes	x	x	• Android • iPhone, iPod & iPad	Free	• Provides quick and easy routines • Video demonstrating exercises	• No community interaction available • Not available for Blackberry
Body Fitness	4.5/5 (50 public reviews)	Yes	x	x	• Android • iPhone, iPod & iPad	Free	• Choose your level of difficulty • In-app trainer voice	• No community interaction available • Not available for Blackberry

*The rating and number of public reviews will change over time. Correct as of November 2012.

Review of apps for monitoring food intake and exercise by Ingrid Hickman and Brooke Elsworthy, Princess Alexandra Hospital, November 2012

Attachment https://www.dropbox.com/s/0z3gxkmyeadfoeh/Smart%20phone%20Apps%20Table.doc

Appendix I: Review Data Analysis

Prototype Review 1 (INT2, TAP1)

Participant	Q#	comments	Themes	Category		
				Positive	Negative	suggestion
P1	1	Yes, It is including pretty much everything that you want to know about (BG, food diary, exercise)	covers all required data	covers main functionality		
dietician		appropriate data				
		I want to know everything they are eating	all food details			
		What the carbohydrate amount is important, also accessing them for nutrient adequacy	Carbohydrate and nutrient adequacy			
	narrow columns	Full nutrition assessment need to be done with dietician				
		App data could help with recall				
		Patients should have knowledge what they are eating and record it correctly in app				
	self learning to manage	Some can. Some are definitely able to do that				

	2	Beneficial to clinicians		Beneficial to clinicians		
		Patient still have to put all the data into their mobile app	Data entry by patient could be challenging with limited knowledge	useful if efficiently entered by patient	challenging to patient to enter data	
	3	I think so	Agrees combines Heterogeneous data	covers main functionality		
		It comes to how easy it is for different apps as they have different interface design	App choice given to patient	app choice		
		Lot of people use different apps, whether food diary is compatible.				
		Calories will not tell you what you have eaten. Need to choose apps which are usable	usable apps, calories not sufficient	calories not enough		
		My patients use 'Myfitnesspal' and share their data with me through email. It has NZ food database. Your mobile phone can scan the barcode of food and the details about the food.	App with food database			
		Apps review is published by DHB dietician group				
		You get the calories, carbohydrate breakdown, protein and fat	carbohydrate, protein, fat			
		Nutrients come directly got from food database	nutrients from food database			
		I am pretty sure it is Excel file and could be wrong in saying that				
	4	Not sure if it is total amount they are eating or the amount of grams of the carbohydrate				

		It would be even better cups reported and grams of carbohydrate.				
		Rice portion might be 100 grams but the actual carbohydrate portion of the rice might be different	cup measurement preferred			
		Myfitness Pal does that	App such as Fitness Pal can calculate grams of carbohydrate			
		Graphs to show the trends date on top of each other.	Useful graphs			
		Glucose readings across the day in a graph and bar chart with carbohydrate intake				
		particularly insulin dosages from there as well				
		Smartlog has glucose readings and insulin readings. Food is missing.				
		Diascend that exactly of what I am thinking of			comparison with Diascend, Type 1 portal	
		Diascend has glucose, insulin and carbohydrate fed in manually				
	5	Very useful. More useful if integrated as a graph.				
	6	Easy and straight forward	easy			
		I don't think it will be too difficult just like anything and just learn and then it will be second nature				
		Hardest thing will be patients putting the data in	patient should feed in appropriate data			
		Fitness Pal has got NZ food and internationally well used				

Participant	Q#	comments	Themes	Category		
P2 dietician				Positive	Negative	suggestion
	1	I can see people's pattern of their eating and timings as well	pattern of eating and BG			
		Instead of all looking at it separately you can see in one view everything	combined			
		This would give a lot of information about their diet for midwives or dietician or doctor for making some decisions from				
	2	Lot of the patients are using technology and they often ask for app for recommendation	Technology driven by patient			
		We are still very paper based.				
	3 , 4	Visually hard to read at the moment. It is somewhere to start from and drag that information to one place.	Optimistic			
		GDM patients are on medication and insulin, that's the type of patients we are getting now				
		Do not need all the times (hour wise) and they would free up space in the report				
		Most of our ladies eat pretty repetitively				
		Though the report is compact all sorts of things you can see				
		that they are eating before the test or not and tested two hours				

		You notice frequency and when people are doing something different which is part of the learning and teaching we give a lot of information	Frequency of food			
	5	Useful, I see the patients once, and could just an eye over the report thereafter even if I don't have an appointment	check patient data on system without appointment			
		Share data within the team and I do not have to ask the midwife for the patient file	Share data in team			
	6	I am not good at computer. I am good at repetitive task.	Learn			
		Once get used to it, trialled with real patient data, get there eventually				
		For start patient may not be good at it.				
		currently some patients email a spreadsheet about their food diary				

Participant	**Q#**	**comments**	**Themes**	**Category**		
				Positive	**Negative**	**suggestion**

P3	1	Wellness data is representative	Required data represented			
obstetrician		Text in narrow column breaking into multiple lines	Column space limitation is not easy to read		usability	
		Easy to compare food diary, exercise, isulin dosage in comparison with BG	Time in hours as heading across is ideal to read	good layout date and time data		
	2	Prototype solves to bring together data	Main functionality solved	combining data well		
		Time consuming to import data	time consuming		concern about data import	
	3	Combines data from various sources	Main functionality solved	combining data well		
		Challenging if all details are entered, difficult to fit in narrow columns	Column space limitation is not easy to read		usability	
		Carbohydrate alone is not enough	Detailed food diary required			Apps with food details with portion size required
	4	Appropriate report useful to clinician generated	Main functionality solved			
		Text in different colours suggested normal range, hyper, hypo	Colour text suggestion			usability
		Not sure what colours best represent the normal and abnormal readings	Colour represenation not sure			usability
		Hover mouse for more details about food	Decluter screen			usability
	5	Can actually use it	clinician ready to use	useful		

		Perception of patient is important	Patient perception unknown		unknown about patient's perception	
	6	Easy. Should not be difficult as it is work related	Work related	work related		

Participant	Q#	comments	Themes	Category		
P4 Ostetrician				**Positive**	**Negative**	**suggestion**
	1	I think so				
		Reflects physical activity and food diary together with treatment and dosage and sugar level	combines data			
	2	self awareness help women to keep their sugar and their weight under control	self aware			
	3	all shown in the same spreadsheet by actual date.				
		Easy to read				
	4	Report give some feedback	Mouse hover for details	Usability		
		Mouse hover to get more details about exercise and food.				
	5	very useful. Currently cannot do lot of work before you see the next lady				
		Women forget to bring their data.				

		cannot recall what they have eaten.				
		gives me the background				
		Clinician can add comments				
	6	Easy and self explanatory	easy			
		I might have little problem in the beginning about navigation. How to move forward when the button on screen says'Back'				
		Once you have learnt the navigation and menu it won't be a problem				
Participant	Q#	comments	Themes	Category		
P5 midwife				Positive	Negative	suggestion
	1	BG is important, insulin not so				
		Type 1 patients know how to manage and are motivated.				
		GDM patients are different	different to Type 1			
		Currently use Excel sheet to feed what they have eaten	electronically track and email			
		BG readings are fudged to please midwife.				
	2	Yes				
	3	Short names used in my notes. Example NR for Nova Rapid	short name			
	4	That's what we look for the gluocse reading, food and exercise				
		I think woul dbe brilliant				
		Carbs is important				

	5	challenging. Everything is new and get used to it.	Challenging to start with			
		Preseumably you could print it out if you want to				
		Share it in the team				
		Might use it				
	6	I don't know if it is easy				

Participant	Q#	Comments	Themes	Category		
Physician				Positive	Negative	suggestion
	1	Give us information at the right time and it integrates wellness app data with BG, which is often a missing link	integrates which is otherwise isolated			
	2	Data entered retrospectively				
		Prototype useful as women forget what they have eaten, do not keep log book	helps with food recall			
	3	Actually look better horizontally way of measuring down several days	Horizontal presentation			
	4	We can share data about patient in our team	share in team			
		When a woman come to my room, I don't have to find a midwife what she said to her and we don't waste time.				
		We can all log into our computers and access the information about the patient whom we want to see.				

	5	time saving will benefit us	time sharing			
		sharing information	sharing information			
		patients can be managed remotely	remotely manage patient			
		paper diaries are not accurate. Bad readings are manipulated	accurate data			
		10% GDM, 1% Type 1, 2 % Type 2.				
		Type 1 are funded to have a portal to share with clinicians				
		Probably close to 80% of GDM go to develop diabetes, would be good they learn to use wellness app				
	6	easy to use, with very little training	easy			

Prototype Review 2 (INT3, TAP2)

F Feedback TAP2	P	R
P1	Once you have start using it more frequently, it is obviously much easier just like anything. I think on the second task I just needed to remind myself about I was about to look and needed to be able to enter or preview the second lot of datayou have entered and had to go 'back' button.	
	Yea couldn't locate to find that data.	Maybe the woman come with their glucose meter, email the mobile app data

	The other thing is about importing data so we went looking for glucose readings from Carensen meter and remembering that to do that I need to go 'Back' to that screen where we could locate. That's fine, you could get to know and if could design better.	Avoid going to a different screen and an option was available on current screen.
usefulness	The combined report with food, exercise, BG together that is really useful. That is all the information in one place. One screen, several days as suppose to many papers and it has the food diary and it has the matching it to other sort of paper is daunting like glucose readings.	We are looking for free apps which women can afford. MyFitnessPal is free but have issues extracting data. We can share the information from their website to a friend. But if we want to put it in a new system like ours it can't. I tried mySugr, that is flexible I can export data to an email in different format like CSV, XML. It is easy to integrate inthis prototype.
	Obviously as the dietician is looking at the food part of it, so they could know if the food contain protein and other nutrients.	mySugr has carbs details required and no other details about
	Yeah	so name of food should be enough
	It is nice that it is incorporated with food database, so it could be of some value. But the amount of time we get to be with the women there probably not have much time.	
	We could not sit and look at each item. If I am looking at calcium and where they are getting it and make a rough estimation	
	So it is not imperative that all the nutrient values are recorded in that.	
	Yeah	Would you be happy if you look for one or two apps because MyFitnessPal

	If that is then it would make it easy.	MyFitnessPal has some main nutrients like protien, mySugr has carbohydrates, calories. This can be shared and those nutrients were extracted straight away from a reliable source.
	Really it just coming down to see the combined report	any other things you are looking would be useful
	Probably I wouldn't be looking for that amount of time. Probably just interested in the last two/three weeks. Something like that. Because oftem times when I see them they have some input from midwives about the changes and two weeks from now testing what they are doing now is good. So it is not very helpful to look at that months ago.	If it is longer time you can see two months together
		Also you had to go back and change the dates because my data was old. But when you are working with patients it will be current data. You don't have to change the date too far and as current date is seen on the screen. It is just clicking the button it will be much faster.
	Atleast you know it is doing something.	Combined report on screen is slow in generating

	(seeing the pdf) This is much nicer to look at. In terms of seeing, you can see what exactly the readings when the readings were taken and what has been eaten with different meals on different days. It is much easier to see in pdf than the first report that was generated (on screen).	pdf file much easier to read
P2	I think it is a good teaching tool. And even for the patient to see what carbohydrates adds up to for the servings.	
	And then here is the combined report for the dates we put in. So now I can look at the blood sugars and the food and the exercise all combined. And you can see it very easily the patient day really. Very good. And also you can see the test that are high as they have been highlighted as red.	
P3	I have clicked one readings and not sure what LOINC readings are?	
	Would be helpful not so much to the obstetrician.	
	Maybe useful to patients because they get it.	
	At the moment I wouldn't go through someone's food diary.	
	For the dietician or the midwife it would be different.	
	I think it is easy. Initial some problems but should be ok.	
	It is good product.	
	Hard to read the update on the blue background.	usability interface button
P6	It is easy to look at and highlighted sugars are good.	
	It looks like it finishes there (on screen seeing part of the data). So it is not a very good.	
	I can see (while scrolling)	
	It is pretty user friendly.	
P7	Lot of them I do see, they send me their full food diary. But they don't have to do that.	

	Because they got GD they don't have to write down what they have been eating. They only need to write down only if they have been eating only for that time what they have had high blood sugars. If their sugars are normal we don't ask them to write down.	
	There is quite a lot of them to get there and there is short amount of time for them to learn how to manage gestational diabetes.	self-management
		carbohydrate, BG, insulin adjustment
	If I can do that for them, I know my patients would find it helpful. To know how many carbohydrate. It may help quantify how much insulin to take or adjust to. If they know they are having less amount of many grams of carbohydrate, then they need x amount of insulin.	
P8	GDM patients have the diabetes condition for short time, many were pre-diabetic and unaware of it	
	Carbohydrate counting is not recommended for GDM	
	Type 1 are educated and are aware of manage with carb counting	
	Most women dietician for 1 hour session in their whole pregnancy	
	The condition is managed by Metformin or insulin or a combination of the two.	
	Mild cases managed on diet	
	Women with GDM identified between 28 and 36 weeks	
	After 36 weeks the damage is done cannot do anything	
	The main aim is to manage baby's growth	
	Baby should grow exponentially	
	All women do not have internet, Wifi at home or smart phones	
	It depends on the culture	
	Chinese women may own technology gadgets, language is a barrier while educating them.	

	Pacific women may not own smart phones.	
	Indian women may be pre-diabetic	
	Readings are changed to please midwives. Hence when actual readings from meter are downloaded by midwives in the clinic, the report with each day readings are printed.	
	3M is a scanning service. All patient notes example hand written ones are scanned and saved.	
	Conceto software (EHR) used in hospital has formal lab test results, doc letters.	
	The issue with patients using apps is about accuracy and telling the truth.	
	The other issue is communication - second language English speakers	
	Patient do not like having their health records saved specially when they have high readings.	
	When asked to record in a template the four readings patient try multiple times to get good readings to record.	
	It is evident when midwives downloaded them in the clinic. The readings do not match the manual recordings in the template.	We could continue the pracitce of extracting BG readings from Caresens by clinicians. The data file is stored in the prototype. The prototype is not integrated with hospital and clinicinas are aware that food diary has come from patients. When women see the midwives the food diary is verified and

		checked for accuracy and any missing data by midwife.
	This has huge implications as insulin dosage is adjusted with BG readings	
	Yes it will be helpul. But we do not have the time to check each food item. We recommend women to record food only hen when the sugar is high	
	Some are good in record keeping.	
	They are taught to adjust insulin dosage too	
	If they have a big meal	
	Some cannot make that decision.	
P9	Most devices track calories and carbs and not food details. It is difficult for women with GDM to calculate them manually and put these details. Dietician, physician and midwives want more details for them assess the women's condition on a regular basis	FD details
	For me this screen is very hard to read because it is round the wrong way.	column display order insulin/BG
	because I want the insulin before the blood glucose	
	cause and effect easily	
	Most woman don't mind doing email. Most woman are on email so emailing blood/sugars	adoption by young women

	Yea I don't know, I think probably 70% of people don't mind, they don't mind, you know, to be honest	
	And if you offer them an app I am sure the young ones especially would be……	
	Every culture has the feed the woman you know, feed the woman feed the woman you can eat whatever you like and you gain 20 kilos.	weight watch
PW1	used Fintesspal, step counter	
	(I would) absolutely use it and comfortable to share the data with clinician if suitable apps are available.	
PW2	The data is well presented and available for testing prototype appropriately. Yes, I feel that it is appropriate and sufficient for representing wellness data from mobile apps and glucose readings.	
	Yes, the prototype does address the issues identified by clinicians in supporting their patients' self-management of GDM.	
	Very well, I see that this can be done via a report which would be quite useful.	
	Yes, by combining data from various data sources the report that is generated would be very useful to clinicians	
	In my opinion the perceived usefulness of the prototype is very appropriate. In the sense that data is available for clinicians on their fingertips. It can be entered into the system directly, taking out the need for unnecessary paperwork which can be time consuming. Also once data is available it can be analysed in various ways for the betterment of patients suffering from gestational diabetes.	

	I think I have kind of answered this in the previous question however, reiterate that once data is available for the various patients – it is very easy to evaluate and use for the betterment of the patients e.g identify trends like if the sugar level is high after consuming a certain type of food. If patient becomes aware of this, they will be better able to manage their diet to avoid this.	