Early Detection and Self-Management of Long-Term Conditions using Wearable Technologies

An Application of Pre-diabetes Detection and Self-management of Diabetes Type – II

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List of Abbreviations

ANFIS	Adaptive-Neuro Fuzzy Inference System
API	Application Programming Interface
AI	Artificial Intelligence
BR	Breathing Rate
B. Glu.	Blood Glucose
BP	Blood Pressure
BT	Bluetooth
CDSS	Clinical Decision Support System
Dia	Diastolic Blood Pressure
GUI	Graphical User Interface
EHR	Electronic Health Record
HMS	Health Monitoring System
HR	Heart Rate
ISR	Information Science Research
I/O	Input/Output
LTCs	Long-Term Conditions
ML	Machine Learning
MKB	Medical Knowledge-Base
MHMS	Mobile Health Monitoring System

PR	Pulse Rate
PMS	Patient Monitoring System
PPG	Photoplethysmography
RHMS	Remote Health Monitoring System
RR	Respiratory Rate
SD	Standard Deviation
Venti	Ventilation
WMS	Wearable Monitoring System

Statement of Originality

‘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 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. It contains results of my investigation, except where otherwise stated. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.’

I understand that my thesis may be made electronically available to the public.

Signed: 

Date: 19 November 2017

Scholarships and Partnerships

Scholarships

- This project has been supported by the Precision Driven Health Summer Research Scholarship 2016/2017 funding.

- Tuition fees for this research project was supported by the Department of IT and Software Engineering, Faculty of Design and Creative Technologies, Auckland University of Technology.

Partnerships

- The research team has established a working partnership with the clinicians at Auckland District Health Board for current and future clinical enhancements to this research.

- We have partnered with Orion Health to utilise the electronic health record software platform currently used in majority of the New Zealand District Health Boards.

- This project partnered and leveraged the real-time data collection capabilities using the advanced wearable monitoring vest developed by Hexoskin, Montreal, Canada – a wearable body metrics company.

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Abstract

Worldwide spending on the long-term or chronic care conditions is increasing to a point that requires immediate interventions and advancements to reduce the burden of the healthcare cost. Managing people with long-term conditions is a global challenge and it is mostly driven by the shifts in demographics and disease status. Today, long-term conditions engage by far the largest and growing share of healthcare budgets globally.

From the literature, it is evident that an immediate intervention is required to slow down the epidemic of long-term conditions. The three time-based priorities for the long-term conditions are; (1) self-management of long-term conditions using advanced technology is identified as one of the immediate recommended actions. (2) In the medium-term, a robust mechanism of early detection and prediction of pre-long-term conditions is required to delay the onset of long-term condition; and (3) as a long-term strategy, in-depth research and investigations are required to reduce and make a positive impact by taking a holistic approach and multiple domain-intervention such as diet, education, cultural, physical, lifestyle, environmental, economic and more.

This research is focused on one of the immediate approaches required to tackle long-term conditions - involving early detection and self-management of pre-long-term condition of diabetes using advanced technology and tools. This study deals with the three important areas of long-term conditions: wearable/remote and real-time monitoring; interpreting and detection for pre-diabetes and self-management of diabetes as a long-term condition.

This research collected heart rate, heart rate variability, breathing rate, breathing volume, activity (steps, cadence and calories), using the advanced body wearable vest/sensors in real-time, and combined (the collected data) with manually collected blood glucose, height, weight, age and sex for individualised trend, baseline values and early detection. The collected data was fed through the clinical knowledge-base to set the baseline values using the existing interventions, guidelines and protocols. The artificial intelligence model using adaptive-neuro fuzzy interference system was developed to early detect pre-long-term conditions, individualised monitoring and self-management of diabetes. The performance of the system was validated through off-line tests with a high-level of agreement between the system and the physicians.

CHAPTER 1 Introduction

1.1 Background

1.1.1 Long-Term Conditions (LTCs)

Long-term conditions (LTCs) are defined as any ongoing, long-term or recurring conditions that can have a significant impact on the person's life [1]. LTCs have become a priority because of the changing burden of disease and the increasing prevalence of conditions such as diabetes, asthma, arthritis and heart disease. Individuals with LTCs are more likely to frequently visit their general practitioner (GP), get admitted to hospital, and stay in hospital for longer compared to people without LTCs. LTC effected individuals are also increasingly involved in managing their conditions with the support of the inpatient (acute) care team, outpatient services and community care [2].

The current practice of reactive, unplanned and episodic approach to care, particularly for those with complex conditions and high intensity needs, is simply inefficient and unsuccessful [3]. The services are there to help them when their condition reaches a crisis point, but often fail to provide the on-going, co-ordinated support needed to prevent such crises from happening in the first place [1-4]. LTCs are now a major challenge for the New Zealand health system. Two thirds of New Zealand adults have been diagnosed with at least one long-term condition and these long-term conditions are a leading driver of health inequalities [5]. Along with the detrimental health outcomes from LTCs, the individual, their family/whānau, the community and the health sector experience considerable financial and social costs. The major risk factors also place a significant economic burden on New Zealand society [6, 7]. This research

focuses on technology enabled self-management of one such LTC – Type II Diabetes (including detection of prediabetes).

1.1.2 Self-management of Diabetes

Diabetes is diagnosed when a person has excess glucose (sugar) in the blood. This happens because the pancreas cannot produce enough insulin. Glucose is an essential source of energy for the brain as well as a source of energy for the body. Glucose in the bloodstream comes from carbohydrate foods high in carbohydrates. These carbohydrates covert into glucose after consumption. The liver stores and produces glucose depending on the body's need. The stored glucose in the liver is released for a later time when the body needs it [8, 9].

Diabetes is the result of the body not being able to create sufficient insulin to keep blood glucose levels in the normal range. It cannot be cured, but it can be controlled, and you can lead a full and active life with self-management of this condition. There are three types of diabetes – Type 1, Type 2 and Diabetes of pregnancy (gestational diabetes) [10].

Prediabetes means a person's blood glucose (sugar) level is higher than normal, but not high enough (yet) to be diagnosed with type 2 diabetes. People with prediabetes are on the road to develop type 2 diabetes and are also at increased risk for serious health problems such as stroke and heart disease [11]. Prediabetes often can be reversed through lifestyle changes such as increased physical activity and weight loss. The earlier people are diagnosed/detected with prediabetes, the more likely that they can reverse it and prevent type 2 diabetes [11].

An estimated 670,000 New Zealanders could be unwittingly living with pre-diabetes, with a further 267,000 already suffering from type 1 or type 2 diabetes [12, 13]. The

prevalence of diabetes has been rapidly rising worldwide. Diabetes can lead to a number of complications such as retinopathy, nephropathy, and macrovascular diseases, all of which decrease patient's quality of life and increase healthcare expenditures. To prevent and minimize complications, it is important to optimise glycaemic control and the basis of glycaemic control is diet and exercise therapy [14]. However, it is difficult for patients to change their lifestyles and maintain desirable behaviour and good glycaemic control. In a study, adherence to diet and physical activity were found to be lower than adherence to medication regimens. As a result, only 36% of patients who received inpatient diabetes education could maintain improvement of haemoglobin A1c (HbA1c) levels for 2 years [15].

With the rapid advance of information and communication technology (ICT), diabetes management is expected to be an area in which the use of the internet and mobile devices could be beneficial [16]. These technologies can overcome time and location barriers through real-time and remote monitoring of data such as vital signs, activity, blood glucose levels at home, and can facilitate communication between patients and healthcare providers. Many ICT-based self-management tools such as mobile applications have been developed for patients with diabetes and have improved patients' physical activity levels and glycaemic control [17].

Understanding patients' need for ICT-based self-management tools is essential for disseminating use of them by patients with LTCs (diabetes)—and that need appears to be increasing around the world [8, 16, 17].

1.2 Technology Assisted Self-management of Long-Term Conditions

There are international and national initiatives and protocols available to promote the best-practice approaches that will lead to improved services and support for people

with LTCs. The specific aims being to produce better health outcomes and quality of life, slow disease progression and reduce disability. This in turn will result in improved quality of life, helping to relieve discomfort and stress and reduce the need for hospital admission [18].

Supporting people with LTCs to manage their conditions becomes more important as the population ages and people are increasingly managing more than one condition. Self-management support can be viewed in two ways: as a portfolio of techniques/tools that help patients choose healthy behaviours [19] and as a fundamental transformation of the patient–caregiver relationship into a collaborative partnership [20]. This research focuses on the techniques and tools that support the self-management of LTC(s) and early detection of prediabetes [19-21].

As per the Ministry of Health, New Zealand [22], any self-management support must:

- Be appropriate for the person with the LTC and their family/whānau
- Be developed in partnership with the person with the LTC
- Focus on reducing inequities in health

People with LTCs have better lives when they are supported to take care for their conditions themselves [19, 23]. If people have a clear understanding of their condition and what they can do, they are more likely to take control themselves [19]. One of the priorities from participants in the 'Your health, your care, your say' [24] consultation was for services based around their needs which help them take control of their health, support their well-being and enabling to lead an independent and fulfilling life [23].

There are three themes identified from the literature for an effective LTC management [19-23]:

- Enabling and supporting health, independence and well-being
- Rapid and conventional access to high quality, cost effective care
- Enabling people more in control of their own health via self-management

Self-management lies at the heart of enabling people in control and plays a key role in improving the management of LTCs. Self-management is "led, owned and done by people themselves" [19-23].

The Long Term Conditions Alliance (now Health and Social Care Alliance Scotland) has identified several key stages where people need support to self-manage their LTCs [25]. Table 1.2-1 summarises these stages, along with the issues for and impact of self-management.

Table 1.2-1 Key stages of support for self-management of LTCs

Key stage	Issues for self-management	Impact of self-management
Diagnosis	By this point, symptoms may already have seriously affected people's life and ability to manage. People feel challenged about their place in the world and the reality of their situation.	Helps people come to terms with their diagnosis. Is a key way of helping people to reconnect with themselves and others. Helps people make better decisions about treatment options.
Living for today	People need information and skills to maintain optimum wellbeing. People are at serious risk of social exclusion.	Supports people to navigate an often difficult journey. Challenges social exclusion by helping build bridges back to society and social roles.
Progression	People experience a cycle of illness and wellbeing as their conditions fluctuate.	Helps to avoid flare-ups or minimise their extent. Enables people to recognise early

	Symptoms become increasingly severe. People struggle to get additional support during flare-ups. They may lose some capacity.	warning signs and react effectively. Tackles psychological impact of flare-ups or progression. Supports changing needs.
Transitions	People move between services, sometimes to different levels/types of support. They are dealing with multiple needs/conditions and therefore a range of services. It is often a stressful time, which can have serious impact, including on person's conditions.	Supports people to manage transition processes. Maintains focus on people's needs so that services are organised around these. Provides people with control at a time when this can be undermined.
End of life	This difficult time involves complex challenges. Death may be premature. People may have to cope with symptoms of the condition along with the challenges of end of life.	Supports people to meet a range of challenges and maintain control. Addresses broader needs e.g., emotional, family and lifestyle.

We aim to monitor (in real-time) the vital signs, activity of daily life, blood glucose and demographics information for point in time capture of key insights as well as trend over time to understand the in-depth health measure. In particular, this research aims to provide early detection/precondition and self-management of a long-term condition – prediabetes and diabetes Type II [25].

1.3 Motivation

This research is motivated by the worldwide rising increase in LTCs, increase in healthcare spending and availability of advanced technologies and tools to address those current healthcare challenges via self-management of diabetes. Key motivating factors are discussed below:

1.3.1 World-wide Increase in the LTCs

In recent years, there is an ever-growing need for a sustainable health eco-system to manage not only acute care but also chronic care including LTCs. A LTC is defined as the health condition that can be managed but often cannot be cured and common examples include diabetes, heart disease, stroke, cancer and arthritis [26]. The number of people with LTCs is increasing, and the majority of people aged over 65 may now have multiple LTCs [27]. The numbers of people with multiple LTCs is likely to continue to increase with the ageing of the population. A couple of major contributing factors are unhealthy lifestyles, along with the impact of the economic downturn on mental and physical health [28]. One of the emerging mechanisms is the prevention or early-detection of LTC by following the health trends using wearable monitoring systems to make early interventions [10, 14-21, 23].

1.3.2 Healthcare Spending on LTCs

Recent estimates on the amount spent annually on long-term care services in the US are between $210.9 billion and $306 billion. For the UK, nearly 29% of the total population now lives with a LTC, while as much as 80% of the healthcare budget is spent on the management of chronic diseases [29, 30]. Around 15 million people in England have one or more LTCs. The number of people with multiple LTCs is predicted to rise by a third over the next ten years and accounted for 50% of the GP appointments and 70% of all inpatient bed days [31] and around 70% of the total health budget is spent on the care of people with LTCs [32]. In Canada, 10.7% of the total healthcare spending, expected to reach $219.1 billion or $6105 per Canadian as of 2015 [33]. New Zealand's total health and disability spending is about $18 billion, or about 9.5 percent of gross domestic product (GDP) and recent New Zealand health strategy for 2020 focuses on the long-term and chronic condition management, treatment,

prevention and early detection [34]. Table 1.3-1 shows the healthcare spending of the organisation for economic co-operation and development (OECD) countries, in terms of per-person spending, public, private and GDP [35].

Table 1.3-1 Healthcare spending of the organisation for economic co-operation and development (OECD) countries [35]

Country	*GDP (%)	Per-person Spending (USD)	Public (%)	Private (%)
United States	17.1	9086	48	52
France	11.6	4361	79	21
Germany	11.2	4920	76	24
Denmark	11.1	4847	84	16
Canada	10.7	4569	71	29
Japan	10.2	3713	83	17
Australia	9.4	4115	68	32
Finland	9.1	3645	75	25
United Kingdom	8.8	3364	87	13
New Zealand	9.5	2983	83	17

*gross domestic product (GDP)

1.3.3 International and National Initiatives to tackle LTC

LTCs consume vast amount of resource in New Zealand – in terms of direct health care and indirect costs on the society. Most studies estimated an annual societal costs of

more than $100 million per condition or risk factor [35, 36]. Indirect costs generally contributed between one-third and two-thirds of the total expenditure. This research project is aligned with the current NZ District Health Boards (DHBs) initiatives, Ministry of Health's (MoH) long-term strategic plans and the national health targets [37, 38]. Some of the national priorities and initiatives are:

"Diabetes is a priority long-term condition" for the New Zealand Government [39]

Addressing the increasing impact of LTCs, including diabetes, is an important task to focus on for the Government to support its vision that all ***New Zealanders live well, stay well and get well***. An estimated 257,700 New Zealanders have diabetes. In 2014, the number of people with diabetes grew by nearly 40 people per day. The high personal and social costs associated with this condition presents a serious health challenge, both now and in the future [12, 40-42]. The government is committed to supporting a sustained and systematic approach to reducing the burden of diabetes, and the associated comorbidities.

Auckland DHB [43]: LTCs are the leading cause of hospitalisations and accounts for most preventable deaths and are estimated to consume a major proportion of our health care funds. They are also a barrier to independence, participation in the workforce and in society.

Counties Manukau DHB [44]: Counties Manukau has the highest growth rate in the population aged over 64 years old in the country. Older people are more likely to have multiple LTCs and accounts for nearly 40% of the group with at least one common LTC.

Waikato DHB [45]: Midland DHB regional approach to the 'Impacts Measures of Performance' includes LTC as one of the key impact measures.

Single National Electronic Health Record: It is essential to have an individualised LTCs scale/score embedded in the individual's health record for timely prevention of LTC managed by the clinical professionals. This could be achieved by stand-alone web tool, healthcare IT systems and current GP/DHBs patient management systems.

This research is placed at the centre of the national and international initiatives looking at reducing LTC by adopting the latest and advanced tools, technologies and scientific methodologies. This will potentially lead to the growth in the wearable body sensors (including consumer health and wellness devices), machine learning model and new data sources for the future of LTC prediction [46-48].

1.4 Research Questions

There are several important areas where this study makes an original contribution by answering the below research questions:

- How individualised monitoring can benefit the individual with LTCs?
- What is the impact of using the wearable technology in self-management of LTCs?
- How advanced tools and technologies can enable early detection of LTCs?

1.5 Research Contributions

The research presented in this thesis deals with three main concepts: wearable monitoring, interpretation of collect data and early detection of prediabetes. These three concepts are interrelated and interconnected as illustrated in Figure 1.5-1.

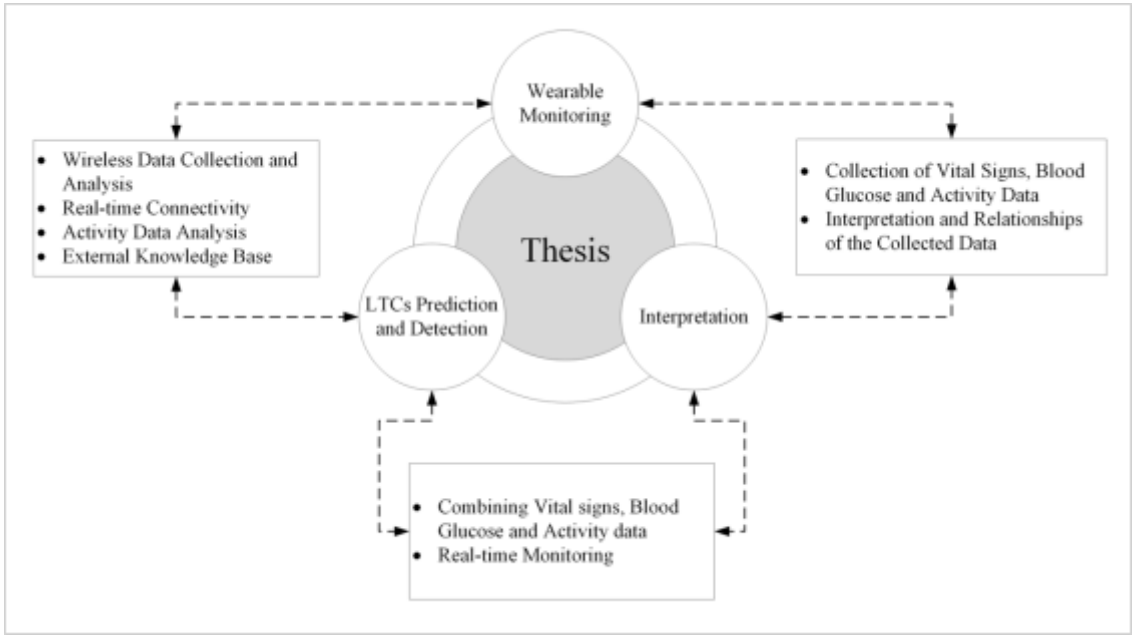

Figure 1.5-1 Scopes of the research as described in the thesis

The original contributions are summarised as follows:

- ***Individualised monitoring framework for self-management of LTC***

  This research focused on the idea that 'no two diabetics are same' and they should be treated individually. This research investigated the existing literature for the technology-led LTC interventions – *theory building.* We focused on the individualised trends and self-management using the available and existing diabetes self-management programs and methods – *relationships and evidence-based reasoning.* Finally, we designed a LTC detection model based on the

individual data trends and not the traditional threshold based outcomes – *Individualised Self-management using ICT.*

- ***Real-time data collection using wearable monitoring system***

  The major contribution documented in this thesis is the configuration and design of an integrated wearable healthcare monitoring system. The most important components required for understanding the current situation/complaint of a person are incorporated into the integrated healthcare system including physical observation, vital signs, activity data and history. The main idea behind the integrated wearable system is that the system should seamlessly integrate with other existing/available systems for a holistic approach to tackle diabetes.

- ***Development of an early LTCs (diabetes) detection model***

  The proposed system is currently capable of identifying pre-diabetic signs that may occur during a patient's life. It has been tested using the recorded data. The proposed system has achieved accuracy of 91.49%, sensitivity of 94%, specificity of 90% and predictability of 72% when compared with the interpretation by a medical expert for the same data. The evaluation of the proposed system has been carried out using Kappa analysis, which measures the agreement between the proposed system and the medical expert's interpretation. The researcher is not aware of any such system available or in use in New Zealand hospitals. The proposed system is superior to other threshold-based systems due to the fact that it uses individualised monitoring, evidence based reasoning, fuzzy templates and weighted scoring parameters for detection and interpretation of diabetes and is fully scalable to incorporate other LTCs as well.

1.6 Summary of Outcomes Achieved

- Ethics approval from the Auckland University of Technology Ethics Committee (AUTEC).
- Configurations and enhancements to the wearable (sensors) monitoring system for individualised data collection in real-time.
- Real-time data collection - This research study collected heart rate, heart rate variability, breathing rate, breathing volume, activity (steps, cadence and calories), and collected blood glucose, height, weight, age and sex manually for data analysis.
- Data analysis for early detection of long-term conditions (e.g. pre-diabetes) using existing long-term condition guidelines/protocols and early LTC detection model was designed, developed and tested.

1.7 Structure of the Thesis

This chapter presented an introduction to the LTC, diabetes as our focused LTC, motivations, challenges and original contributions of the research. The following chapters are as follows:

CHAPTER 2: Literature Review

This chapter provides an overview of the state-of-the-art wearable monitoring systems, methods of activity monitoring and diagnosis with issues and challenges. Different monitoring techniques and methods for LTCs are reviewed in order to establish the research gap and its associated research problems.

CHAPTER 3: Methodology

This chapter presents the methodology adopted in the research and discusses the approach used for theory building and observation.

CHAPTER 4: Data Collection, Analysis and Results

This chapter presents data collection process and protocols adopted. Data statistics and related information including data transmission, wireless wearable sensors used and data analysis are described. The important relationship between vital signs and activity data with demographic data is also discussed.

CHAPTER 5: Discussion

This chapter discusses the methods and results and other major aspects of this research.

CHAPTER 6: Conclusion

This chapter discusses the main conclusions with suggestions for the future work.

CHAPTER 2 Literature Review

As wearable devices, sensors and body-worn garments become smaller, cheaper, and more consumer accessible, they will be used more extensively across a wide variety of contexts. The expansion of wearable systems and personal data collection offers the potential for patient engagement in the self-management of long-term conditions and chronic diseases [49]. The rapid curve in the global adoption of the wearable monitoring systems started noticing in the last couple of decades. Some of early foundation research includes; (1) Wearable health-care system (WEALTHY) project, which targets clinical patients during rehabilitation and other high-risk patients using the fabric integrated sensors; (2) A custom-developed ubiquitous health-care (u-health-care) system consisting of custom 802.15.4-capable nodes interfaced with ECG and blood pressure sensors as well as a basic cell phone device for data display and signal feature extraction; (3) The Human++ project in The Netherlands has developed a body area network consisting of three sensor nodes and a base station; (4) The CodeBlue project developed by researchers at Harvard University; (5) The researchers from the Media Laboratory of the Massachusetts Institute of Technology (MIT) have designed LiveNet; (6) SmartVest is a wearable physiological monitoring system that consists of a vest and a variety of sensors integrated into the garment's fabric to collect several biosignals; (7-9) Three European IST FP6 programs are the MERMOTH project, MyHeart and HeartCycle, as recent examples of wearable systems/sensors for patient monitoring [50-53].

2.1 Wearable Monitoring Systems

Wearable systems/sensors and wireless medical devices are used to collect individual's personal health data [54]. The wearable monitoring applications use the advanced communication protocols and sophisticated sensors to capture the health data

continuously. The collected data is then used for processing and interpretation [54]. Wearable sensor technology seamlessly integrated into the standardised clinical data sets are a few examples of the impact and potential of wearable monitoring on wider healthcare systems especially patient monitoring, decision support, self-management of long-term and multiple conditions management [55].

The chronic and progressive nature of an individual's health condition often time-boxed and fluctuate rapidly, require a flexible monitoring model and technology that consider the timely nature and precise support [56]. Wearable monitoring applications are deployed into the community care to examine the gait, activity of daily life and data trends [57]. The increase of wearable monitoring systems will lead to huge streams of new data which will amplify the database and, therefore, complement and improve the accuracy of its predictive models [58].

Majority of wearable technology is distributed into, *biopotential sensors*, such as electrocardiography (ECG), electromyography (EMG) and electroencephalography (EEG) sensors. Secondly, *motion sensor units*, such as accelerometers and gyroscopes. Finally, *environmental sensor units* such as video cameras, vital signs monitors (such as heart rate, pulse rate and temperature) and pressure sensors [59].

Some studies suggested that the three-dimensional (3-D) printing technology may play an important role in this concept [60]. This technology has shown the potential of allowing any person equipped with a 3-D printer to fabricate their own 3D model/objects and if this technology is combined with a seamless integrated wearable sensor then this combination can produce some thoughtful outcomes for the healthcare delivery. Such innovations have potential to change the way healthcare is being

managed today and healthcare information exchange will be much more easy for any service provider to access the relevant information and provide better care [51].

2.1.1 Remote Patient Monitoring Applications

Remote monitoring applications are based on the integrated network using internet as a connectivity channel to transmit the data, including, vital signs, video data, ECG recordings, etc. to support the healthcare delivery when distance separates the clinicians and patients. Remote monitoring applications are often a combination of mobile communication-based systems and wearable monitoring technology. With its many advantages, this technology has provided innovative solutions to deliver healthcare by remotely monitoring a patient. Some of these applications are still in the development stage, and others have already been implemented in the medical environment [61-63].

An advanced wearable application has been developed using sensor's energy to communicate and transmit the data in real-time [64]. In [65], the researchers have developed a mobile ECG monitoring application backed by the RFID to transmit data continuously to the local server. The system is depended on the battery life of mobile and RFID tags. Similarly, another application, Prognosis [66], is based on the fuzzy logic, mapped to the various signs, symptoms and disorders for identification of the health conditions. Such applications are heavily depended on the specific use-case and limited in the saleability to incorporate the wider disease and conditions due to the limit of data collection using the sensors and accuracy of the wearable body sensors [67].

Such applications aim to surface key physiological parameters for real-time information viewing. The data collector application then transmits the data in the cloud for complex processing which require high computational powers. The processed data will be available on the web for viewing and an alert or warning will be pushed back to

the mobile application for timely actions. This communication poses serious security and privacy threat to the health data. Security and privacy are considered one of the most important issues and a challenge when using such applications in clinical care settings. Table 2.1-1 summaries the selected wearable systems.

Table 2.1-1 Summary of the selected studies related to the wearable monitoring applications (including LTCs)

Author and Year	System/ Application	Study Aims	Outcomes/ Findings	Platform/ Type of Sensor Used
Etemadi et al. 2016 [68]	Long-term monitoring; chronic care monitoring	To develop a low power, low cost patch for measuring activity using ECG and seismocardiogram (SCG) sensors	The developed patch measured the combined activity, environmental context, and hemodynamics, for longer than 48 hours with continuous recording	Three-channels of SCG; one-lead ECG; the pressure sensor; an average current consumption of less than 2 mA from a 3.7 V coin cell (LIR2450) battery.
Thomas et al. 2016 [69]	Non-invasive continuous blood pressure (BP) monitoring	To develop a wrist watch-based BP measurement system using ECG and photoplethysmogram.	The study recorded the average root mean square error between the measured systolic BP	A PPG sensor with both IR and red LEDs; two differential electrodes; third bias electrode; BioWatch comes with two analog front ends (AFE): the TIADS1292 for acquiring ECG signal and the TI AFE4400 for reading PPG.
Wu et al. 2015 [70]	Biofeedback system to monitor and learn from physiological signals	To develop a wearable biofeedback system for personalised emotional management using heart rate variability	The results indicated that the real-time HRV biofeedback is significantly effective in cases of negative emotion	A conductive textile material as the electrodes for ECG and breathing activity; a differential separation filter and a common signal conditioning
Xu et al. 2016 [52]	Treatment, in-community rehabilitation and	To develop a contextual online learning method for activity classification based on data captured	Real-time learning system and contextual multi-armed bandits (MAB)	Context driven activity classification and feedback; a set of sensors with a smart device attached to the

	athlete training	by low-cost, body-worn inertial sensors	approach that enables efficient, personalized activity classification	user; activity classification module (ACM) and the context classification module (CCM)
Sardini et al. 2015 [50]	Posture Monitoring and Rehabilitation Exercises	To develop a wireless wearable T-shirt for posture monitoring during rehabilitation or reinforcement exercises	The wireless wearable sensor produced reliable data compared with the data obtained with the optical system	A copper wire and a separable circuit board; the actuator is a vibration micromotor (Pico Vibe) commercialized by Precision Microdrivers
Spano et al. 2016 [71]	Remote patient monitoring; ECG monitoring	To develop an ECG remote monitoring system that is dedicated to non-technical users in need of long-term health monitoring in residential environments and is integrated in a broader Internet-of-Things (IoT)	Developed an integrated 1) ECG prototype sensors with record-low energy per effective number of quantized levels and 2) an architecture providing low marginal cost per added sensor/user	The wearable ECG sensor consists of a battery-powered chest belt; two dry plastic electrodes and the electronic printed circuit board; The circuit extracts, filters, amplifies and digitizes the ECG signal, which is then acquired by the microcontroller
Melillo et al. 2015 [72]	Risk assessment of vascular events and falls in hypertensive patients	To design and develop a flexible, extensible, and transparent, and to provide proactive remote monitoring via data-mining functionalities	Future vascular event was predicted within the next 12 months with an accuracy of 84%	BioHarness Bluetooth logging protocol application was used to collect the data

2.1.2 Machine Learning and Decision Support

With the increase in adoption of wearable patient monitoring systems, it is expected that the variety of new data sources will be created, which will also complement the health record. Using machine learning, the raw data needs to be transformed in to the meaningful and actionable data. But, the current issue with the expert-or knowledge-based systems is the accuracy and the reliability of these models [73-75]. Majority of current models contain medical knowledge about a very specifically defined task and can analyse the collected data from individual patients only. When insufficient

knowledge is encountered, machine-learning approaches can be used to analyse a series of clinical cases to characterize the condition of a given patient or disease. The current state of wearable monitoring systems can be further enhanced with the integration of such techniques into the hardware or in the cloud for real-time processing [48].

One of the bottlenecks to consider for the third generation of pervasive sensing platforms is to achieve rapid and scalable processing for large datasets. From a software point of view, processing big data is usually linked to programming paradigms [76]. Several open-source frameworks such as Hadoop [77] are frequently used to store a distributed database in a scalable architecture, as a basis for tools (such as Cascading, Pig, Hive) [77] that enable developing applications to process vast amounts of data (by the order of terabytes) on commodity clusters. However, when combined with continuous streams of pervasive heath monitoring, this also requires capacities for iterative and low-latency computations, which depends on sophisticated models of data caching and in-memory computation. Thus, other frameworks such as Storm and Spark have been created to fulfil this gap [77].

2.2 Current Issues and Challenges related to the Wearable Monitoring Systems

The next generation of WPM systems is likely to improve the quality of human life by assuring high comfort while increasing the intelligent use of limited resources [78-81]. Further improvements in textile sensors design, signal quality, miniaturization and data acquisition techniques are required to fulfil these expectations. Figure 2.2-1 shows the overview model of WPM systems and lists four key areas which are currently limiting the wider clinical adoption of wearable technology [79-84]. The following sections elaborate the issues pertaining to these four key areas.

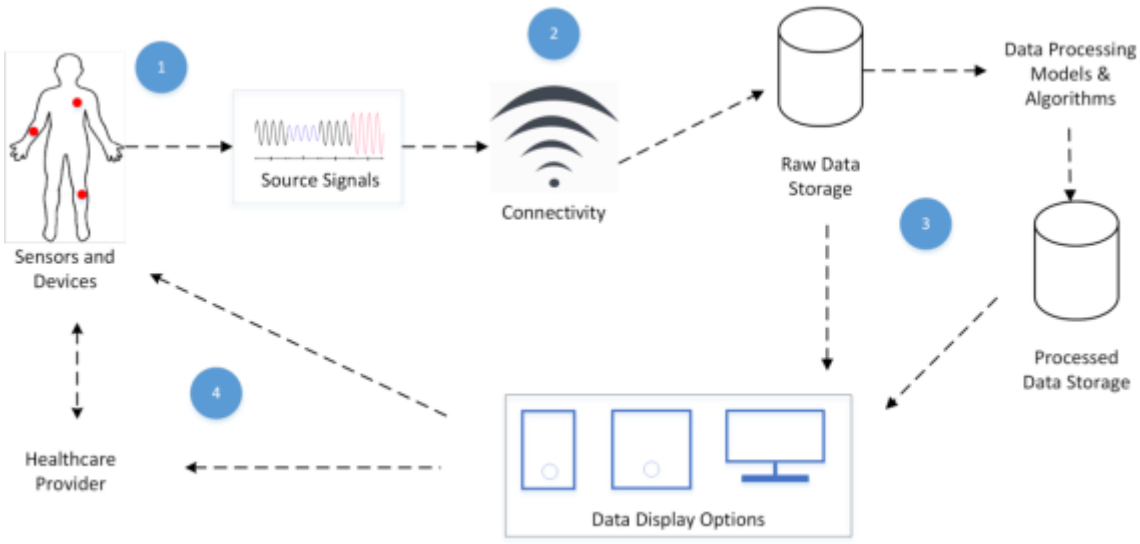

Figure 2.2-1 Overview model of wearable monitoring systems

2.2.1 Sensors and Signals

The number of biosensors used in current WPM systems is generally large and requires specific on-body placement or body postures in order to provide reliable measurements [85]. One of the technical barriers when using WPM systems is the obstruction of feature extraction from the signal due to motion artefacts. This is due to body movement or respiration and needs to be resolved [86]. A study by Etemadi et. al [68] utilized advanced signal processing to collect accurate and reliable seismocardiography (SCG). To increase the quality and accuracy of the SCG, linear filtering, detecting the R-wave peak timings from the ECG, and using these timings as a fiduciary for ensemble averaging the SCG were implemented. In a similar study that investigated biofeedback training for emotion management and patient monitoring [70], the signals collected were unreliable and disturbed by a variety of noises.

Most body-worn applications reported that the system's accuracy is hampered by noises such as: electromagnetic interference of power line, poor quality of contact between the electrode and the skin, baseline wander caused by respiration, electrosurgical instruments and movement of the patient's body. Most of these noises

cannot be filtered out completely over the hardware-processing unit due to the processing limitations [79, 81, 83]. Therefore, it is necessary to filter out these noises as much as possible in the software platform. The researchers from this study adopted the Butterworth Notch Filter (BNF) and finite impulse response (FIR) band-pass filter to eliminate power line interference and baseline wander, and a novel multi-scale mathematical morphology (3M) filter to reduce the impact of the non-linear noises caused by poor electrode contact and motion artefacts.

Similarly, an another study used a wireless wearable T-shirt to monitor the patient's posture during rehabilitation exercise [87]. The researchers manually sewed an enamelled copper wire of 1mm diameter to a T-shirt and constituted the sensor (about 9 cm long and 2.5 cm wide with a total length of 50 cm). The copper wire was stitched with a zigzag pattern on the back and the chest, thus allowing the lengthening of the T-shirt and sensor in the sagittal plane. The study achieved good outcome in a small setting, but the impedance value of the sensor changed due to the different factors such as the relaxation of the T-shirt or skin conductivity variation. The T-shirt with the sewn copper wire was washed (expecting a relaxation) after it was used, but no variation was observed [50].

2.2.2 Wearable Device Connectivity

One of the most common issues with wearable systems is the delay in providing results and generating alerts due to data loss, buffering, network communication, monitoring or processing [69, 88, 89]. These systems were developed for specific setup and care settings in order to assist patients' specific need. WPM systems using 3G/4G data suffer connectivity issues due to the remote network, low signal strength in remote places, low battery life time, low transmission speed, thus resulting in delay or low quality data for periods of short time [88, 90]. To address these issues, a cross-layer

framework has been developed based on unequal resource allocation to support secure wireless wearable data encryption and transmission [91]. The low battery life issue occurs due to continued connectivity of device/sensor with the Bluetooth, Wi-Fi or 3G/4G networks [92-94]. Moreover, if the power supply is not an issue, then the mobility of the device may become problematic, especially for older adults.

A portable ECG monitoring device developed by Lee et al. [93] can easily measure the ECG by connecting the measuring module to a patch with a minimized electrode array using a snap button. The measuring module is small (38 mm wide, 38 mm long and 7 mm thick). The weight of the module including the battery is 10 g. The study reported that an ECG signal was collated using a commercial device that was similar to the conventional Holter monitor. The study reported that even with the wires firmly fixed, the ECG signal quality was often disturbed, as the wires moved depending on the subject's body movements. According to another study, the ratio of motion peaks to normal peaks was estimated as being about 10% when the ECG was taken from a freely moving patient using the Holter monitor [92]. For this reason, ECGs obtained using Holter monitors are limited, and algorithms used to eliminate noise from the data have been actively developed. As important as it is to detect and exclude generated noise from the analysis, it is even more important to reduce the occurrence of noise itself in the first instance, and this is a common issue with almost all sensor-based WPM systems [93, 95].

In real-time scenarios, wearable data transmission often requires some data processing and therefore network delays. Some systems produced good results when tested offline but reported delay when tested in real-time [88]. Prakash et.al [96] demonstrated an efficient connectivity and communication framework in a real-time wireless hospital sensor network, which could be adopted for acute care settings.

2.2.3 Data Processing, Integration and Clinical Decision Support

Machine learning and artificial intelligence techniques have the potential to transform healthcare services by improving diagnostics and predictive modelling. The utilisation of these techniques in healthcare is still emerging, as it requires considerable analysis to provide reliable results that clinicians would actually use [97]. The raw data collected from wearable sensors would provide a data source that did not exist before. These data would undergo further analysis to be transformed into meaningful and actionable information. This process would be supported by real-time machine learning processing techniques. Advanced signal processing algorithms for faster processing, low power consumption, low cost, and less complexity have been applied to healthcare settings. However, such algorithms are often tested by simulation or under fixed conditions. Implementation of these algorithms in the wearable monitoring in an acute care environment led to poor results due to significant processing time and delay. A medical grade remote monitoring system with a reliability exceeding 99% has been developed, but a 2.4 second initial buffering delay, as well as a small processing and network delay were reported [98].

The current concern with the deployment of expert systems in healthcare is accuracy and reliability [80, 99]. To achieve higher accuracy in decision support, a complete data set must be employed for different stages of training, testing and validating of expert systems. Currently, the majority of existing clinical decision support models contain medical knowledge of a specific or pre-defined task and therefore can analyse the collected data from individual patients or from small data sets only. Thus, highlighting the issue of scalability and wider integration is a challenge for future research and development [4, 18, 28]. Moreover, machine-learning approaches can be used to analyse the streaming of real-time clinical data and map it to known/existing

condition(s). The current state of wearable monitoring systems can be further enhanced with the integration of such techniques into the hardware or in the cloud computing platforms for real-time processing [100].

One of the bottlenecks to consider for third generation of pervasive sensing platforms is to achieve rapid and scalable processing for large datasets. From a software point-of-view, processing big data is usually linked with programming paradigms [76]. Several open-source frameworks such as Hadoop [77] are being used to setup distributed database environments via a scalable architecture. This provides a basis for further usage via other tools (such as Cascading, Pig, Hive) [77] that enable developing applications to process vast amounts of data (by the order of terabytes) on commodity clusters. However, when combined with continuous streams of pervasive heath monitoring, this also requires capacities for iterative and low-latency computations, which depends on sophisticated models of data caching and in-memory computation. Thus, other frameworks such as Storm and Spark have been created to fulfil this gap [77].

Rich clinical decision support could be achieved by using the insights gained by taking a machine-learning approach to the data collected via wearable sensors and/or wireless medical devices [101]. A cloud-based clinical decision support system embedded with machine learning techniques could include: drug-drug allergies, individualised drug dosing, clinical risk scores/scales and gaps in care – alerts, reminders, warnings and notifications [99, 102, 103].

2.2.4 Information Exchange

Mostly, mHealth applications are developed either web-based or local machine-based. In both cases, they will be connected to other services for the transfer of information.

However, the local application usually does not have data integration capabilities with other clinical databases to fetch patient data for processing, they mostly relay on local patient data and limited to specific area or an issue. Local machine-based applications have the advantage of patients' information security and privacy, but have two critical drawbacks; memory space and limited patient data access [104]. However, fully connected applications have the advantage of analysing more patient data from other data repositories to predict/interpret the decision support. Such applications will also be connected to cloud-based environment for information transmission but require an ICT infrastructure – with cost implications at the initial stage. Another issue is the privacy and security of patients' personal information [105]. It is suggested that there should be balance between clinical use and ICT dependence for mHealth applications. For example, if the medical device or hospital internet connectivity fails then the whole application will be useless for clinicians, because normally all data is stored in the cloud due to the smartphone/tablet's limited space [104, 106].

It is recommended that, in a limited resource setting, it is optimal to use the local smartphone application for the specific healthcare area so that huge ICT-related costs could be saved. Wilcox et al. [107] attempts to minimize such barrier by using advanced data encryption process before and after the data transmits, so that the data available locally as well as data available on the cloud is secure and no breach during the data transmission could take place. The issue of integration/connectivity is addressed by using a native application with secure data storage rather than a desktop computer with added layer of data security including a browser security for web-based forms. This poses the risk of mobile device theft and ending up in remote wipe of the whole device data [107], which again points towards the ICT infrastructure to store and handle huge amount of incoming patient data. However, storing information on the

hand-held device introduces the risk of losing the device (easier to lose the smartphone device than desktop work station) and one cannot physically steal or lose the cloud.

2.3 Summary of Wearable Monitoring Systems

We believe that one of the core advantages of WPM systems is the patient's (user's) self-engagement with the treatment – which is often missing. There is a shift in wider thinking of WPM systems as 'only data collectors' to viewing them as being self-engaging and motivating systems which allow rich interactions between patients and clinicians [108-110]. Due to WPM systems being traditionally regarded as data collectors only, the majority of wearable systems lack user-engagement and user-interaction aspects. The wearable systems are often focused on providing real-time health data to clinicians for timely treatment and actions, but are missing user-acceptance and engagement. User-engagement and user-interaction are some of the key uptake factors among consumers (non-clinical care settings) for wearable technologies [111-113].

An advanced WPM system named Hexoskin^{TM} [114] (ClinicalTrials.gov Identifier: NCT02591758) with a vest and embedded sensors is being developed. It provides the user with seamless and fully integrated information regarding heart rate, breathing rate, minute ventilation, heart rate maximum, resting heart rate, heart rate recovery, maximal oxygen uptake and cadence. It uses textile-integrated sensors for activity, respiration and heart rate and intelligently makes use of the three-cardiac dry and textile electrodes. The cardiac sensors for ECG uses 1 channel, 256 Hz, heart rate 30-220 beats/min, 1Hz with QRS event detection, RR intervals and heart rate variability analysis. For breathing monitoring, the system uses two channels, 128 Hz; breathing rate 3-80 breaths per minute, 1Hz; tidal volume (last inspiration) 80-10000 mL, 1Hz; minute ventilation (inductance plethysmography) 2-150 L/min, 1Hz and inspiration and

expiration events: 8 ms resolution. Hexoskin™ provides users with real-time and remote monitoring via secure Bluetooth connected mobile app (iOS and Android), a web dashboard, up to 14 hours of battery life (rechargeable), free data storage in cloud and secure access anytime [114, 115]. Hexoskin™ allows users to download the raw data in machine readable format, as well as provide users with raw, processed and/or meaningful data. The access to the application programming interfaces (APIs) and raw data in machine-readable format enables the healthcare professionals, researchers and developers to leverage the existing open platform for data mining, machine learning for various clinical, social, behavioural and physical (activity-related) use-cases and explore the data further for enormous healthcare benefits.

CHAPTER 3 Methodology and Approach

3.1 Introduction

In this research, mixed method approach is applied to gain deep insights from the analysed qualitative literature and medical data and apply the protocols on the collected quantitative data. This research adopted the well-established and robust multi-methodological approach used in the information systems research (ISR), originally introduced by Nunamaker Jr et. Al in 1990 [116]. It consists of four research strategies/phases - observation, theory building, systems development and experimentation. The phases are not in any particular order but they are all mutually connected to support creation and validation of a system with multiple iterations. Nunamaker Jr et al. [116] believes that having an integrated approach will enable ISR to keep pace with technological advancements and organization acceptance. Figure 3.1-1 shows Nunamaker's multi-methodological approach to IS research and below is a summary of four research phases from Nunamaker Jr et al. [116].

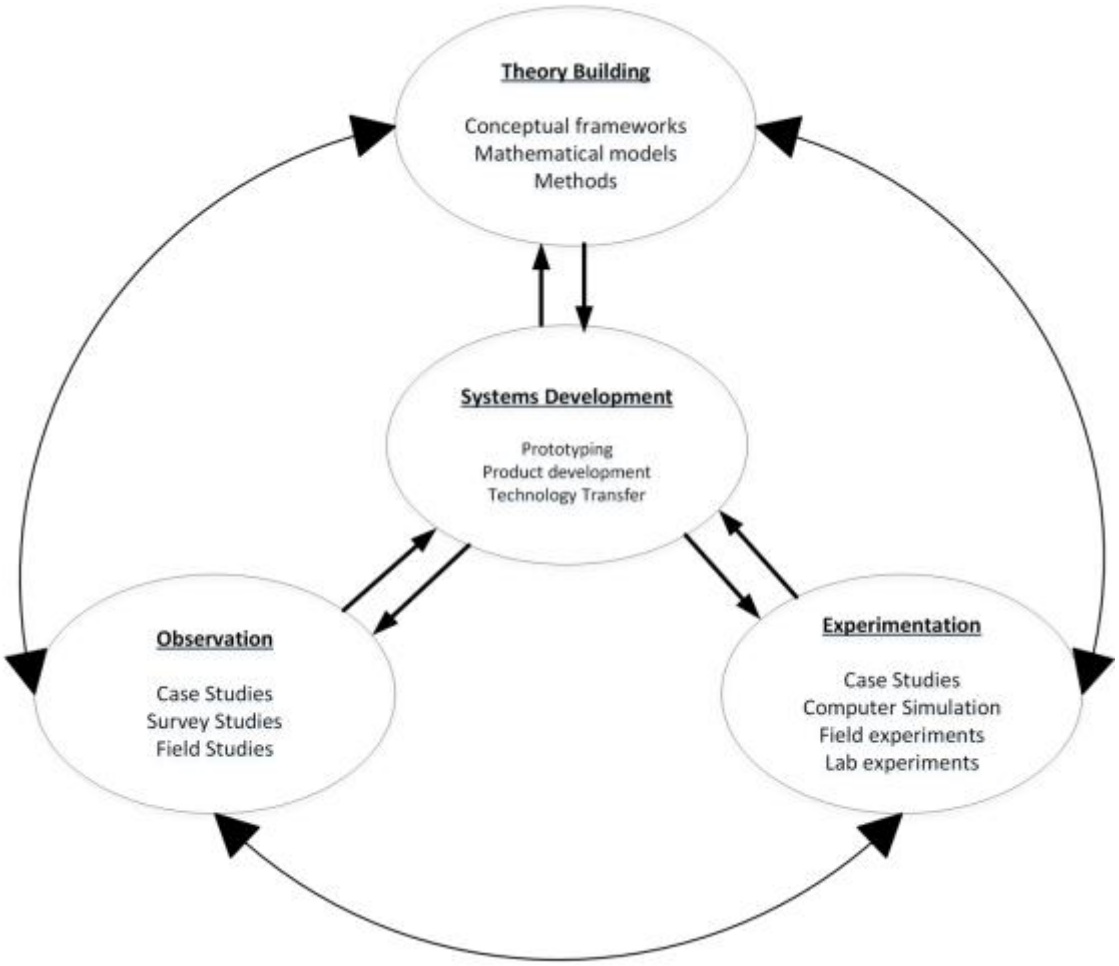

Figure 3.1-1 Nunamaker's Multi-Methodological Approach to IS Research [116]

3.2 Multi-methodological Approach

For this study we adopted the multi-methodological approach used in information systems research. Figure 3.2-1 shows the high-level multi-methodological approach workflow diagram adopted in this research. The four research strategies/phases of this research are described in detail below – observation, theory building, experimentation and systems development and its associated workflow is depicted by numbers #1 to #9 [116].

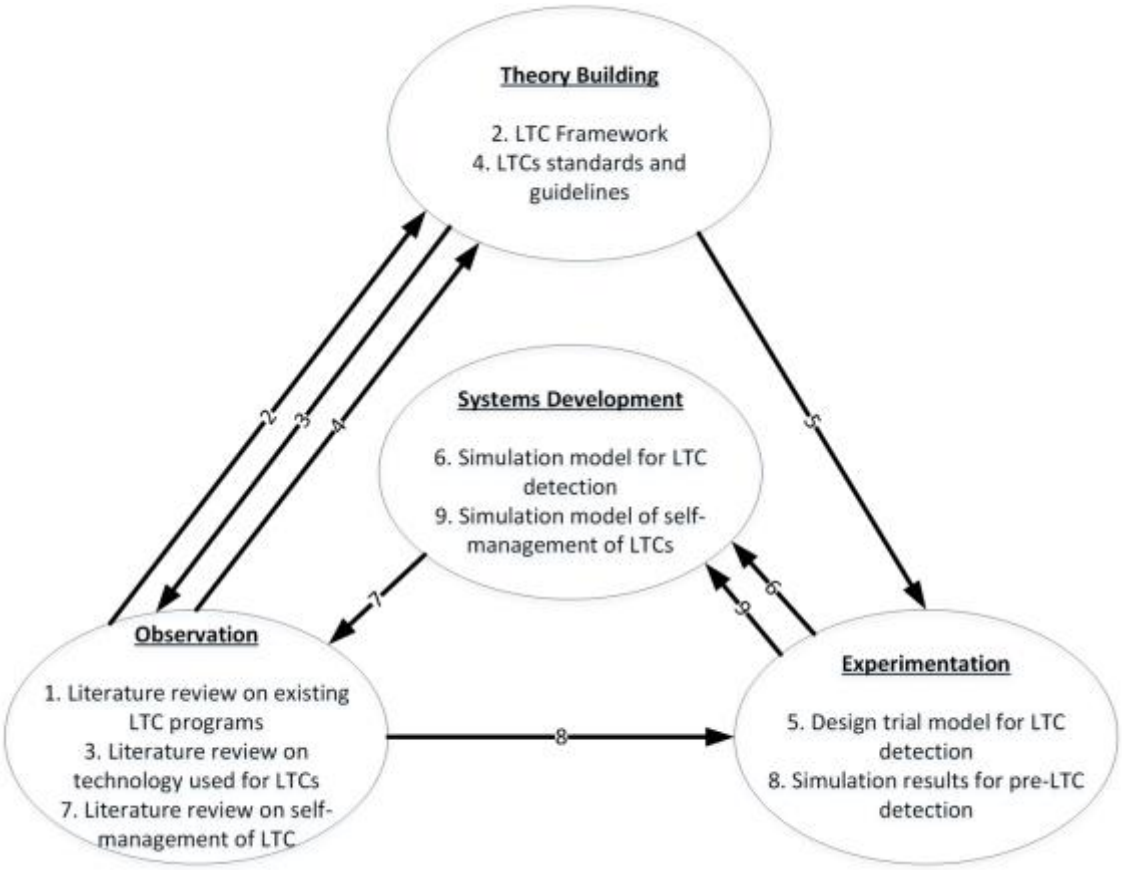

Figure 3.2-1 Adopted multi-methodological approach displaying research phases for this research study (based on [116])

3.2.1 Observation

This phase includes research methodologies such as case studies, field studies and empirical review to bring clarity to the research domain [116]. This research uses the quantitative, experimental research approach to minimise the preconceptions due to the fact that the technology-led diabetes self-management interventions have few or no predetermined research available to support the success or failure of this method. We reviewed the existing literature for existing LTCs programs, technology-led LTCs intervention and outcomes of self-management of LTCs to determine the known and existing facts and establish the research gap and strengthen our focus on solving the LTC using technology-led self-management of diabetes. Figure 3.2-2 shows phase 1 of the multi-methodological approach we adopted.

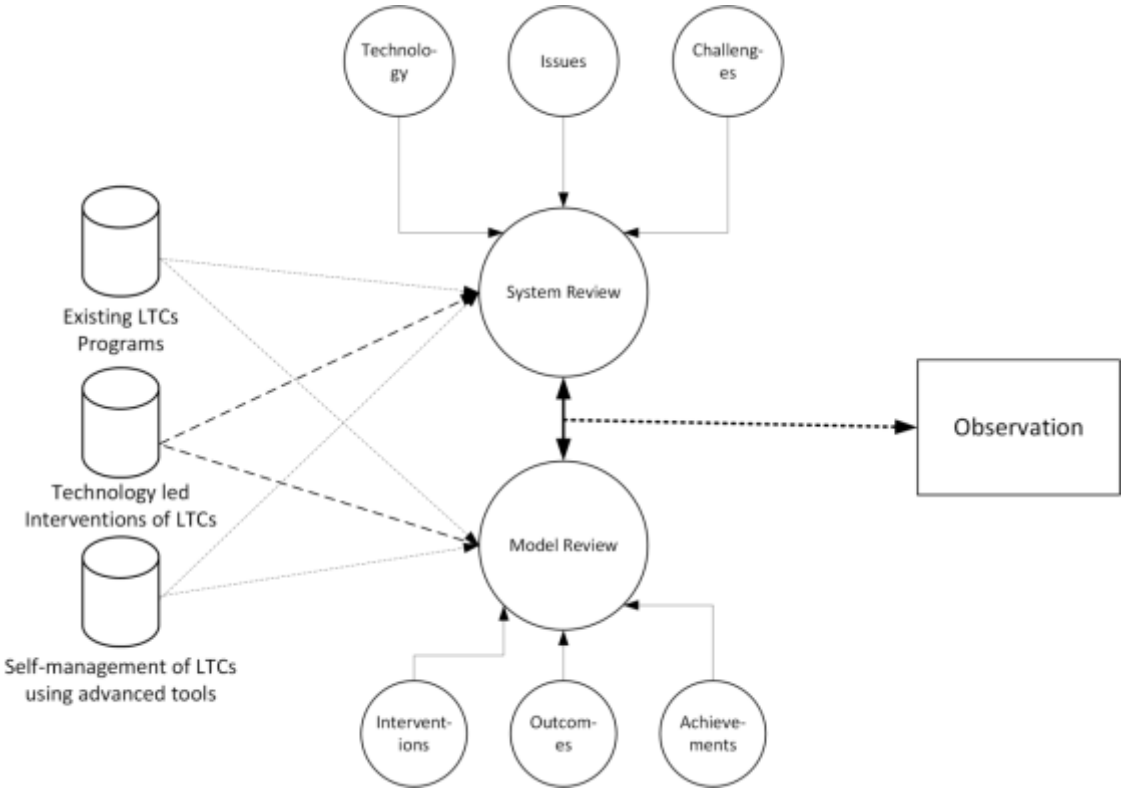

Figure 3.2-2 Phase 1 Observation of the multi-methodological approach to IS Research (dotted lines represent the direct association and dashed lines represent the indirect association)

3.2.2 Theory Building

Figure 3.2-3 shows phase 2 – Theory Building of the multi-methodological approach. This phase includes design and development of new ideas, models and frameworks [116]. Mostly, the artefacts identified in the observation phase could be used/implemented here to construct the design concept of the framework and thus, support in suggesting research hypotheses and design of experiments.

This research followed the below methods in order to conceptualize the theory:

- Investigation and evaluation of the existing best-practice clinical guidelines, national recommendations and care plans for diabetes

- Design the clinical mapping of the existing information

- Design to conceptualize the latent data patterns, trends and structures of the area of interest through the process of constant comparison and evaluation including the use of an inductive approach to generate substantive insights or trends from the data

- User engagement and interaction approaches for an effective data collection application

- Analysis and mapping of New Zealand specific best-practice clinical guidelines, national recommendations and care plans for diabetes with the detection model

- Review of the existing pre-build models on diabetes as a base threshold for detecting pre-LTCs

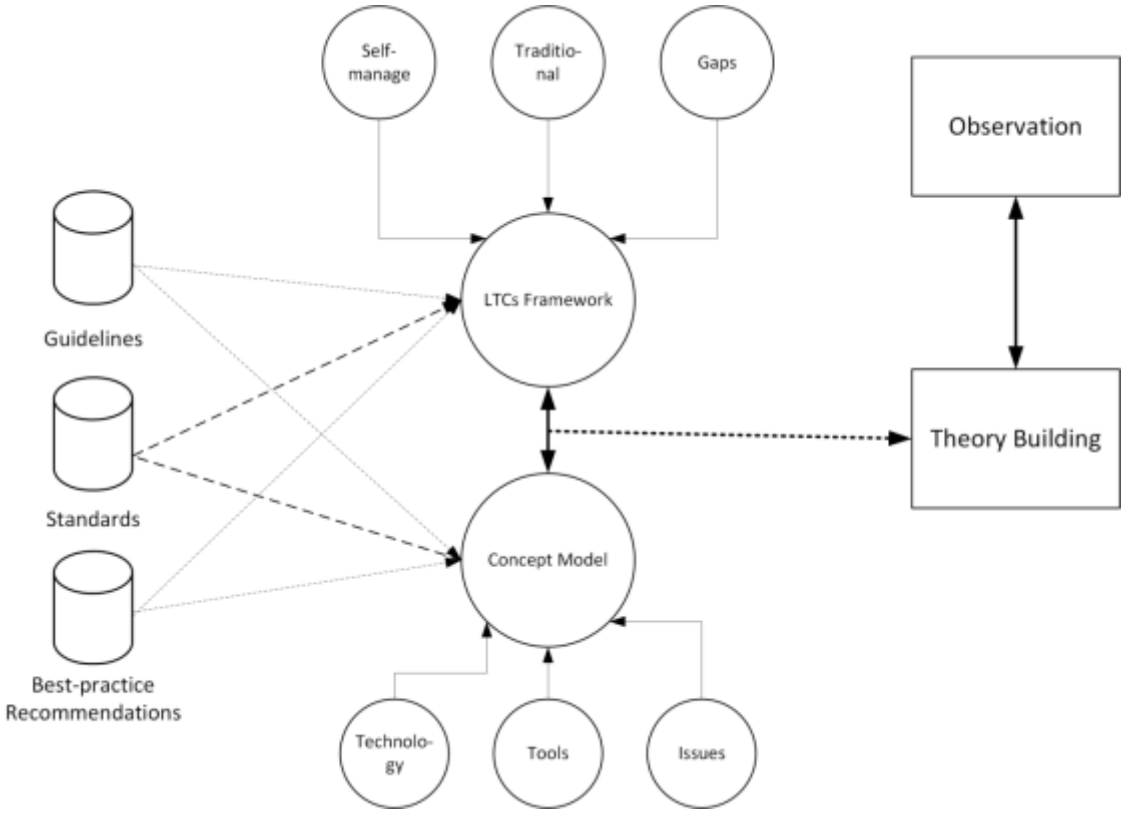

Figure 3.2-3 Phase 2 Theory Building of the multi-methodological approach to IS Research (dotted lines represent the direct association and dashed lines represent the indirect association)

3.2.3 Experimentation

Phase 3 is conducting lab/field experiments, simulations or interviews. The design of experiment in this research is heavily motivated by the theory building (phase 2) and partially supported by system development (phase 4) [116]. The experimentation was supported by Hexoskin using their advanced body sensors vest as wearable monitoring system.

The data collected to conduct this research study are; heart rate, heart rate variability, breathing rate, breathing volume, activity (steps, cadence and calories), blood glucose, height, weight, age and sex. The existing and available pre-build models are used to validate the proposed study, which is validated for NZ long-term conditions to provide early indication of any pre-long-term condition detection, including in the UK [117, 118]. This will measure the impact of the proposed intervention among NZ population from wider areas of community than those studied previously on geriatrics rehabilitation wards or with specific set of patient cohort [119-121].

In summary, we conducted the data analysis for individualised and personalised monitoring and early detection (rather than threshold-based limits) using the data clustering approach and weighted parameters mechanism.

Advanced data analysis technique was applied using the identified LTC models for detecting pre-LTCs (fuzzy logic-based artificial intelligence technique). The developed model is then deployed and compared to test the accuracy and efficiency.

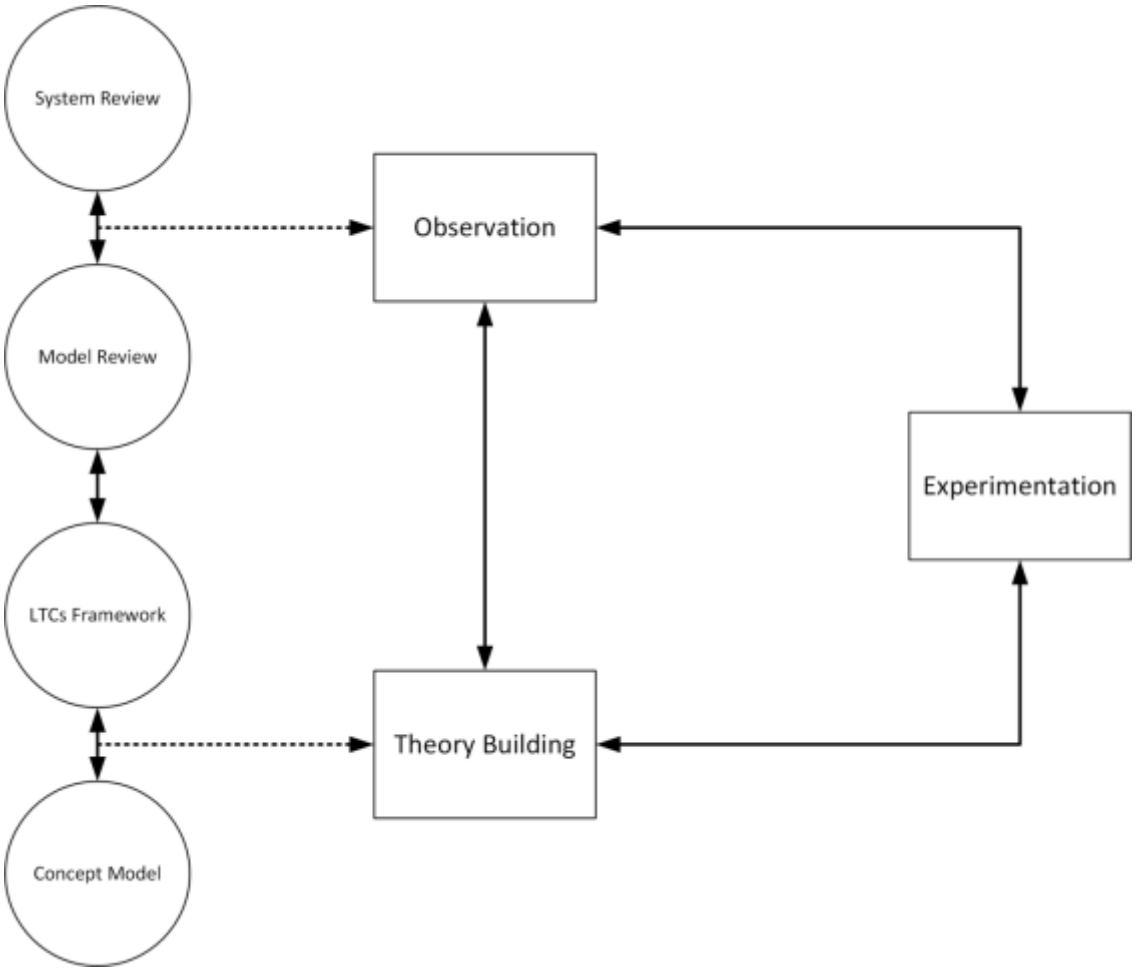

Figure 3.2-4 Phase 3 Experimentation of the multi-methodological approach to IS Research (dotted lines represent the direct association and dashed lines represent the indirect association)

3.2.4 System Development

There are five stages of system development: concept design, constructing the system architecture, prototype, product development, and technology transfer. Concept design is incorporation of technological and theoretical concepts into potential practical applications. Development of prototype (proof-of-concept) is used to demonstrate feasibility of the system [116].

An adaptive-neuro fuzzy inference system (ANFIS) was developed to interpret and detect early pre-LTC using collected vital signs and activity data. It plays an important role in the diagnosis of individualized monitoring instead of threshold-based or age-based detection. The system learns the normal parameters for each individual using

adaptive-neuro fuzzy system modelling. The relation between vital signs and activity data with the set pre-diabetic conditions can be established by consulting with physicians and related medical assessment.

The interpretation of the diagnostic values and the relationship between vital signs, activity data, demographics data and their clinical interpretation are mapped to the ANFIS rules. Moreover, clinical acceptability of assessment procedures via expert agreement analysis is evaluated and factors that affect on-going data collection, barriers to this intervention, accuracy and the potential for person' self-management will also be measured.

Figure 3.2-5 shows a block diagram overview of the interpretation engine and the proposed multi-layered outcome for early detection of pre-LTC. The proposed system has been tested for both real-time as well as offline data. Extensive data analysis and pre-processing were carried out so that the input feeding data has a unique path and features throughout the monitoring phase. The interpretation engine consists of four key components (individualised monitoring, evidence-based reasoning, weighted parameters and medical knowledge base) which complement each other when the information is complete and works individually when information is limited and/or incomplete. A multilayer concept has been introduced to enhance the overall outcome reliability and accuracy of the proposed system. The multilayer outcome has the potential of early detection of LTC. This mechanism is best utilised in this context by feeding a multiple input-output combinational relationship. Detailed results and validation of testing and enhancements are described in Chapter 4.

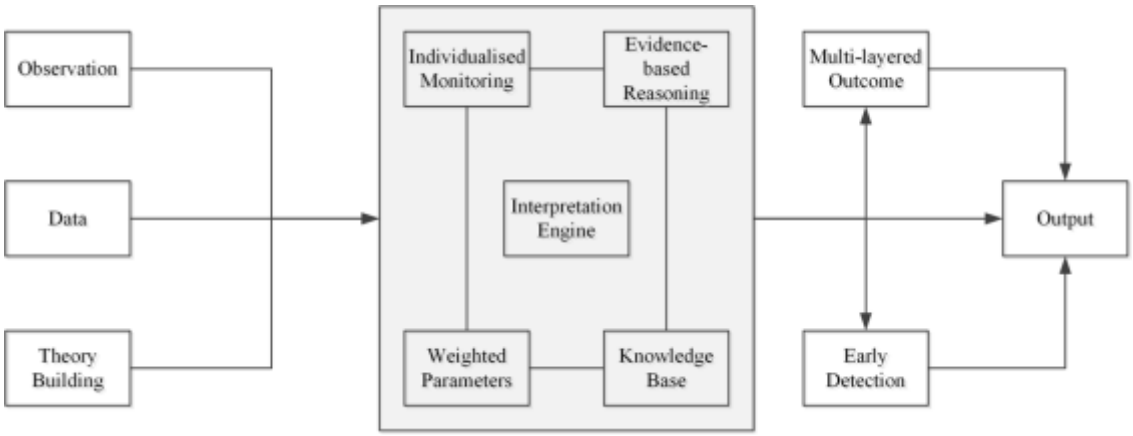

Figure 3.2-5 Overview of interpretation engine using four components - Individualised monitoring, Evidence-based reasoning, Knowledge-base and Weighted parameters

3.3 Diabetes Screening Mechanism and Protocols for New Zealand

The New Zealand Guidelines Group [12] recommended that HbA1c screening for type 2 diabetes be completed as part of a LTC risk assessment. The New Zealand Society for the Study of Diabetes [12] advised that the following groups be given priority for diabetes and pre-diabetes screening [122, 123]:

- Those adults over 25 years of age who:
    - have known ischaemic heart, cerebrovascular or peripheral vascular disease
    - are on long-term steroid or antipsychotic treatment
    - are obese (BMI ≥30 kg/m2 or ≥27 kg/m2 in Indo-Asian)
    - have a family history of early age onset of type 2 diabetes in more than one first degree relative
    - are women with a past history of gestational diabetes mellitus.
- Obese children and young adults (BMI ≥30 kg/m2 or ≥27 kg/m2 in Indo-Asian) if:
    - there is a family history of early onset type 2 diabetes
    - they are of Māori, Pacific or Indo-Asian ethnicity.

3.4 Diabetes Screening Mechanism and Protocols for the United Kingdom

In England, integrating care for the self-management with a LTC, including the ability to promote and support self-care, has become a core strategy for its National Health Service (NHS). For example, the government set a central commitment to provide the opportunity for all 15.4 million people in England who have a LTC to receive an integrated and personalised care plan [124-126]. Figure 3.4-1 shows the NHS and social care LTC model. This research is highly aligned with one of the successful LTC model - the NHS LTC model. The model highlights the infrastructure of decision support system required to support the self-care to cater for the self-management of LTC [29, 127].

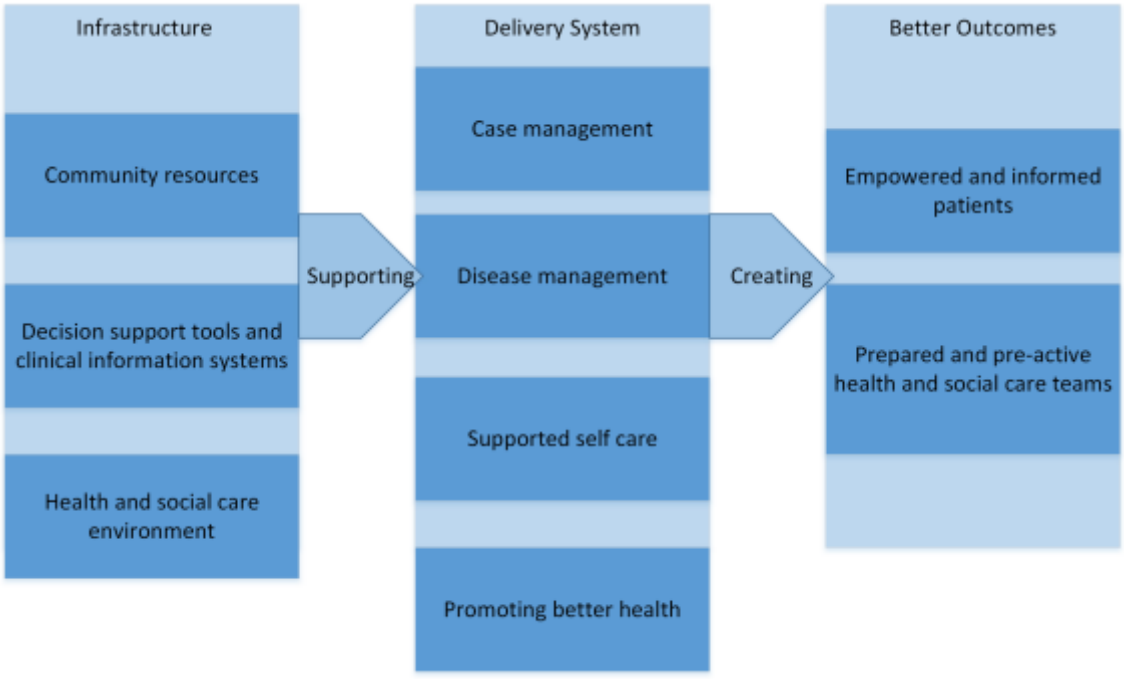

Figure 3.4-1 The National Health Services (UK) and social care long-term conditions model [127]

Some of the core LTCs' policies for the UK are [128, 129]:

- The active promotion of self-care strategies to enable people with LTCs

- To live independently in the home environment

- Investment in population-oriented health management through the use of predictive modelling techniques that enable at-risk individuals and populations to be targeted with appropriate interventions

- A movement towards new integrated care organisations, which potentially provide an in-house set of comprehensive health and social care services to registered patients

3.5 Stratification Mechanism for Managing the Risk of LTC for Prediabetes

This research used a combined use case for detection the pre-LTCs using the below key points [10, 18, 27, 47, 123]:

- People with pre-diabetes are at increased risk of developing diabetes
- Given the disproportionately high prevalence of diabetes and pre-diabetes in Māori, Pacific and Indo-Asian people, these groups are especially at risk of developing type 2 diabetes and associated comorbidities
- Pre-diabetes should be managed along with associated cardiovascular risk factors e.g., tobacco smoking, high blood pressure, high cholesterol
- Lifestyle interventions can delay or reduce progression to type 2 diabetes, and possibly reduce long-term morbidity and mortality
- A range of interventions are effective and the choice will depend on individual/ whānau/family preferences and community resources
- Many interventions can provide better results than usual care, but ongoing support and follow up are required to enable behaviour change

- Efficacy increases with multiple behaviour changes, with weight loss being dominant
- For overweight or obese people, aim for a long-term loss of at least five percent of initial weight

Randomised controlled trials of subjects with LTCs have confirmed the potential for lifestyle interventions (such as dietary counselling, increased physical activity, weight loss and behaviour modification) [49]. These interventions could lead to a 27% reduction to the incidence of diabetes over 15 years. Lifestyle interventions could delay the development of diabetes by 3 to 4 years. For every one kilogram of weight loss, the risk of diabetes could reduce by 16 percent. Addition of vital sign data to the activity data gives this research study a unique combination for accurately detecting early long-term conditions [29-31, 49, 68].

3.6 Guidelines and Standards on the Risk of Prediabetes

The symptoms of Pre-diabetes are [11-13]:

- Feeling tired and lacking energy
- Feeling thirsty
- Going to the toilet often
- Getting infections frequently
- Getting infections which are hard to heal
- Poor eyesight or blurred vision
- Often feeling hungry

Globally, it is agreed that in order to manage type 2 diabetes [11-13], the person has to:

- Stay physically active and get regular exercise. Aim for at least 30 minutes of moderate physical activity each day or 5000 to 10000 steps per day (according to the person's physical health)
- Eat healthy food
- Keep your weight in a healthy range

Table 3.6-1 shows the global pre-diabetes guidelines and risk measures adopted in the proposed detection model. Figure 3.6-1 shows one of the most common and widely used pre-diabetes risks score (paper version), designed and developed by DoIHavePrediabetes.org.

Table 3.6-1 Global comparison of pre-diabetes guidelines and risk measures

Questions	NZ	UK	US
Overweight or Obese (BMI)	✓	✓	Check Height and Weight
Male or Female	✓	✓	✓
Inactive	Lifestyle	Activity	Activity/Exercise
Family History	✓	✓	✓
High Blood Pressure	✓	✓	✓
Have given birth to a baby who weighed over 9 pounds (4kg?)	✓	✓	✓
South Asian **Asian**	✓ (also Maori/ Pacific)	✓ (also White European)	✓ (also Asian American)

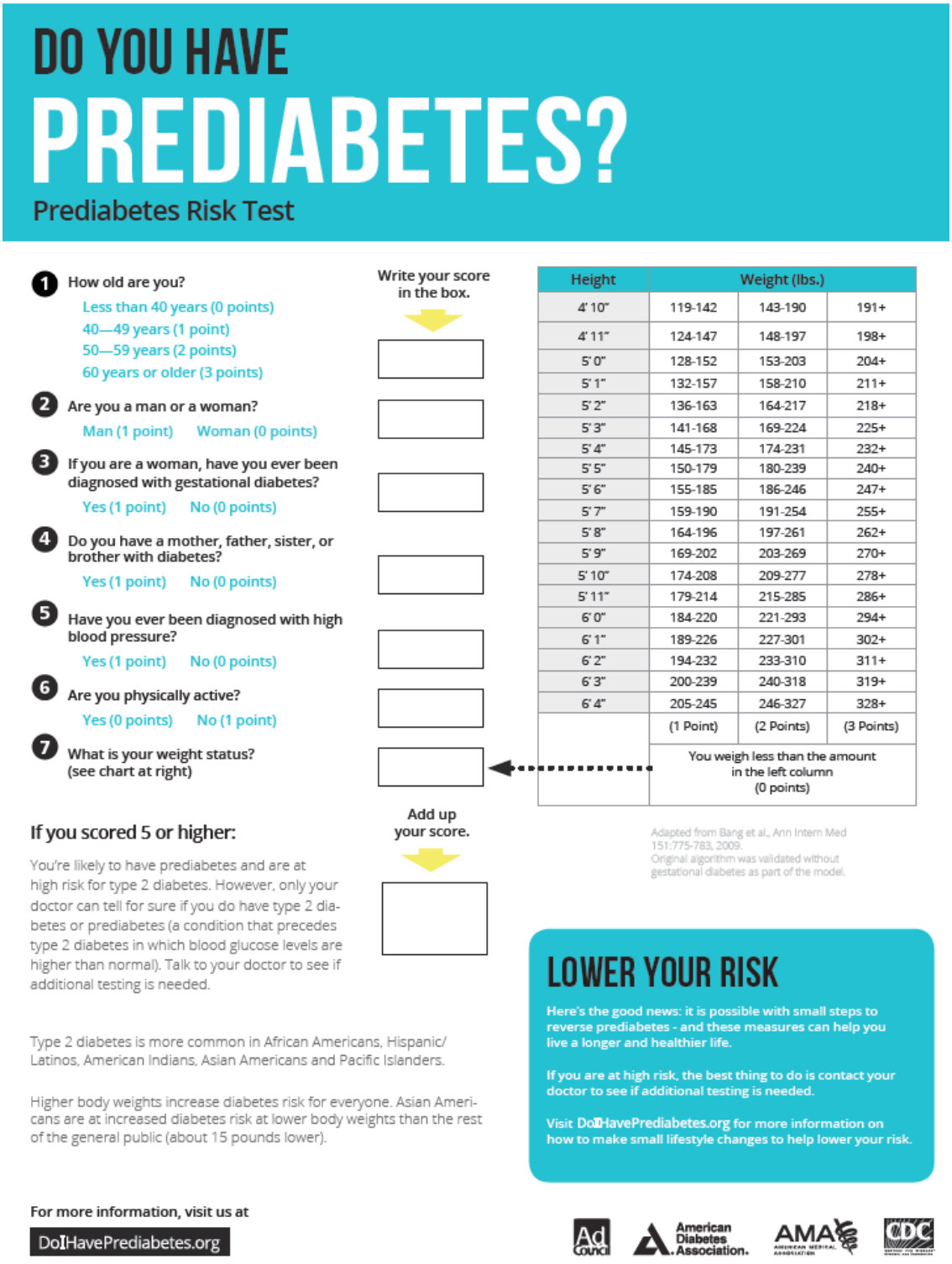

Figure 3.6-1 One of the most common and widely used pre-diabetes risk score (paper version)

CHAPTER 4 Data Collection, Analysis and Results

4.1 Introduction

Healthcare organisations want to reduce costs and improve their financial assets while seeking maximum level of care, accuracy and patient satisfaction. In fact, health professionals have to anticipate the increasing demand in healthcare services caused by the ageing population, chronic conditions and LTCs [130]. These factors clearly emphasise the need for efficiency, and the necessity for further enhancements in the self-management of LTCs. The past few decades have failed to witness a real improvement in the self-management of LTCs and patient monitoring using wearable body sensors [131].

One of the important areas related to this research is the person's vital signs, activity data and the demographics data on which the whole development is based. This chapter in-detail discusses the data collection methodology, adoption of data collection (including ethics approval) and the test-bed prepared for the data analysis and early detection of prediabetes and Diabetes.

The vital signs are an essential part of the patient's medical record. Even the best of healthcare cannot be defended or referred to if there is no clear record that such care took place. The essential purpose of maintaining the electronic record of the vitals data is to analyse the individual's trends, range, history and known health issues. Overall the record also helps to understand how an individual patient responds to the treatment.

The rapid development of telecommunication and information technologies has accelerated development in the patient's electronic record [132]. This work also explores the possibility of realizing a reliable and efficient wearable monitoring and the

development of an early detection of LTCs. Wearable patient monitoring systems not only increase the mobility of patients and medical personnel, but also improve the quality of health care [133]. With respect to the remote monitoring of patients, many groups have demonstrated the transmission of vital signs and activity data using: GPRS, 2G, 3G, 4G and 5G (under development) networks [134]. Some researchers have used cellular phones to transmit vital signs from the ambulance to the hospital, either in store-and-forward mode [135] or in real-time mode [136]. In the following sections of this chapter, the details of patients' data collection are discussed, followed by data acquisition devices, protocols and the proposed model.

4.2 Ethical Approval, Wearable Smart Shirt and Data Collection

4.2.1 Ethical Approval

The collection of vital signs and activity data from humans (patients) is considered as clinical trial, and it is defined by World Health Organisation (WHO) as,

'a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. [137]'

The research described in this thesis has successfully obtained ethics approvals in order to conduct the data collection from the Auckland University of Technology Ethics Committee (AUTEC):

- Auckland University of Technology Ethics Committee (AUTEC) approval number – 16/412, approved November 2016) - **APPENDIX A**
- Participant information sheet (page 1 of 2) – **APPENDIX B**
- Participant information sheet (page 2 of 2) – **APPENDIX C**
- Consent Form - **APPENDIX D**
- Participant Advertisement Sheet - **APPENDIX E**

4.2.2 Participant Recruitment, Inclusion and Exclusion Criteria

a) ***Acceptance and Rejection Criteria:*** Any healthy, 16 years (or over) individual who can give their own consent will be considered for this study. Participants with a known medical condition, which may restrict the activity of daily life performance, participants who cannot give their own consent and participants with known skin allergy are excluded as there will be no useful data in such case

b) ***Data Storage:*** The data will be stored securely on AUT premises in a location separate from the consent forms. Electronic data is downloaded to an external storage device (e.g. an external hard drive, a memory stick etc.) and securely stored for up to 10 years

c) ***Number of participants:*** 02 (due to the data collection time and the project scope and timelines)

d) ***Participants selection:*** First in first served to required number of participants

e) ***Participant Invitation:*** the participants are invited using study advertisement and participant information sheet

f) ***Consent:*** The consent of participants is obtained via written consent form. Participants have given the right to decide whether or not they wish to

participate in research. They need not give reasons for refusing to participate in research

g) ***Risk or discomfort:*** There is no way that the participant will be put under any sought of risk

4.2.3 Selection of Wearable Monitoring System

This research adopted market available and clinically validated body-wearable sensors that were incorporated into one vest. Development of a wearable monitoring system was beyond the scope of this research. Extensive market research, involving senior engineers, clinicians, IT firms and healthcare companies has been conducted to refine a reliable, advanced and wearable patient monitoring system. The selection of wearable system was made after finalising the system architecture, and a number of critical as well as functional requirements were identified as essential for the device to be considered for this project.

Table 4.2-1 describes the features/functionalities considered for a suitable wearable monitoring system. System features are divided into five categories; wearable (project theme), reliability (to collect data in real-time), transmission (seamless data transmission to other machines), size/power/cost (end user's ease and affordability) and operational usability.

Table 4.2-1 Features identified for inclusion of wearable monitoring system

Categories	Features
Wearable (Wireless)	Bluetooth Class II Wireless Range Standard Data Transmission Protocol
Reliability	Clinically Validated Stable Certified (International Standards) High Accuracy
Transmission	Continuous/Time based Data Collection Automatic Transmission Customisable data collection
Size/Power/Cost	Small Size Light Weight Battery Operated Low Cost Low Maintenance
Operational	Simple to Understand Easy to Operate High Readability Multi-Capture Fully Customisable Clear Message/Indicators

4.2.4 Body-Wearable Shirt for Real-time Monitoring

This research project used market available wearable vest – Hexoskin (www.hexoskin.com) through the research collaboration. Hexoskin's biometric shirt can provide more biometric data than any other wearable on the market [138]. It can monitor heart rate, breathing rate, ventilation, recovery, cadence, and oxygen levels. It is designed to be an equally effective sleep-tracking device. Hexoskin is used by space agencies, military organizations, and sports teams around the world [139]. The shirt pairs with an app that tracks the wearer's performance across different activities and can be used to monitor health, fitness, and more. It is machine washable and comes in several different models for men and women [138-142].

Figure 4.2-1 shows the overall architecture diagram with data flow from Hexoskin wearable shirt, smartphone application, desktop/laptop application and cloud connectivity.

The Hexoskin smart shirt can monitor:

- Heart Rate, HRV (allowing to estimate stress and fatigue), Heart Rate Recovery, and ECG
- Breathing Rate (RPM), Minute Ventilation (L/min)
- Activity intensity, peak acceleration, steps, cadence and sleep positions

The key features of the Hexoskin shirt are:

- 14+ hours of battery life
- 600+ hours of standalone recording
- Bluetooth connectivity with iPhone, iPad and Android
- Safe for any kind of activity

Sensors Details:

- Analog 256Hz ECG data
- Analog dual-channel 128Hz breathing sensors
- Analog 3D 64Hz acceleration

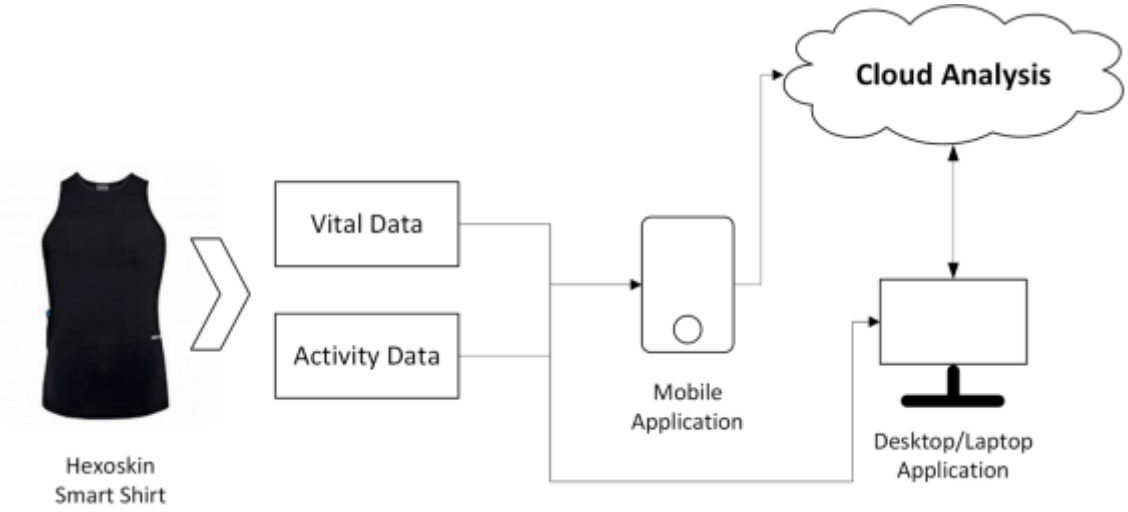

Figure 4.2-1 Overall architecture diagram with data flow

4.2.5 Data Collection

This research collected three types of data sets: (1) vital signs: heart rate, heart rate variability, breathing rate, breathing volume, oxygen saturation and pulse rate, (2) Activity Data: steps, cadence, distance and calories and (3) Demographic Data: height, weight, age, sex and blood glucose.

4.2.6 Participant Information and Data Statistics

Statistical information was found to be an important feature in developing a reliable interpretation model. Data trends from various viewpoints gave deep insight into the pattern modelling, for example, data trends between 65+ males and females are different and the 65-79 age groups is different from the 80+ age group. The difference is minor but this data analysis gave the interpretation model high reliability by considering minute details such as: gender, age group (65-79 and 80+) and maximum, minimum, range and standard deviation (SD) for each individual.

Table 4.2-2 and Table 4.2-3 below show the variety of statistical information related to the patient data collected. In the tables below HR is heart rate in beats per minute, SpO2 is oxygen saturation in percentage, B Glu is blood glucose level in mg/dl (mg/dl divided by 18 gives mmol/l and mmol/l times 18 gives mg/dl) and activity data is in number of steps and calorie. Due to the limited time, this research collected data from two participants only, Table 4.2-2 gives the statistics information of the collected data and Table 4.2-3 shows the participant's statistical information for demographic data, vital signs and activity data including blood glucose readings. Detailed statistics for all collected variables are shown in **APPENDIX F**.

Table 4.2-2 Mean values of the collected data

Parameter	Mean Value
Number of Patient	02
Age (years)	57
Sex (M/F) %	50/50
Heart Rate (beats per minute)	149.5
Oxygen Saturation (%)	96.12
Minute Ventilation	38.5
Blood Glucose	61 mmol/mo

Table 4.2-3 Participant's statistical information for demographic data, vital signs and activity data

Data/Participant	Participant 1	Participant 2
Demographic Data	• Age: 60 • Sex: Male • Weight: 84 kgs • Height: 168 cms	• Age: 53 • Sex: Female • Weight: 69 kgs • Height: 149 cms
Vital Signs Data	• Heart rate (Min=70; Max=191; AVG=158) • Breathing rate (Min=9; Max=82; AVG=43) • Ventilation (Min=51; Max=65; AVG=32)	• Heart rate (Min=66; Max=172; AVG=141) • Breathing rate (Min=10; Max=42; AVG=23) • Ventilation (Min=44; Max=69; AVG=45)
Activity Data	• Activity (Min=0; Max=1.9; AVG=0.63) • Cadence (Min=51; Max=243; AVG=132)	• Activity (Min=0; Max=1.1; AVG=0.55) • Cadence (Min=69; Max=191; AVG=122)
Blood Glucose (average)	• 70.33 mmol/mo	• 52 mmol/mo
Time	3.5 hours (multiple sessions)	3.5 hours (multiple sessions)

4.3 Overview of the Proposed Model

High importance has been given to the accuracy and reliability of the overall system. Figure 4.3-1 shows the key building blocks of the proposed model. This section discusses in detail the core modules (methodologies) integrated into the interpretation engine.

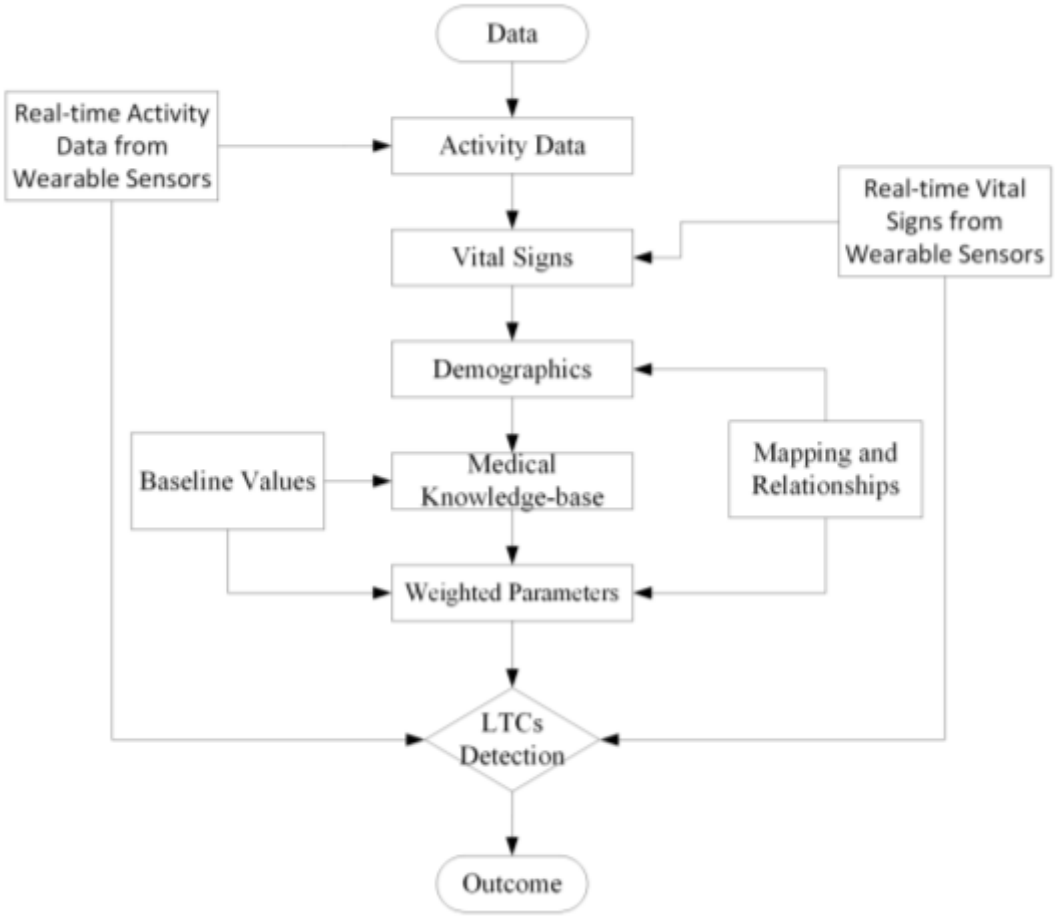

Figure 4.3-1 The proposed model's overview diagram

4.3.1 Fuzzy Logic-based Early Detection Model

The primary objective of fuzzy logic is to map an input space of 'data' to an output space of 'useful information'. This mapping is controlled by using IF-THEN statements known as rules. The order in which these rules are applied is irrelevant, since all rules run concurrently. It provides a remarkably simple way to draw definite conclusions

from vague, ambiguous or imprecise data. In a sense, it resembles human decision making with its ability to work with approximate data yet find precise solutions [143]. The concept of Adaptive Neuro Fuzzy Interference system (ANFIS) [144] as system identification has been used in this project. The fuzzy-logic defuzzification used by ANFIS is based on a zero-order Sugeno fuzzy model (or FIS, Fuzzy Inference System) [145]. The following sections will present and develop ideas such as sets, membership functions, logical operators, linguistic variables and rule bases.

4.3.2 Fuzzy Sets, Membership Functions and Logical Operators

Introduction to Fuzzy Sets, Fuzzy Logic and Logical Operators of the fuzzy control systems establishes a strong foundation for designing and analysing fuzzy control systems under uncertain and irregular conditions.

4.3.2.1 Fuzzy Sets

Fuzzy sets are sets without clear or crisp boundaries. The elements they contain may only have a partial degree of membership. They are, therefore, not the same as classical sets in the sense that the sets are not closed. Fuzzy sets can be combined through fuzzy rules to represent specific actions/behaviour and it is this property of fuzzy logic that will be utilised when implementing a fuzzy logic controller in subsequent sections.

4.3.2.2 Membership Functions

A membership function (MF) is a curve that defines how each point in the input space is mapped to the set of all real numbers from 0 to 1. This is really the only stringent condition brought to bear on an MF. A classical set may be, for example, written as:

$$A = [x \mid x > 3] \quad \textbf{(4.1)}$$

Now if X is the universe of discourse with elements x then a fuzzy set A in X is defined as a set of ordered pairs:

$$A = [x, \mu A(x) \mid x \varepsilon X] \quad \textbf{(4.2)}$$

Note that in the above expression $\mu A(x)$ may be called the membership function of x in A and that each element of X is mapped to a membership value between 0 and 1. Typical membership function shapes include triangular, trapezoidal and Gaussian functions. The shape is chosen on the basis of how well it describes the set it represents.

Figure 4.3-2 shows the example of fuzzy sets created in the triangular shape. In this example, the MFs are created as S is small; MS is medium small; M is medium, ML is medium large and L is large. The values of these sets vary from 0 to 1 in both the axes.

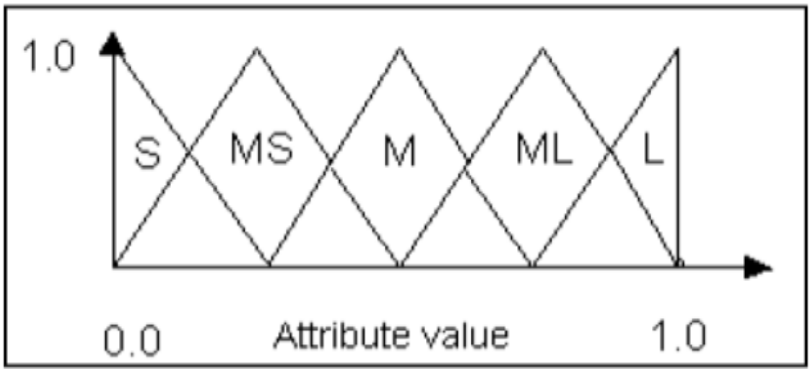

Figure 4.3-2 Example of Fuzzy Set. S is small; MS is medium small; M is medium, ML is medium large; L is large

Figure 4.3-3 shows the example of fuzzy sets created in the Gaussian shape. In this example, the MFs are created as poor, good and excellent. The value of these sets on x-axis is 0 to 100 and on y-axis is 0 to 1.

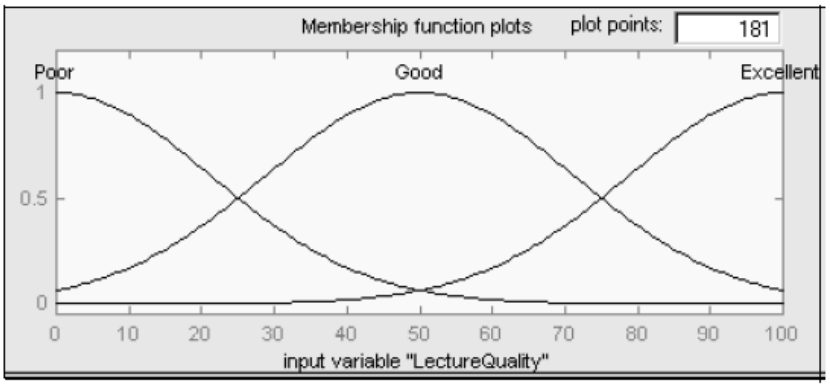

Figure 4.3-3 Example of a three-part Gaussian shaped MF

4.3.2.3 Logical Operators

Fuzzy logic reasoning is a superset of standard Boolean logic, yet it still needs to use logical operators such as AND, OR and NOT. Firstly, note that fuzzy logic differs from Boolean yes/no logic in that although TRUE is given a numerical value '1' and a FALSE numerical value is given '0', other intermediate values are also allowed. For example, the values 0.2 and 0.8 can represent both not-quite-false and not-quite-true, respectively. It will be necessary to do logical operations on these values that lie in the [0, 1] set, but two-valued logic operations like AND, OR and NOT are incapable of doing this.

4.3.3 Individual parameters

The majority of systems used today have adopted the generalised monitoring model based on either set threshold ranges or standard deviation changes which are implemented specifically for certain age groups (older adults, adults and children) [146, 147] and/or particular illness/health issue(s) [148, 149]. The proposed model has adopted individualised monitoring because of the fact that vital signs and activity data are different in each individual, hence threshold or SD based monitoring models often give high false alarms [150], eventually reduce the reliability of the overall system. Table 4.3-1 shows the heart rate statistics for the age range vs. participant data

(participant #1 and participant #2). Figure 4.3-4 shows the graphical view of difference between participant 1, participant 2 and the age range for 50-60 years old in terms of mean, maximum and minimum.

Table 4.3-1 Heart rate statistics for the age range vs. participant data (participant #1 and participant #2)

Heart Rate (beats per minute)	Age range (50-60 years)	Participant #1	Participant #2
Mean	80-140	158	141
Maximum	170	191	172
Minimum	65	70	66

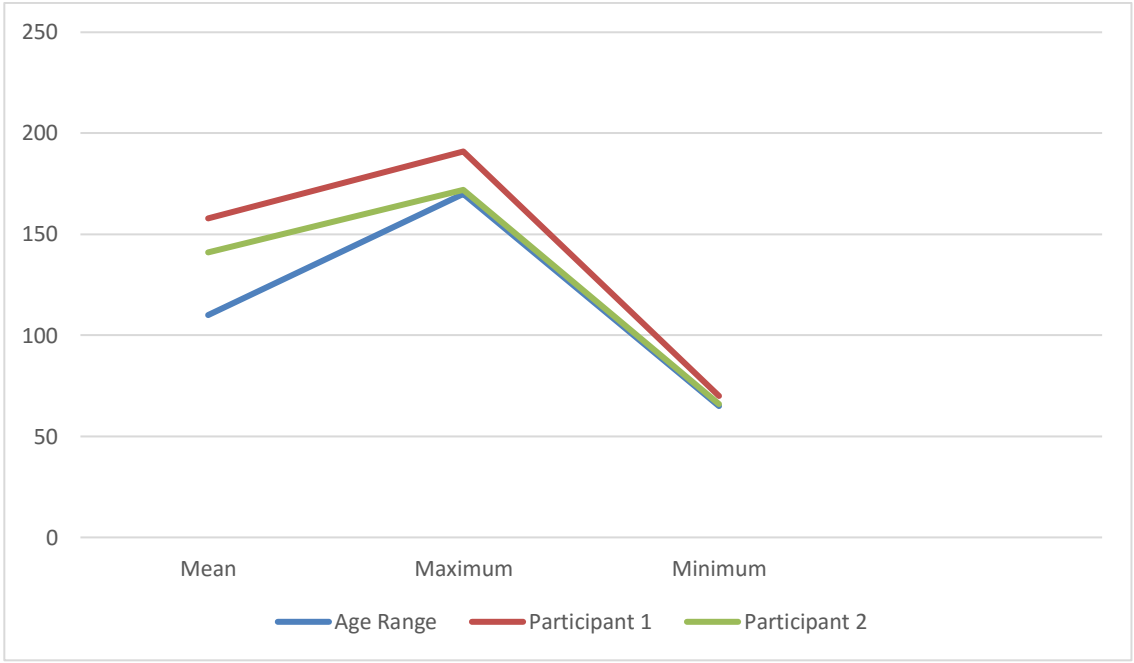

Figure 4.3-4 The graphical view of difference of heart rate values between participant #1, participant #2 and age range for mean, maximum and minimum

The implementation of the threshold or SD range based model would have high chances of getting high false alarms due to the difference between the mean, maximum

and minimum values of participant #1 and participant #2 when compared to the age-based range data.

The proposed model uses the individual data for the interpretation called 'individualised monitoring' and fixed ranges (based on age or gender) only serves as the baseline of the framework. The unique feature of the individualised monitoring module is that its adaptive boundary limits will be changing throughout the monitoring phase. Every 10^{th} recording, or every 10 minutes, the engine updates the limits and compares this with the previous ones so that any considerable changes can be detected. The adaptive limits have an accuracy advantage over the set limits, in cases of diabetes where blood glucose will be high (higher than normal for that particular person) and upon treatment (medication) blood glucose may be normal, this doesn't mean that the patient will always have normal blood glucose from now on.

While set individual limits will detect the confirmed diabetes, it resets the status to normal upon/after medication because no attempt has been made to update/change the set limits. Whereas, the proposed adaptive limits will detect the prediabetes, early diabetes and upon continuous update of the limits, will have a higher accuracy for transient or persistent diabetes detection, if the particular health issue persists in the future for that patient (iterative optimisation).

4.4 Medical Knowledge-base

Medical Knowledge-base (MKB) has become a successful technique for evidence-based systems in this context. Briefly, MKB means retrieving former, already solved problems similar to the current ones and attempt to modify their solutions to fit the current problems. The underlying idea is the assumption that similar problems have similar solutions. Though this assumption is not always true, it holds for many practical

domains. MKB fulfils two main tasks: the first is the retrieval, which means to search for or to calculate the most similar events. If the event base is small, a sequential calculation is possible, otherwise faster non-sequential indexing or classification algorithms are applied. The second task, the adaptation (reuse and revision), means a modification of solutions of former similar events to fit a current one. If there are no important differences (defined by the system) between a current and a similar previous event, a simple solution transfer is sufficient.

The evidence based reasoning module sets the universal (already known) facts as standards and establishes the main association link between the input and the output parameters. The baseline values using MKB was pre-loaded into the system as this functionality and development is huge and complex, thus out of scope of this research.

4.5 Weighted Parameters Mechanism Adopted for the Proposed Model

We adopted the Centre for Disease Control (CDC) Prediabetes Screening Test (US), NICE Diabetes guidelines (UK), Diabetes New Zealand (NZ) and DOIHavePrediabetes.org as our reference screening tool to creating the scoring model.

The globally accepted seven questions (as mentioned in Table 3.6-1) are assigned each "Yes" answer, add the number of points listed. All "No" answers are 0 points.

- Are you a woman who has had a baby weighing more than 9 pounds at birth? (1 point, if yes)
- Do you have a sister or brother with diabetes? (1 point, if yes)
- Do you have a parent with diabetes? (1 point, if yes)

- Find your height on the chart. Do you weigh as much as or more than the weight listed for your height? (5 point, if yes)
- Are you younger than 65 years of age and get little or no exercise in a typical day? (5 point, if yes)
- Are you between 45 and 64 years of age? (5 point, if yes)
- Are you 65 years of age or older? (9 point, if yes)

Additionally, we used the below factors for the point-based analysis (in addition to the above):

- BMI more than 25 (10 points, if yes)
- Heart rate (avg) less than 120 and more than 150 (10 points, if yes, for a 10 mins activity window)
- Breathing rate (avg) less than 20 and more than 40 (10 points, if yes, for a 10 mins activity window)
- Ventilation (avg) less than 35 and more than 40 (10 points, if yes, for a 10 mins activity window)
- Number of steps within a 24 hour period less than equal to 5000 (10 points, if yes)

We excluded the blood glucose and HbA1c due to the fact that, it is highly unlikely to find high blood sugar levels in pre-diabetic (also given the scope of this project using two participants). The abnormal or high HbA1c values are considered only for the confirmed type 2 diabetes, thus, would be considered as part of the diabetes self-management module of the workflow.

4.6 Data Analysis and Processing

4.6.1 Data Processing

The data analysis tasks performed on the raw data, such as: plotting data, computing descriptive statistics, performing linear correlation analysis, data fitting, removing and interpolating missing values, removing outliers, smoothing and filtering and de-trending the data (explained in the following sections).

4.6.2 Removing Missing Values

The missing data has been removed in order to make the data more accurate for the processing. Each row with missing or zero values has been deleted including the time section for the accurate results with respect to time. This removes the activity data, vital signs and other relevant data points for that time for accuracy and meaningful data analysis. As this study deals with two participants, replacing the missing values or zeros with the average values would significantly bias the outputs and overall outcome.

4.6.3 Sampling Data

The raw data collected contains a sampling rate of 10sec to 30sec, which means in one minute the participant data has sample value at every 10 seconds, which is 6 samples in one minute of data, in some files the sampling rate was 30sec, so to have a uniform data throughout, all the data has been sampled at 30sec.

The collected ventilation data value was multiplied by 100 to its original value, so Vent. value was made to its real range for all data by dividing by 100.

4.6.4 Plotting Raw Data

The sample data contains some noise, zero values, missing values and outliers. Figure 4.6-2 shows the raw (noisy) data is plotted in its original state, as collected and received from the wearable sensors. Figure 4.6-1 shows the snap shot of the excel sheet exported from the Hexoskin cloud dashboard. The data points collected are time, breathing rate, minute ventilation, activity, heart rate and cadence.

	time [s/256]	breathing_rate	minute_ventilatior	sleep_position [N/	activity [g](/api/dat	heart_rate [bpm](	cadence [spm](/api/datatype/53/)
2	3.79174E+11			nan			
3	3.79174E+11	10	7861.76	2	0.2890625	70	65
4	3.79174E+11	10	7861.76		0.2890625	70	65
5	3.79174E+11	10	7861.76		0.2890625	70	65
6	3.79174E+11	10	7861.76		0.47265625	70	65
7	3.79174E+11	10	7861.76		0.046875	70	65
8	3.79174E+11	12	7861.76		0.2890625	70	65
9	3.79174E+11	19	9535.04		0.2578125	70	65
10	3.79174E+11	29	9535.04		0.140625	70	65
11	3.79174E+11	34	9535.04		0.04296875	70	65
12	3.79174E+11	35	9535.04		0.1875	119	65
13	3.79174E+11	33	9508.48		0.0859375	117	65
14	3.79174E+11	27	9508.48		0.05859375	116	65
15	3.79174E+11	23	8857.76		0.0390625	116	65
16	3.79174E+11	23	10491.2		0.0390625	109	65
17	3.79174E+11	26	10491.2		0.01953125	108	65
18	3.79174E+11	28	9920.16		0.015625	107	65
19	3.79174E+11	29	9920.16		0.0234375	107	65
20	3.79174E+11	29	10265.44		0.0234375	106	65
21	3.79174E+11	28	10265.44		0.03125	105	65
22	3.79174E+11	28	10265.44		0.02734375	103	65
23	3.79174E+11	28	11434.08		0.01953125	102	65
24	3.79174E+11	28	11434.08		0.015625	101	65
25	3.79174E+11	28	11022.4		0.015625	100	65
26	3.79174E+11	27	11022.4		0.05859375	100	65
27	3.79174E+11	26	11022.4		0.03125	100	65
28	3.79174E+11	26	10624		0.0234375	100	65
29	3.79174E+11	28	10624		0.01953125	99	65
30	3.79174E+11	29	10624		0.1171875	99	65
31	3.79174E+11	29	10624		0.2265625	98	65
32	3.79174E+11	29	16852.32	5	0.140625	98	65
33	3.79174E+11	27	16852.32		0.02734375	98	65
34	3.79174E+11	26	16852.32		0.0234375	98	65
35	3.79174E+11	25	16852.32		0.015625	98	65
36	3.79174E+11	26	16852.32		0.01953125	98	65

Figure 4.6-1 Participant #1 data in exported excel sheet

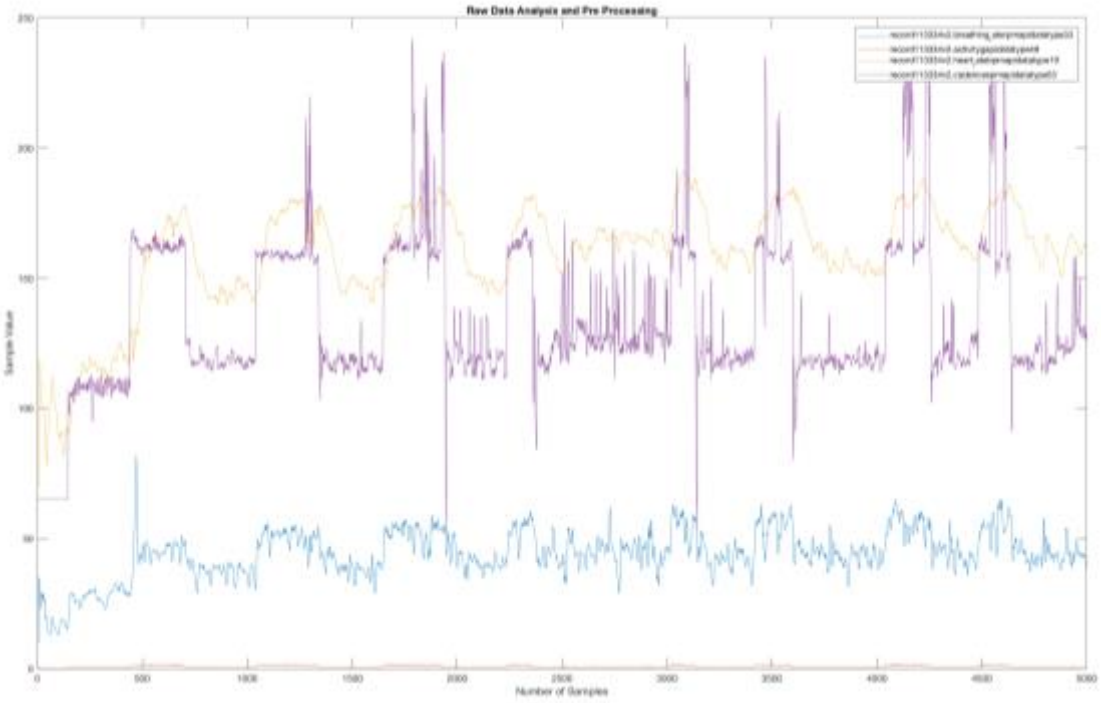

Figure 4.6-2 Participant #1 raw data plotted in Matlab

4.6.5 Calculating Mean and Standard Deviation

Calculating mean of the whole data set (approximately 5000 samples values) and calculating the standard deviation to carry out the data processing.

Matlab command returns the values, where me is the Mean and SD is the standard deviation of HR, Vent. and Breathing respectively.

Matlab algorithm for Mean and Standard Deviation
me = *71.1683 119.5440 25.2603* *st =* *11.7159 22.6697 26.0972*

4.6.6 Checking and Removing Outliers

In the data plot, there are some points that appear to dramatically differ from the rest of the data. In such case, it is reasonable to consider that such points are outliers, or data values that do not appear to be consistent with the rest of the data.

First, we check for any outliers in our data set and if there are any then we remove it. The condition for this data set is that, outliers work only when it is more than 4 STD away from the mean value.

Matlab algorithm for Checking Outliers

```
% checking for outlier
% Outliers works only when it is more than 4 STD away from Mean
[n,p] = size(p1);
% Create a matrix of mean values by replicating the me vector for n rows
MeanMat = repmat(me,n,1);
% Create a matrix of standard deviation values by replicating the sigma vector for n rows
SigmaMat = repmat(st,n,1);
% Create a matrix of zeros and ones, where ones indicate the location of outliers
outliers = abs(p1 - MeanMat) > 4*SigmaMat; (shows the 4 STD condition)
% Calculate the number of outliers in each column
nout = sum(outliers);
```

Matlab command nout for outliers returns these values,

nout =

5 5 0

This means there are 5 outliers in the HR data, 5 in the Ventilation data and none in the breathing data. To remove the entire row of data containing the outlier, Matlab command used is:

P1(any(outliers,2),:) = [];

Same process was carried out for rest of the data sets

4.6.7 Smoothing/Filtering Data

This technique is not applied to all collected data, instead, after initial investigation of the data and by its statistics, the filtering is done on that selected data. Using this moving average filter the data will be smoother. By using the moving-average filter the noise from the raw data is filtered and also the filtered data is further smoothed. The average data signals over a 4-hour window. Matlab function used in this case is;

Matlab algorithm for Smoothing/Filtering the data

```
% Smoothing/Filtering the data
% Moving average filter
a= 1;
b=[1/4 1/4 1/4 1/4];
hr=p1(:,1);
hrfiltered=filter(b,a,hr);
Vent=p1 (:,2);
ventfiltered=filter(b,a,bp);
br=p1 (:,3);
brfiltered=filter(b,a,pv);
```

4.6.8 Comparing Original and Filtered Data

Matlab coding for plotting the comparison of filtered data over original data is;

Matlab algorithm for comparing the original data and the filtered data

```
% comparing the original data and the filtered data
t1 = 1:length(hr);
figure;
subplot (3,1,1); plot (t1,hr,'-.',t1,hrfiltered,'-'),grid on
title('Heart Rate');
legend('Original HR','Filtered HR',2);
xlabel('Number of samples');
ylabel('Value of Samples');
t2 = 1:length(vent);
subplot (3,1,2); plot (t2,vent,'--.',t2,ventfiltered,'--'),grid on
title('Ventilation');
legend('Original vent','Filtered vent',2);
xlabel('Number of samples');
ylabel('Value of Samples');
```

```
t3 = 1:length(br);
subplot (3,1,3); plot (t3,br,'-..',t3,brfiltered,'--'),grid on
title('Breathing Rate');
legend('Original br','Filtered br',2);
xlabel('Number of samples');
ylabel('Value of Samples');
figure;
plot (t3,hr,'-.',t3,hrfiltered,'-*'),grid on
title('Heart Rate');
legend('Original HR','Filtered HR',2);
xlabel('Number of samples');
ylabel('Value of Samples');
figure;
plot (t1,vent,'-.',t1,ventfiltered,'-*'),grid on
title('Ventilation');
legend('Original vent','Filtered vent',2);
xlabel('Number of samples');
ylabel('Value of Samples');
figure;
plot (br,pv,'-.',t2,brfiltered,'-*'),grid on
title('Breathing Rate');
legend('Original br','Filtered br',2);
xlabel('Number of samples');
ylabel('Value of Samples');
```

Apart from the sample code snippets shown above, **APPENDIX G** shows the Matlab code for the various data analysis and processing techniques used in this model.

4.7 Fuzzy Rules

A rule set represents one fuzzy logic rule and performs the preconditioned matching of a rule. The knowledge of a fuzzy rule comes from two sources: one from data analysis and pre-processing (as discussed in the above section) and the other source is from the medical expert/knowledge-base. The optimised rule set is given below, the total number of rules were limited to seven for high accuracy and low noise-error ratio.

1. If (SEX is male) and (FAMILY is No) and (BMI is Normal) and (AGE is 40-50) and (HR is Normal) and (STEPS is 5000+) then (Diagnosis is Normal) (1)

2. If (SEX is Female) and (FAMILY is No) and (BMI is Normal) and (AGE is 40-50) and (HR is Normal) and (STEPS is 5000+) then (Diagnosis is Normal) (1)

3. If (SEX is male) and (FAMILY is yes) and (BMI is Overweight) and (AGE is 51-60) and (HR is High) and (STEPS is 3001_-_5000) then (Diagnosis is Prediabetes) (1)

4. If (SEX is male) and (FAMILY is yes) and (BMI is Obese) and (AGE is 51-60) and (HR is Ver_High) and (STEPS is 3001_-_5000) then (Diagnosis is Prediabetes) (1)

5. If (SEX is male) and (FAMILY is yes) and (BMI is Obese) and (AGE is 61+) and (HR is High) and (STEPS is 0-3000) then (Diagnosis is Prediabetes) (1)

6. If (SEX is Female) and (FAMILY is yes) and (BMI is Obese) and (AGE is 61+) and (HR is Ver_High) and (STEPS is 0-3000) then (Diagnosis is Diabetes_Type_2) (1)

7. If (SEX is male) and (FAMILY is yes) and (BMI is Obese) and (AGE is 61+) and (HR is Ver_High) and (STEPS is 0-3000) then (Diagnosis is Diabetes_Type_2) (1)

Rules are carefully derived from the knowledge source and auto-generated rules from the fuzzy inference rules engine based on the given data set. The rules are interpreted as below:

- SEX – male or female
- Family – covers parents and siblings
- BMI – automatically calculates the BMI using height and weight
- Age – represents the age range for the baseline values
- HR – heart rate
- STEPS – is the number of steps in a 24-hour period
- Diagnosis – the outcome is categorised as normal, prediabetes and diabetes type-II

- (1) – at the end of each rule (1) represents the confirmation that, the number of fuzzy rules equals the number of nonzero ‘Lagrange’ multipliers (to avoid the exponential increase of fuzzy rules with the increase in the inputs)

4.8 Results and Outcomes

4.8.1 Diabetes and Prediabetes Detection

In total, we collected 7.25 hours of data (combined, in multiple sessions), total of 435 minutes of data. We applied 1 minute (60 seconds) sampling window on the 435 samples for moving-window data analysis. The four possible outcome arrangements for an accurate diagnosis are; true positive, true negative, false positive and false negative. Figure 4.8-1 shows the prediabetes detection using adaptive-neuro fuzzy inference model. The (red) highlight shows the model matched the clinical guidelines and global standards for prediabetes for the sample values from 450 to 520 (Partial data sample list is shown in **APPENDIX H**).

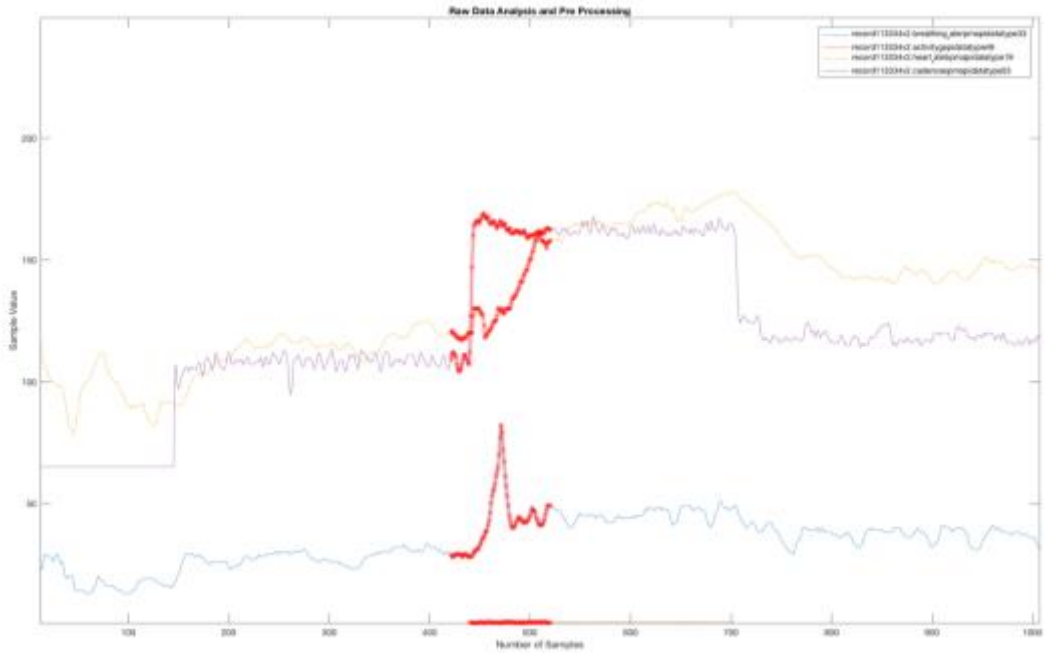

Figure 4.8-1 Prediabetes detection using adaptive-neuro fuzzy inference model. The (red) highlight shows the model matched the clinical guidelines and global standards for prediabetes

Figure 4.8-2 shows the diabetes type 2 detection using adaptive-neuro fuzzy inference model. The (red) highlight shows the model matched the clinical guidelines and global standards for diabetes type 2 for the sample values from 1750 to 2050 (Partial data sample list is shown in **APPENDIX H**).

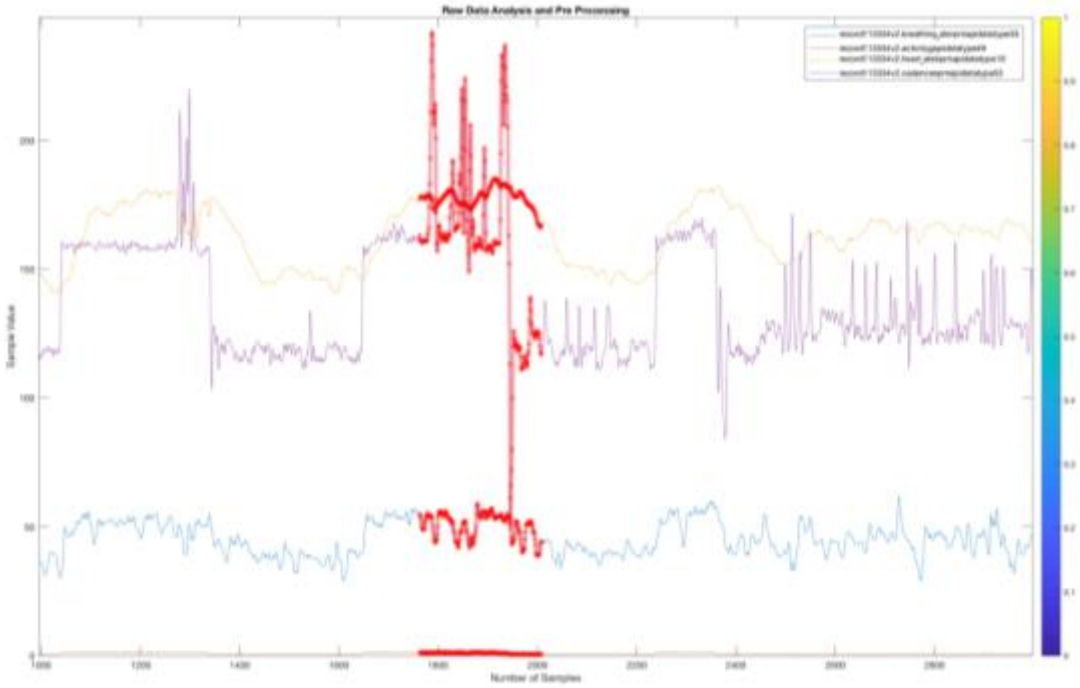

Figure 4.8-2 Diabetes detection using adaptive-neuro fuzzy inference model. The (red) highlight shows the model matched the clinical guidelines and global standards for diabetes type 2

4.8.2 Kappa Analysis

For computing the level of agreement between the clinicians' diagnosis and system diagnosis, the output was divided into four classes. Based on the positive or negative diagnosis generated by the proposed model and the diagnosis by the expert, there were four possible permutations for pre-diabetes diagnosis:

a) Both Model and Expert agree that pre-diabetes exists (TruePOS).

b) Both Model and Expert agree that pre-diabetes does not exist (TrueNEG).

c) Model gives positive diagnosis while Expert gives negative diagnosis (FalsePOS).

d) Model gives negative diagnosis while Expert gives positive diagnosis (FalseNEG).

Using these classifications, the Kappa analysis was performed on the collected data and Table 4.8-1 shows the values for TruePOS, TrueNEG, FalsePOS and FalseNEG derived from the expert analysis as shown in **APPENDIX H**.

Table 4.8-1 Kappa Analysis values for the collected data

	Expert (+ve)	Expert(-ve)	Total
System (+ve)	82 (TP)	32 (FP)	114
System (-ve)	5 (FN)	316 (TN)	321
Total	87	348	435

Based on the data from Table 4.8-1 the sample Kappa analysis is carried out. The calculation shows the positive agreement (P_{pos}) and negative agreement (P_{neg}) indices were calculated as follows.

$$P_{pos} = \frac{82 + 82}{(82 + 32) + (82 + 5)} = 0.82$$

$$P_{neg} = \frac{316 + 316}{(32 + 316) + (5 + 316)} = 0.94$$

The third index of agreement gives the overall agreement (P_o) level between the expert and the proposed model.

$$P_o = \frac{82 + 316}{435} = 0.91$$

$$P_e = \left(\frac{114}{435}.\frac{87}{435}\right) + \left(\frac{321}{435}.\frac{348}{435}\right) = 0.64$$

Agreements between the two diagnoses may be affected by chance. Kappa (k) is a measurement of agreement between the expert and the model which has been corrected for error by chance. Kappa (k) is calculated by subtracting the proportion of readings that are expected to agree by chance (P_e) from the overall agreement (P_o) and dividing the remainder by the number of cases on which agreement is not expected to occur by chance.

$$K = \frac{P_o - P_e}{(1 - P_e)} = 0.75$$

The standard error (SE) of k is,

$$SE = \sqrt{\frac{P_o(1 - P_o)}{n(1 - P_e)^2}}$$

$$SE = \sqrt{\frac{0.91(1 - 0.91)}{435(1 - 0.64)^2}} = 0.038$$

The 95% confidence intervals (CIs) for k could be calculated with the following equation.

$$CI_{95\%} = K \pm 1.96 \times SE$$

CIs for k were

a) 0.75 + 1.96 * 0.038 = 0.82 , and

b) 0.75 - 1.96 * 0.038 = 0.67

Table 4.8-2 Kappa analysis of the whole collected dataset

Overall Agreement	Positive Agreement	Negative Agreement	Agreement by Chance	Standard Error	95% Confidence Intervals for K
P_o	P_{pos}	P_{neg}	P_e	SE	$CI_{95\%}$
0.91	0.82	0.94	0.64	0.038	0.82 and 0.67

The overall Kappa value was K = 0.75, Table 4.8-3 shows the K-values expressed as strength of agreement.

Table 4.8-3 K-values expressed as strength of agreement

K – Value	Strength of Agreement beyond chance
<0	Poor
0 - 0.2	Slight
0.21 – 0.40	Fair
0.41 – 0.6	Moderate
0.61 – 0.8	Substantial
0.81 - 1	Almost perfect

For the tests (retrospective analysis) performed, the Kappa based statistical analysis showed substantial level of agreement (k = 0.75) between the experts' and system's diagnoses as shown in Table 4.8-3.

The proposed system has been successfully tested. The initial result shows the higher efficiency and accuracy in wearable monitoring system with the K value of 0.75 (Table 4.8-2). The performance results of the system (k value) placed the overall performance of the detection model at a substantial level (Table 4.8-3).

After the determination of the described overall agreement, quantitative categories like sensitivity, specificity and predictability is also calculated:

$$Accuracy = \sum \frac{True\ Positive + True\ Negative}{True\ Positive + True\ Negative + False\ Positive + \ False\ Negative}$$

$$Sensitivity = \sum \frac{True\ Positive\ Alarms}{True\ Positive\ Alarms + False\ Negative\ Alarms}$$

$$Specificity = \sum \frac{True\ Negative\ Alarms}{True\ Negative\ Alarms + False\ Positive\ Alarms}$$

$$Predictability\ = \sum \frac{True\ Positive\ Alarms}{True\ Positive\ Alarms + False\ Positive\ Alarms}$$

From the above equations, it has been calculated that the detection model has an accuracy of 91.49%, sensitivity of 94%, specificity of 90% and predictability of 72%.

4.9 Summary

In this chapter, selection of wearable monitoring system was reported as this was one of the critical block of this research – to collected multiple data sets accurately in real-time. The data analysis, pre-processing, fuzzy logic model and results were also described. The unique feature of the developed model is the capability to self-adjust the baseline-values by ‘individualised monitoring’ and ‘weighted parameter’ to gain high accuracy and overall reliability.

CHAPTER 5 Discussion

5.1 Overview

The use of automated monitoring and detection systems in clinical care can improve quality of care as well as efficiency in healthcare delivery. With the advancement of wireless sensor technologies, the wearable monitoring systems becomes much accurate, advanced and cheaper than before [151]. Wearable monitoring system used in this research is an advanced-sensors integrated vest with Bluetooth connected mobile app and a cloud-based web dashboard to access your data in real-time. There is a huge potential for such systems to be utilised in clinical care settings (inpatient) as well community care settings, including home care for remote patient monitoring [151, 152].

The proposed early detection model could be customised to suit the most common chronic diseases and long-term conditions encountered in New Zealand population. This research work will yield a highly-specialised model that has the potential to lower the LTC rates of the nation's population due to automated, accurate and early detection of prediabetes. This research was aimed to evaluate and develop an intelligent detection model using multiple data sets; activity data, vital signs and demographic data for early detection of prediabetes. It was also aimed to improve the performance of current LTC programs by identifying the shortfalls of existing technology and barriers.

Three main concepts have been addressed in this thesis: wearable monitoring, development of detection model using multiple data sets and early detection of prediabetes and diabetes type-II. This section serves to present the major conclusions of this thesis. It summarises important concepts and justifies the adopted methods.

5.2 Timeline View of the Participants' Diabetes Profile

The timeline view of the HbA1c of the participant #1 is illustrated in Figure 5.2-1, shows the HbA1c values taken at the start of the study, during the study and at the end of the study with poor management. Participant #1 was not using any technology (wearable) or tool to self-manage diabetes type-II (Participant #1 was on the usual diabetes management treatment as prescribed by the participant's General Practitioner).

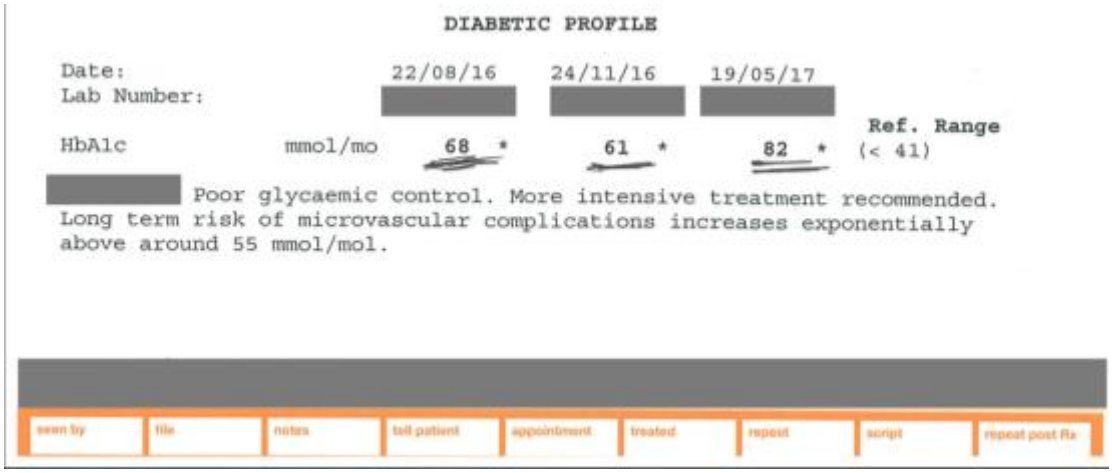

Figure 5.2-1 Participant #1 HbA1c profile showing the values before, during and after the study

Figure 5.2-2 shows the HbA1c values taken at the start of the study and Figure 5.2-3 shows the HbA1c values taken at the end of the study from participant #2, shows an excellent control and self-management of diabetes. Participant #2 was using the wearable vest, mobile apps/tools to self-manage the diabetes and was registered for the online patient portal (Participant #2 was also on the usual diabetes management treatment as prescribed by the participant's General Practitioner).

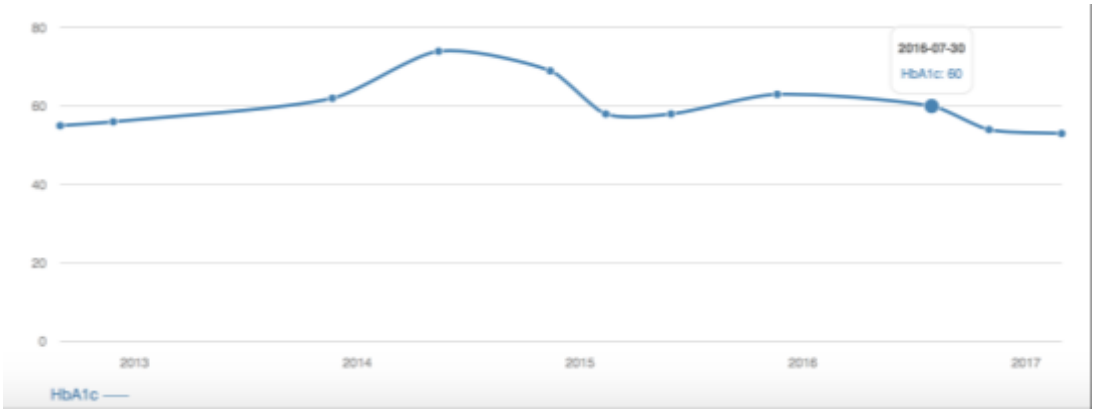

Figure 5.2-2 Participant #2 HbA1c profile showing the values recorded at the start of the study

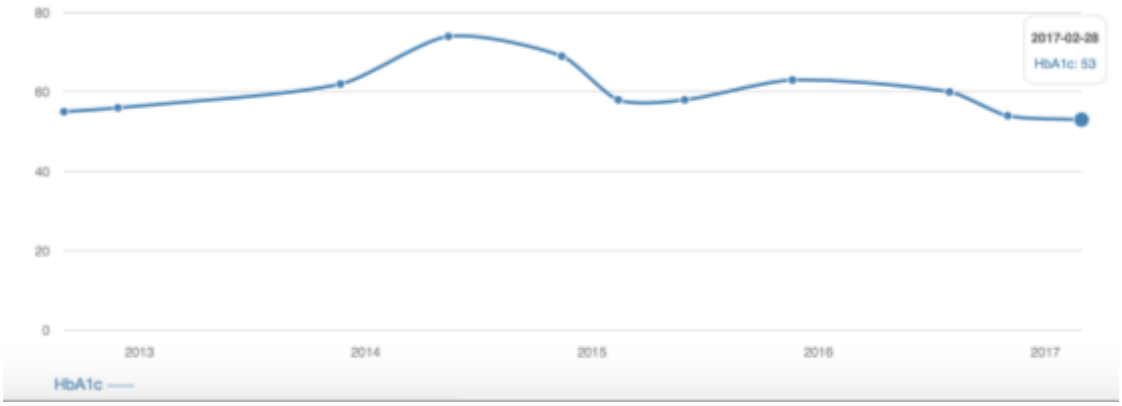

Figure 5.2-3 Participant #2 HbA1c profile showing the values recorded towards the end of the study

5.3 Major Learning Outcomes

Some of the important areas covered in this research are:

- ***Literature Review:*** This research is backed by literature review, theory building and observations to understand and establish the current research gaps. Due to the wear-ability, the issue of accuracy and power is the most identified, followed by the comfort and usability. There is a growing evidence available that identifies the user (clinician and/or patient) acceptance is also equally important and should be addressed. Currently, there is no balance between the

technical design and development vs information presentation, which could be a reason delaying the global adoption of wearable healthcare application in acute care, outpatient, home and community care settings (see section 2.2 and 3.2).

- ***Data Collection:*** Data collection phase of this research was very critical for the overall success of the proposed model. We obtained ethics approval and other related requirements to collect data. The understanding of wearable monitoring shirt/vest was challenging and time taking due to the complex integration and access to the data. Accurate data collection using wearable shirt with integrated sensors and visualising the collected data in real-time for errors was a good learning curve. The data accuracy was one of the highest priority, as the collected data will be fed to the model (after pre-processing due to the noise and missing values) (see section 4.2).
- ***Clinical Knowledge and Interpretation:*** Deep understanding of the medical side of this project work was curtailed to map the data with its associated outcome. The clinical knowledge support was gathered from the authentic medical knowledge-bases and clinicians (experts) from Auckland District Health Board. The most important data points to collect, data points with most influence on the person's diabetes, time of data collection, duration, frequency and observational data to support the proposed model was challenging and sensitive to handle the participant health data (see section 3.3, 3.4, 3.5 and 3.6).
- ***Detection Model:*** Fuzzy logic has been studied for the development of the proposed detection model. The important areas in fuzzy logic that were investigated are ANFIS, FIS, clustering, and different types of fuzzy models. The individualised monitoring and weighted parameter mechanism proved to be accurate in detecting prediabetes and diabetes type 2 (see section 4.3, 4.6 and 4.7).

5.4 Outline of Outcomes Achieved

5.4.1 Results Analysis

The collected data is mapped against the pre-build LTC models and approved clinical guidelines for known LTCs. The proposed model is compared with a clinician's finding using 'Kappa' analysis. Kappa measures and allows the agreement between the human expert and the computer system (i.e. a machine learning model) using the true positive, true negative, false positive and false negative measures. The importance of observer reliability lies in the fact that it represents the extent to which the data collected in the study are correct representations of the variables measured.

5.4.2 Data Mapping and Interpretation

The existing clinical models, LTC guidelines/checklists and known LTC data is mapped to the collected data. The model mapped the input required to the intended outcome/diagnosis using weighted parameter mechanism (see section 4.5). The data interpretation was developed using the age-based range to set the baseline values. The individual data trends were used to further refine the baseline values as well as the overall threshold model for detection prediabetes and diabetes type 2. This research aims to leverage the success of the IoT, wireless, remote and body-wearable technology for accurate and continuous patient monitoring.

5.5 Challenges and Limitations

Below are some of the challenges and limitations identified in this research:

- Wearable monitoring systems lack holistic approach in healthcare – Majority of systems are heavily focused on the technical considerations to make it a clinical success and thus, failing the clinical acceptance. The negligence of the wider

integration of clinical and non-clinical data is making such applications under-utilised and limited to a specific use-case only.

- It is evident from the literature that there is a clear gap in detecting LTCs using computerised detection model. It is also evident in the literature that the early detection of LTC can reverse or delay the onset of LTC significantly. Thus, there is an immediate need of an automated pre-LTC detection model to serve as a global framework, standard protocol or guideline in order to reduce LTCs.

- Data was limited to two participants due to the time and resource of this research. However, the developed model is capable to detect prediabetes and diabetes type 2 with any number of participant data.

- The complexity of 'big data' computation requires significant amount of processing power during data analysis and also at the time of processing/executing the complex algorithms/models. These complex models are beyond the capabilities of the current wearable monitoring systems to support point-of-care delivery.

- The self-management of diabetes type 2 was covered in this research, but to prove its success, further 6-12 month of monitoring is required to see the participant's activity level, vital signs and diabetes profile/control using wearable shirt and detection model. The model will then be able to compare the initial trend vs data trends at 6 or 12 months to establish the success of self-management of diabetes type 2.

CHAPTER 6 Conclusion

The early detection model tested in this investigation is not designed to replace clinicians, but rather to assist them in making better and informed decisions by rapidly processing the vast amount of information available from wearables/sensors, and to convey this information in a meaningful manner so that rapid intervention can occur.

6.1 Overview of the Wearable Monitoring Systems

Wearable monitoring systems (WMS) for people with single or multiple LTCs are getting good clinical acceptance due to versatile nature of the connectivity with the individual. It gives the individual freedom and flexibility while they are monitored. Very few studies have reported a high percentage of acceptances for wearable monitoring systems mainly due to its low-invasive nature and non-interference in their normal daily activities. A study by Bergmann and McGregor reported that 93% of patients in an elderly care facility accepted the wearable system, because of its low invasiveness and its non-interference with their normal daily life activities [153].

A recent study [151] reviewed 20 wearable monitoring systems by selecting peer reviewed articles published between 2015 to 2017 in order to evaluate the technological advancements, implementation of advanced sensors and data collection techniques. The design concepts of wearable systems, identified key specifications and parameters such as sensors and signals, data processing, integration, signal quality and user-engagement and user-interaction that require attention are highlighted (addressed in this research, see section 2.2) [151].

With the ever growing use of WMSs, end-user acceptability is becoming an important aspect of the design of such systems. The acceptance of any system in the healthcare

domain depends on user-awareness, as well as clinician and patient acceptance. Data connectivity is one of the main drawbacks of deployed WPM systems where patients are ‘constrained’ within fixed spaces fitted with monitoring devices within small Bluetooth range [31, 94, 109, 154, 155].

6.2 Detection and Prediction Models

A marked change in healthcare delivery is occurring which has been made possible by the ever-growing prediction and detection using machine learning models. Such models are supported by the technological revolution and advancements in wearables, medical devices, consumer devices, the Internet of Things (IoT), and the potential of employing machine learning and artificial intelligence to the ‘big data’. The treatment of many medical conditions are guaranteed to benefit from the use of wearable technology [90].

Validation of clinical and scientific findings is an important task to take on in this new context. The determination of repeatability and reliability of the new assessment tools based on wearable technologies and the IoT remains challenging. Likewise, the extent to which these new methods of diagnosing and treatment will replace or complement the existing assessment, therapeutic tools and detection/prediction models is a wide open topic for experimentation and to debate in the global healthcare community [89, 94].

In conclusion, the advancement of wearable technology and possibilities of using artificial intelligence in healthcare is a concept that has been investigated by many studies but lack in chronic care or long-term conditions. The outcome of this research shows the future LTCs monitoring and its medical treatments will build upon efficient and affordable solutions of predictive modelling integrated with wearable/IoT technology.

6.3 Key Highlights/Achievements of this Research

The overall aim of this research was to design and develop a novel, automated LTC detection model using multiple data sources; vital signs, activity data and demographic data. The specific objectives achieved in this research are:

a) Identification of the important factors in improving the accuracy of computerised early detection of long-term condition (prediabetes and diabetes type-II)

b) Evaluation of vital signs and activity data towards a reliable detection of various long-term conditions

c) Analysis of the collected data and to map it with the clinical checklist for accurately detecting multiple pre-long-term conditions

d) Investigating the effective factors for individualised long-term condition detection and accuracy of the detection using weighted parameter approach

6.4 Future Work

It is forecasted that the healthcare information will be available on to the cloud where pieces of observations from various ubiquitous devices (including wearables) would be integrated. Furthermore, data analytics and machine learning techniques could be applied to the collected data for precise care, accurate outcomes and individualised treatment (precision medicine) [156, 157]. This research is the first step toward the forecasted future of healthcare journey.

This research supports the effectiveness of artificial intelligence (fuzzy logic) in patient monitoring and detection of LTC. The model is tested in a real-time environment to

show its full clinical worth with two participants. Testing this model with diverse and large number of participants would surely increase the accuracy and reliability of the model.

Further enhancements to the early detection model will mature the current application to better handle the clinical care environment. Extending the current detection model to other common long-term conditions would be beneficial.

Some of the areas to make further improvements are accuracy in data collection, integration of clinical and non-clinical data sources and real-time detection using a mobile device are some of the future works identified.

As stated in the introduction of this thesis, the research presented here sits at the intersection of a number of domains. The potential for further research in related areas is therefore enormous. The above paragraphs outline the possibilities ranging from theoretical to practical innovations. However, the research presented in this thesis would be an investigation of other suitable approaches applied to wearable monitoring and LTC detection, as a deep knowledge representation.

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Appendix A – Ethics Approval Letter

AUTEC Secretariat

Auckland University of Technology
D-88, WU406 Level 4 WU Building City Campus
T: +64 9 921 9999 ext. 8316
E: ethics@aut.ac.nz
www.aut.ac.nz/researchethics

14 November 2016

Mirza Baig
Faculty of Design and Creative Technologies

Dear Mirza

Re Ethics Application: **16/412 Wearable patient monitoring system**

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 10 November 2019.

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 10 November 2019;
- 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 10 November 2019 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: Hamid Gholam Hosseini; Farhaan Mirza

Appendix B – Participant Information Sheet (Page 1 of 2)

Participant Information Sheet

AUT
TE WĀNANGA ARONUI O TĀMAKI MAKAU RAU

Date Information Sheet Produced:

14 November 2016

Project Title

Wearable Patient Monitoring System

An Invitation

Hello, I am a research officer at AUT working on the health and well-being research. You are invited to take part in a study that is part of the data collection for analysing the early detection of any pre-conditions for respiratory and cardiac related problems heart rate, heart rate variability, breathing rate, breathing volume, activity (steps, cadence and calories), and height, weight, age and sex - using the wearable system (wearable vest). The collected information will be analysed and compared against the standard trends and guidelines to early detect (if any) pre-conditions.

What is the purpose of this research?

The purpose of this research is to collect the above information and process it to gain further insights from the data for any possibility of pre-condition of respiratory and cardiac related health issues, by combining the vital signs and activity data.

How was I identified and why am I being invited to participate in this research?

This research aims to help the monitoring and health and well-being of the adults, which helps us determine the health impact (if any) on the individual's pre-conditions of respiratory and cardiac conditions as well as self-management of any long-term condition.

What data is being collected?

Using the wearable vest this research will collect heart rate, heart rate variability, breathig rate, breathing volume, activity (steps, cadence and calories). Also, height, weight, age and sex will be collected manually only once for data analysis purposes.

About the Wearable Vest

The wearable vest is provided by Hexoskin. The vest is similar to the t-shirt which will be worn by you (same as a shirt or a t-shirt, made by fine Italian fabric for maximum comfort) for the data collection. Once the data collection session is completed, the participant needs to return the vest to the researcher and/or the research team either by the agreed time/ date or by appointment.

The vest must be returned at the end of the study.

How the discovery of the any health conditions will be communicated to you?

Should any information indicating that any medical concern, then we will immediately inform you and advice you to see your general practitioner/ family doctor.

How do I agree to participate in this research?

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you in anyway. You are able to withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

What will happen in this research?

You are requested to wear a wearable vest (with integrated sensors to collect the data) while you perform the activity of daily life. We aim to collect a maximum of 4 hours of data from you (not necessary to be in single session).

What are the discomforts and risks?

There are no discomfort and risk involved in this study.

Appendix C – Participant Information Sheet (Page 2 of 2)

How will my privacy be protected?

No material which could identify you personally will be used in any reports on this study. Records are stored in a locked cabinet and within a secure computer server.

What are the costs of participating in this research?

There is no cost involved for participating in this project, but we appreciate your time and willingness towards this project.

What opportunity do I have to consider this invitation?

Your participation is entirely voluntary (your choice) and whether or not you choose to participate will neither advantage nor disadvantage you in anyway. If you do agree to take part you are free to withdraw for the study at any time, without having to give a reason and this will not affect your standard entitlements (for example, entitlements to health and disability care).

Will I receive feedback on the results of this research?

Yes, the summary of the research finding will be made available to you and the results from this research will be published in a scientific journal and other academic publications and presentations. No individual will be identified. There will be no reference to you or your name in any publications.

Can I get my data and summary of research results?

Yes, we can give you your data in an easily readable format (excel sheet). If you wish to receive a summary of the research findings and/or your personal data, please tick yes on the consent form and we will provide you with the summary of the research finding and your data via email at the end of the study.

Inclusion and Exclusion Criteria

Healthy participants, 16 years and over are included in this study and participants who cannot give their own consent and participants with known medical condition or any skin allergy which may restrict the participation are excluded.

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, Dr. Mirza Baig, mirza.baig@aut.ac.nz 921 9999 ext 8755.

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?

Please keep this Information Sheet and a copy of the Consent Form for your future reference. You are also able to contact the research team as follows:

Researcher Contact Details:

Mirza Mansoor Baig, mbaig@aut.ac.nz

Project Supervisor Contact Details:

Dr Hamid GholamHosseini, hgholamh@aut.ac.nz and Dr Farhaan Mirza, farhaan.mirza@aut.ac.nz

Approved by the Auckland University of Technology Ethics Committee on *14 November 2016*, AUTEC Reference number *16/412*.

Appendix D – Consent Form

AUT
TE WĀNANGA ARONUI O TĀMAKI MAKAU RAU

Consent Form

Project title: ***Wearable Patient Monitoring System***

Researcher: ***Dr Mirza Baig, PhD***

- ○ I have read and understood the information provided about this research project in the Information Sheet dated 14 November 2016.
- ○ I have had an opportunity to ask questions and to have them answered.
- ○ I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without being disadvantaged in any way.
- ○ I understand that if I withdraw from the study then I will be offered the choice between having any data or tissue that is identifiable as belonging to me removed or allowing it to continue to be used. However, once the findings have been produced, removal of my data may not be possible.
- ○ I do not have any skin allergies or any known medical condition which may restrict me from taking part in this research.
- ○ I agree to take part in this research.
- ○ I wish to receive a summary of the research findings (please tick one): Yes○ No○
- ○ I wish to receive my personal data summary (please tick one): Yes○ No○

Participant's signature: .....

Participant's name: .....

Participant's Contact Details (if appropriate):

.....

.....

.....

.....

Date:

Approved by the Auckland University of Technology Ethics Committee on 14 November 2016 AUTEC Reference number 16/412

Note: The Participant should retain a copy of this form

Appendix E – Participant Advertisement Sheet

AUT
TE WĀNANGA ARONUI O TĀMAKI MAKAU RAU

A Research Study on Wearable Patient Monitoring

School of Engineering, Computer and Mathematical Sciences, Auckland University of Technology

Research Summary

You are invited to take part in a study that is part of the data collection for analysing the early detection of any pre-conditions for respiratory and cardiac related problems heart rate, heart rate variability, breathing rate, breathing volume, activity (steps, cadence and calories), and height, weight, age and sex - using the wearable system (wearable vest). The collected information will be analysed and compared against the standard trends and guidelines to early detect (if any) pre-conditions.

Who is Eligible?

- Healthy participants,
- 16 years and over
- No skin allergy and known medical condition

What will you be asked to do?

Wear the vest (with integrated sensors) and perform your activities of daily life for data collection. Vest will collect heart rate, heart rate variability, breathing rate, breathing volume, activity (steps, cadence and calories). Additionally, height, weight, age and sex will also be collected manually.

Risk Involved?

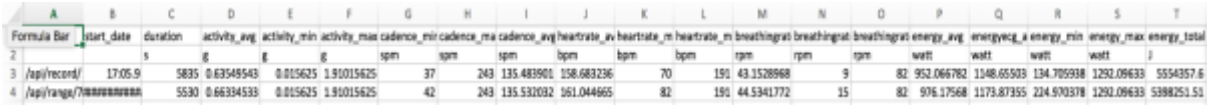
There is no risk involved as the wearable vest is a market available and widely used product, made up of highest grade Italian fabric (textile) for maximum comfort (similar to a t-shirt or a shirt).

If you have any questions or are interested in participating, please contact:

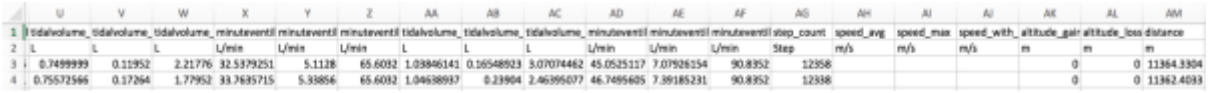
Dr Mirza Baig, PhD, Level 3, WU Building, City Campus, Auckland, AUT or Email: mirza.baig@aut.ac.nz or +64 9 921 9999 Ext. 8755

Approved by the Auckland University of Technology Ethics Committee on *14 November 2016*, AUTEC Reference number *16/412*.

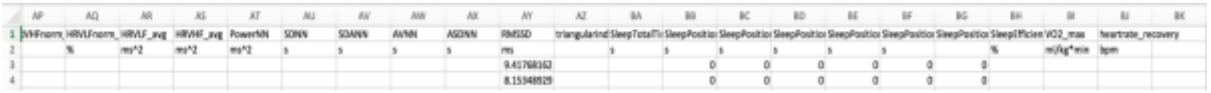
Appendix F – Statistics for all Collected Variables



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
1	Formula Bar	start_date	duration	activity_avg	activity_min	activity_max	cadence_min	cadence_ma	cadence_avg	heartrate_av	heartrate_m	heartrate_m	breathingrat	breathingrat	breathingrat	energy_avg	energycg_a	energy_min	energy_max	energy_total
2			s	g	g	g	spm	spm	spm	bpm	bpm	bpm	rpm	rpm	rpm	watt	watt	watt	watt	J
3	/api/record/	17:05.9	5835	0.63549543	0.015625	1.91015625	37	243	135.483901	158.683236	70	191	43.1528968	9	82	952.066782	1148.65503	134.705938	1292.09633	5554357.6
4	/api/range/7		5530	0.66334533	0.015625	1.91015625	42	243	135.532032	161.044665	82	191	44.5341772	15	82	976.17568	1173.87355	224.970378	1292.09633	5398251.51



	U	V	W	X	Y	Z	AA	AB	AC	AD	AE	AF	AG	AH	AI	AJ	AK	AL	AM
1	tidalvolume_	tidalvolume_	tidalvolume_	minuteventil	minuteventil	minuteventil	tidalvolume_	tidalvolume_	tidalvolume_	minuteventil	minuteventil	minuteventil	step_count	speed_avg	speed_max	speed_with_	altitude_gair	altitude_loss	distance
2	L	L	L	L/min	L/min	L/min	L	L	L	L/min	L/min	L/min	Step	m/s	m/s	m/s	m	m	m
3	0.7499999	0.11952	2.21776	32.5379251	5.1128	65.6032	1.03846141	0.16548923	3.07074462	45.0525117	7.07926154	90.8352	12358				0	0	11364.3304
4	0.75572566	0.17264	1.77952	33.7635715	5.33856	65.6032	1.04638937	0.23904	2.46395077	46.7495605	7.39185231	90.8352	12338				0	0	11362.4033



	AP	AQ	AR	AS	AT	AU	AV	AW	AX	AY	AZ	BA	BB	BC	BD	BE	BF	BG	BH	BI	BJ	BK
1	dVHFnorm	HRVLFnorm	HRVLF_avg	HRVHF_avg	PowerNN	SDNN	SDANN	AVNN	ASDNN	RMSSD	triangularind	SleepTotalTi	SleepPositio	SleepPositio	SleepPositio	SleepPositio	SleepPositio	SleepPositio	SleepEfficie	VO2_max	heartrate_recovery	
2		%	ms^2	ms^2	ms^2	s	s	s	s	ms		s	s	s	s	s	s	s	%	ml/kg*min	bpm	
3										9.41768162			0	0	0	0	0	0				
4										8.15348829			0	0	0	0	0	0				

Appendix G – Sample Matlab Code

```
gui_Singleton = 1;
gui_State = struct('gui_Name',       mfilename, ...
                   'gui_Singleton',  gui_Singleton, ...
                   'gui_OpeningFcn', @untitled_OpeningFcn, ...
                   'gui_OutputFcn',  @untitled_OutputFcn, ...
                   'gui_LayoutFcn',  [] , ...
                   'gui_Callback',   []);
if nargin && ischar(varargin{1})
    gui_State.gui_Callback = str2func(varargin{1});
end

if nargout
    [varargout{1:nargout}] = gui_mainfcn(gui_State, varargin{:});
else
    gui_mainfcn(gui_State, varargin{:});
end
% End initialization code - DO NOT EDIT


% --- Executes just before untitled is made visible.
function untitled_OpeningFcn(hObject, eventdata, handles, varargin)
% This function has no output args, see OutputFcn.
% hObject    handle to figure
% eventdata  reserved - to be defined in a future version of MATLAB
% handles    structure with handles and user data (see GUIDATA)
% varargin   command line arguments to untitled (see VARARGIN)

% Choose default command line output for untitled
handles.output = hObject;

% Update handles structure
guidata(hObject, handles);

% UIWAIT makes untitled wait for user response (see UIRESUME)
% uiwait(handles.figure1);


% --- Outputs from this function are returned to the command line.
function varargout = untitled_OutputFcn(hObject, eventdata, handles)
% varargout  cell array for returning output args (see VARARGOUT);
% hObject    handle to figure
% eventdata  reserved - to be defined in a future version of MATLAB
% handles    structure with handles and user data (see GUIDATA)

% Get default command line output from handles structure
varargout{1} = handles.output;

function createfigure(YMatrix1)
%CREATEFIGURE(YMATRIX1)
%  YMATRIX1:  matrix of y data

% Create figure
figure1 = figure;

% Create axes
axes1 = axes('Parent',figure1);
hold(axes1,'on');

% Create multiple lines using matrix input to plot
plot1 = plot(YMatrix1,'Parent',axes1);
set(plot1(1),'DisplayName','record113334v2.breathing_raterpmapidatatype33');
set(plot1(2),'DisplayName','record113334v2.activitygapidatatype49');
set(plot1(3),'DisplayName','record113334v2.heart_ratebpmapidatatype19');
set(plot1(4),'DisplayName','record113334v2.cadencespmapidatatype53');

% Create xlabel
xlabel({'Number of Samples'});

% Create title
title({'Raw Data Analysis and Pre Processing'});

% Create ylabel
ylabel({'Sample Value'});

box(axes1,'on');
% Create legend
```

```
legend(axes1,'show');
% Create figure
figure1 = figure;

% Create axes
axes1 = axes('Parent',figure1);
hold(axes1,'on');

% Create multiple lines using matrix input to plot
plot1 = plot(YMatrix1,'Parent',axes1);
set(plot1(1),'DisplayName','record113334v2.breathing_raterpmapidatatype33');
set(plot1(2),'DisplayName','record113334v2.activitygapidatatype49');
set(plot1(3),'DisplayName','record113334v2.heart_ratebpmapidatatype19');
set(plot1(4),'DisplayName','record113334v2.cadencespmapidatatype53');

% Create xlabel
xlabel({'Number of Samples'});

% Create title
title({'Raw Data Analysis and Pre Processing'});

% Create ylabel
ylabel({'Sample Value'});

% Uncomment the following line to preserve the X-limits of the axes
% xlim(axes1,[995.088868101029 2996.95977549111]);
% Uncomment the following line to preserve the Y-limits of the axes
% ylim(axes1,[0 247.742052023121]);
box(axes1,'on');
% Create legend
legend(axes1,'show');

% Create colorbar
colorbar('peer',axes1);
```

Appendix H – Kappa Analysis for Complete Data Set

PROPOSED DETECTION MODEL					AGREEMENT		DISAREEMENT	
Time	Expert Diagnosis	NORM-AL	PRE-DIABETES	DIABETES TYPE-2	TRUE POS FLMS +ve Expert +ve	TRUE NEG FLMS -ve Expert -ve	FALSE POS FLMS +ve Expert - ve	FALSE NEG FLMS - ve Expert +ve
00								
15								
30								
45								
00								
15	N	P					1	
30	N					1		
45	N					1		
00	N					1		
15	N					1		
30	N					1		
45	N					1		
00	N					1		
15	N					1		
30	N					1		
45								
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00								
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30								
45	N					1		
00	N					1		
15	N					1		
30	N					1		
45	N					1		
00	N					1		
15	N					1		
30	N	P					1	
45	N					1		
00	N					1		
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30	N					1		
45								
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30	N					1		
45	N					1		
00	N					1		
15	N					1		
30	N					1		
45	N	P					1	
00	N	P					1	

15	N					1		
30	P		P	P	1			
45	P			P	1			
00	P			P	1			
15	P			P	1			
30	P		P	P	1			
45	P	P	P		1			
00	P	P			1			
15	P							1
30	N					1		
45	N					1		
00	P							1
15	N					1		
30	P	P	P		1			
45	P		P		1			
00	P		P		1			
15	P		P		1			
30	N					1		
45	N					1		
15	N					1		
30	N					1		
45	N					1		
00	N					1		
15	N					1		
30	N					1		

45	N					1		
00	N					1		
15	P		P		1			
30	N		P				1	
45	N		P				1	
00	N					1		
15	N					1		
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45	N					1		
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15	N					1		
30	N					1		
45	P		P		1			
00	P			P	1			
15	P		P		1			
30	P		P		1			
45	P	P			1			
00		P					1	
15			P					
					82	316	32	5

*N is negative, P is positive, 1 represents agreement for either true positive, true negative, false positive or false with respect to the table column and this is not the full list of the data analysis as is very long with approximately 25,000 rows, if exported in excel sheet or table.