Smart Vital Signs Monitoring and Novel Falls Prediction System for Older Adults

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List of Abbreviations

ADLs	Activities of Daily Living
ANFIS	Adaptive Neuro Fuzzy Inference System
ANN	Artificial Neural Networks
ARDS	Acute Respiratory Distress Syndrome
B Glu	Blood Glucose Level
BAN	Body Area Network
BP	Blood Pressure
BT	Bluetooth
CDSS	Clinical Decision Support System
Dia	Diastolic Blood Pressure
DICOM	Digital Imaging and Communications in Medicine
DST	Dempster-Shafer Theory
EBR	Evidence Based Reasoning
ECG	Electrocardiography
EWS	Early Warning Score
FCM	Fuzzy C-Means Clustering
FIS	Fuzzy Inference System
FKM	Fuzzy K-Means Clustering
FLMS	Fuzzy Logic Monitoring System
GPRS	General Packet Radio Service
GPS	Global Positioning System
GSM	Global System for Mobile
GUI	Graphical User Interface
H	High
EHR	Electronic Health Record
HFRM-II	Hendrich Falls Risk Model II
HMS	Health Monitoring System
HR	Heart Rate
I/O	Input/Output
ICO_2	Inspired (inhaled) Carbon-Dioxide
ICU	Intensive Care Unit

J2ME	Java Platform, Micro Edition
K	Kappa value
L	Low
LAN	Local Area Network
MAN	Metropolitan Area Network
MF	Membership Function
MFS	Morse Fall Scale
MHMS	Mobile Health Monitoring System
mmHg	Millimetres of mercury
OT	Operating Theatre
P	Pulse
P1/P2	Priority – 1/ Priority - 2
PAN	Personal Area Network
Pleth	Plethysmography
PMS	Patient Monitoring System
PPG	Photoplethysmography
RFID	Radio Frequency Identification
RHMS	Remote Health Monitoring System
RR	Respiratory Rate
SD	Standard Deviation
SHMS	Smart Health Monitoring System
SpO2	Oxygen Saturation
Sys	Systolic Blood Pressure
Temp. or T	Tympanic Ear Temperature
VH	Very High
VL	Very Low
VSMS	Vital Signs Monitoring System
WAN	Wide Area Network
WHMS	Wearable Health Monitoring System

Attestation of Authorship

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

Signed: ………………..

Date: …………………..

List of Publications

Book and Book Chapter

1. Baig, M. M., Gholamhosseini, H., & Connolly, M. J. (2014). mHealth Monitoring Systems for Hospitalised Older Adults - Current Issues and Challenges. In S. Adibi (Ed.), *(accepted) Mobile Health (mHealth): The Technology Road Map* USA: Springer

2. Baig, M. M. (2013). Smart Monitoring Systems for Diagnosis of Anaesthesia Related Events: A Computerized Anaesthesia Monitoring & Diagnostic System using Fuzzy Logic Modelling: LAP Lambert Academic Publishing. Retrieved from http://www.amazon.com/Monitoring-Systems-Diagnosis-Anaesthesia-Related/dp/3659366471

Peer Reviewed Journals

1. Baig, M. M., GholamHosseini, H., Lindén, M. & Connolly, M. J. (2014). Review of Vital Signs Monitoring Systems – Patient's Acceptability, Issues and Challenges. (accepted), Journal of Neuroscience and Biomedical Engineering.

2. Baig, M. M., Gholamhosseini, H., & Luo, D. (2014). A Secure Wireless Telehealthcare Monitoring System and its Web Application. *Applied Mechanics and Materials, 541-542*(2014), 1309-1312. doi:10.4028/www.scientific.net/AMM.541-542.1309

3. Baig, M. M., GholamHosseini, H., & Harrison, M. J. (2013). Fuzzy logic based anaesthesia monitoring systems for the detection of absolute hypovolaemia. Computers in Biology and Medicine, 43(6), 683-692. doi:http://dx.doi.org/10.1016/j.compbiomed.2013.01.023

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Peer Reviewed Conferences

1. GholamHosseini, H., Baig, M. M., Connolly, M. J., & Linden, M. (2014). A Multifactorial Falls Risk Prediction Model for Hospitalized Older Adults (presented) at the meeting of the Engineering in Medicine and Biology Society, EMBC, 2014 Annual International Conference of the IEEE, Chicago, USA.

2. Baig, M. M., GholamHosseini, H., Connolly, M. J., & Kashfi, G. (2014, 1-4 June 2014). Real-time vital signs monitoring and interpretation system for early detection of multiple physical signs in older adults Symposium conducted at the meeting of the Biomedical and Health Informatics (BHI), 2014 IEEE-EMBS International Conference on doi:10.1109/bhi.2014.6864376.

3. Baig, M. M., GholamHosseini, H., Connolly, M. J., & Kashfi, G. (2014, 1-4 June 2014). A wireless patient monitoring system for hospitalized older adults: Acceptability, reliability and accuracy evaluation Symposium conducted at the meeting of the Biomedical and Health Informatics (BHI), 2014 IEEE-EMBS International Conference on doi:10.1109/bhi.2014.6864370

4. Dhar, S., Mukhopadhyay, S. K., Mitra, S., Baig, M. M., & Mitra, M. (2014, 31 January - 2 February). Noise Reduction and Lossless ECG Encoding. presented at the meeting of the 2014 International Conference on Control, Instrumentation, Energy and Communication (CIEC 2014), University of Calcutta, India. ISBN: 978-1-4799-2044-0

5. Dhar, S., Mukhopadhyay, S. K., Mitra, S., Baig, M. M., & Mitra, M. (2014, 31 January - 2 February). *Noise Reduction and ECG Feature Extraction Using Interpolation and Hilbert Transform.* presented at the meeting of the 2014 International Conference on Control, Instrumentation, Energy and Communication (CIEC 2014), University of Calcutta, India. ISBN: 978-1-4799-2044-0

6. Baig, M. M., Gholamhosseini, H., & Luo, D. (2014). *A Secure Wireless Telehealthcare Monitoring System and its Web Application*. presented at the meeting of the International Conference on Mechanical, Electronics and Computer Engineering (CMECE 2014) 24-26 January, Sanya, China.

7. Baig, M. M., Gholamhosseini, H., Connolly, M. J., & Sabouri, P. (2013, 27-29, November). *Web-based Vital Signs Monitoring and Early Warning/Detection System for Hospitalised Older Adult Patients*. presented at the meeting of the Annual Health Informatics New Zealand, 27-29, November, Rotorua, New Zealand

8. Sabouri, P., Gholamhosseini, H., Collins, J., & Baig, M. M. (2013, 27-29, November). *Smart skin cancer diagnosis using advanced embedded vision systems*. presented at the meeting of the Annual Health Informatics New Zealand, 27-29, November, Rotorua, New Zealand

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15. Baig, M. M., GholamHosseini, H., and Harrison, M. J. (2010). Fuzzy Logic-based System for Anaesthesia Monitoring, in 32nd Annual International Conference of the IEEE EMBS, Buenos Aires, Argentina, pp. 3974-77, Aug. - Sep. 2010

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Ethical Approval

This study successfully obtained the ethical approvals from the following committees; approval letters are attached in APPENDIX A1 – A4;

- Northern X regional ethics committee
  Approval Number: NTX/12/EXP/073
  Approved Date: March-2012

- Auckland University of Technology Ethical Committee (AUTEC)
  Approval Number: 12/117
  Approved Date: May 2012

- Waitemata District Health Board's (WDHB) Maori research review committee, Awhina Research & Knowledge Centre.
  Approved Date: March 2012

- The proposed research/clinical trial has been registered at Australia and New Zealand Clinical Trials Registry (ANZCTR)
  (https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=347922)

Abstract

Health monitoring systems have rapidly evolved during the past two decades and have the potential to change the way healthcare is currently delivered. Smart monitoring systems automate patient monitoring tasks and thereby improve the patient workflow management. Moreover, expert systems have the potential to improve clinicians' performance by accurately executing repetitive tasks, to which humans are ill-suited. Clinicians working in hospital wards are responsible for conducting a multitude of tasks which require constant vigilance and thus the need for a smart decision support system has arisen. In particular, wireless patient monitoring systems are emerging as a low cost, reliable and accurate means of healthcare delivery.

This study focuses on three important areas of healthcare: wireless, remote and real-time vital signs monitoring, interpreting multiple physical signs and falls detection and prediction for hospitalised older adults.

Vital signs monitoring systems are rapidly becoming the core of today's healthcare deliveries. The paradigm has shifted from traditional and manual recording to computer based electronic records and further to handheld devices as versatile and innovative healthcare monitoring systems. The system proposed in this thesis aims to aid in the diagnosis of patients' health conditions from the collected vital signs and assist clinicians with the interpretation of multiple physical signs. Data from a total of 30 patients have been collected in New Zealand Hospitals under local and national ethics approvals. The system records blood pressure, heart rate (pulse), oxygen saturation (SpO2), ear temperature and blood glucose levels from hospitalised patients and transfers this information to a web-based software application for remote monitoring and further interpretation. Ultimately, this system achieved a high level of agreement with clinicians' interpretation when assessing specific physical signs such as bradycardia, tachycardia, hypertension, hypotension, hypoaxemia, fever and hypothermia, and was able to generate early warnings. The performance of the vital signs interpretation system was validated through off-line as well as real-time tests with a high level of agreement between the system and the physician.

Another aim of this study was to develop a robust falls detection as well as falls risk prediction system. The proposed system employs real-time vital signs, motion data, falls

history and other clinical information, which is a valuable tool for hospital falls prevention. The falls risk prediction model has been tested and evaluated with 30 patients using the hospital's falls scoring scale.

CHAPTER 1   Introduction

We are witnessing one of the greatest technological shifts in every area of life, especially in daily life activities and healthcare delivery. The use of information and communications combined with medical and engineering technologies enable healthcare researchers to enhance patient monitoring at home, hospital and outdoors. Customised monitoring is also available for children, adults and older adults including people with disabilities and people with special healthcare needs. Today, clinicians, nurses and family members can receive instant alert/messages about health information of their patients on a smartphone, tablet, laptop, personal digital assistant (PDA) or personal computer (PC). The most commonly performed monitoring is the collection of patients' vital data using state-of-the-art medical devices, sensors and wearable textiles which collect and transmit the data to a remote server or processing unit for analysis, storing and generating alerts to other devices [1].

Advanced information technology and communication devices enable healthcare providers to facilitate complex medical problems, minimise errors and reduce the overall healthcare costs. According to the World Health Organization (WHO):

"The delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities" [2].

Recent research is highly focused on the area of remote/mobile and wireless patient monitoring using body sensors, wireless devices and/or wearable systems. Patient monitoring systems (PMS) are playing a critical role in decision support, early diagnosis and knowledge-based support to the healthcare professionals. Such systems have been established as expanding areas of research using their advanced features and capabilities to turn 'data' into 'useful information'. It is reported that an ideal vital signs monitoring system should be able to: (i) collect high quality data via medical devices/sensors; (ii) interpret and present collected data in a meaningful and valuable manner; (iii) facilitate decision support via expert knowledge into real health situations and (iv) perform

appropriate actions with clinicians' feedback to the patient on the basis of collected data [3, 4]. Such systems are being designed and developed for every possible healthcare scenario i.e. emergency departments and remote monitoring of indoor and outdoor locations [5]. Remote monitoring systems, in particular, play an important role when patient and doctor are at a distance and such systems are capable of reducing healthcare related costs and enhancing the quality of patient healthcare delivery [5].

The healthcare focus has been gradually evolving from traditional medical treatment of existing conditions to include prediction, prevention and/or early detection [6]. A number of reviews, surveys and interviews have been conducted to evaluate the benefits of such systems. The use of internet based social and professional services offered across computers and smartphones potentially enables such applications. Patient monitoring systems (PMS) in particular are playing a critical role in decision support, early diagnosis and knowledge-based support to healthcare professionals [1, 7, 8]. Email reminders, short messaging services, electronic health records, medical history and e-prescriptions are already part of healthcare services and are cost effective and reliable [9]. This research focuses on the monitoring and interpretation of vital signs.

1.1   Need for a Computerised Vital Signs Monitoring System

There is increasing interest in potentially preventable causes of in-hospital morbidity and mortality [10]. Evidence suggests that the management of many critically ill patients can be improved with the result that some cardiac arrests, deaths and intensive care unit (ICU) admissions may be avoided [11]. It is reported that prior to cardiac or respiratory arrest up to 84% of patients have significant physiological deterioration (vital signs) [12]. Often insufficient action is taken, despite up to 60% of arrests on general hospital wards having potentially correctable antecedent events, such as hypoxia and hypotension [12].

To assist in the early detection of physical signs, many hospitals now use an 'early warning score' (EWS) that allocates points to routine vital signs measurements on the basis of their changes from a ''normal'' range [13]. These points provide EWS and the outcome from the weighted values requires the appropriate set action to be taken by the ward staff. The process by which EWS is obtained involves the accurate vital signs collection, the correct recording (manually) of a weighted value according to the degree of change and the arithmetical addition of weighted values to form EWS. Each of these

stages can introduce error, which may influence the EWS. Errors may also occur in the transcription of raw or derived data on to paper charts. There is always the chance of over-scoring that may lead to the unnecessary calling of medical staff. Underscoring is also possible which may lead to a delay in the detection of patient health deterioration [13]. Some of the studies reported that as many as 80% of ward patients have physiological parameters outside normal ranges within the 24 hours preceding intensive care unit (ICU) admission [14].

There is thus an argument for a reliable automated (computerised) early detection and vital signs monitoring system in hospitals' general wards. This research aims to develop the remote/wireless vital signs monitoring and early detection system in order to detect multiple physical signs in older adults in hospital ward settings.

1.2 Classification of Patient Monitoring Systems

Patient monitoring systems (PMS) are classified into various categories according to their operation. Remote health monitoring systems (RHMS) refer to those with remote access or systems which can send data to/or from a remote location. The function of this type of system ranges from a single to multiple parameters which cover a variety of symptoms and physical signs and can be utilised in individual homes as well as hospitals. Mobile health monitoring systems (MHMS) refer to smartphones, personal digital assistants (PDAs) and pocket personal computer (PPC) based systems which are used as the main processing station or in some cases as the main working module. RHMS and MHMS are considered to be more convenient and cost effective than traditional, institutional care, since they enable patients to remain in their usual environment whilst receiving professional healthcare services [15]. Wearable health monitoring systems (WHMS) refer to wearable devices or biosensors, consisting of WHMS, RHMS and/or MHMS that can be worn by patients. Smart health monitoring systems (SHMS) are often referred to as advanced technology or a new approach to healthcare monitoring, including vital signs monitoring systems (VSMS). They usually consist of smart devices or a so-called 'smart' approach to address healthcare issues. Vital signs include heart rate (pulse) (HR), blood pressure (BP), electrocardiography (ECG), oxygen saturation (SpO_2), body or tympanic (ear) temperature (Temp. or T) and respiratory rate (RR). Figure 1.1 demonstrates the classification of the HMS and its subsections.
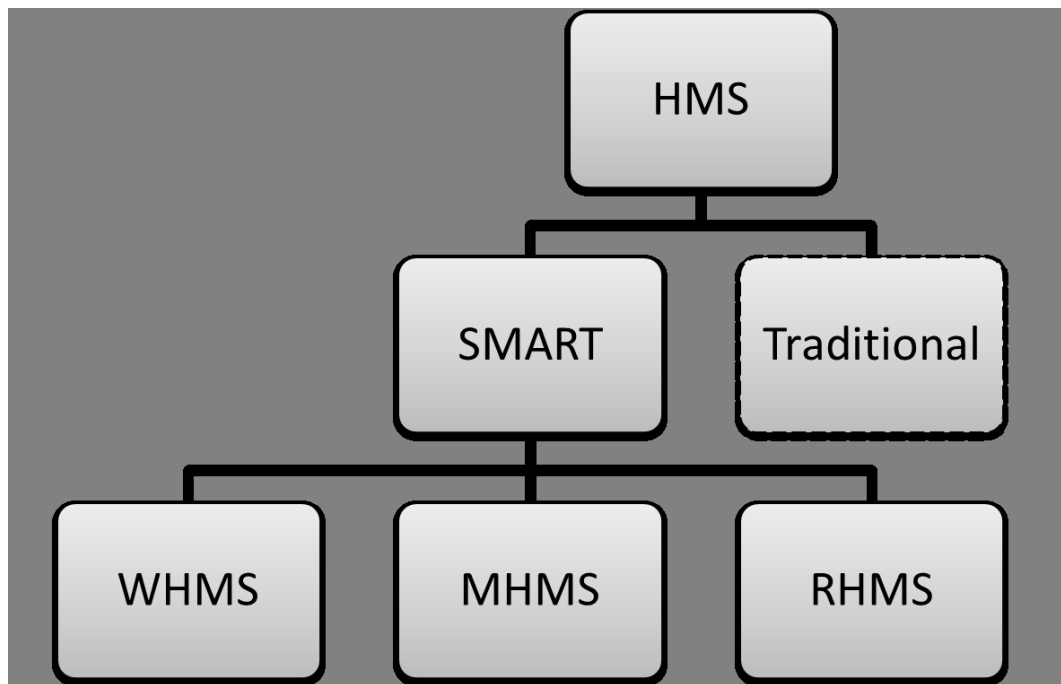
Figure 1.1 Classification of health monitoring systems (HMS), where WHMS is wearable health monitoring system, MHMS is mobile health monitoring system, and RHMS is remote health monitoring system.

1.3 Overview of Current Monitoring Systems

During the past decade there has been rapid growth in advanced health monitoring techniques and methods to assist healthcare professionals to more accurately monitor older adults [16-18] in relation to age-related diseases such as dementia [19, 20], Alzheimer's Disease [21, 22] and Parkinson's Disease [23-25]. Since there are no restrictions to HMS applications, they can be used in hospital [26-29], residential [18, 30, 31] and outdoor settings using mobile broadband, global positioning system (GPS) [32] or radio frequency identification (RFID) technology [20, 33].

Although the technology is becoming more sophisticated and advanced, still there are some concerns with quality of medical data, security of patient medical information, stability of complex monitoring systems, acceptability by the medical staff, usability, comfort and the frequency of false alarms being generated. However, a number of studies have been conducted in the last two decades to address these concerns. For instance, Imhoff and Kuhls [34] have identified that up to 90% of all alarms in critical care monitoring, are false positives. Others researchers have proposed further measures to reduce these false alarms, which include; modifying the range of parameters,

reducing threshold values, or incorporating a time delay in generating the alarms [35]. Current issues and challenges facing by PMS are discussed in Section 1.6.

The architectural model of smart health monitoring systems with the communication technologies are demonstrated in Figure 1.2. In general, most systems employ similar behavioural models with some modifications to the software and/or technology.
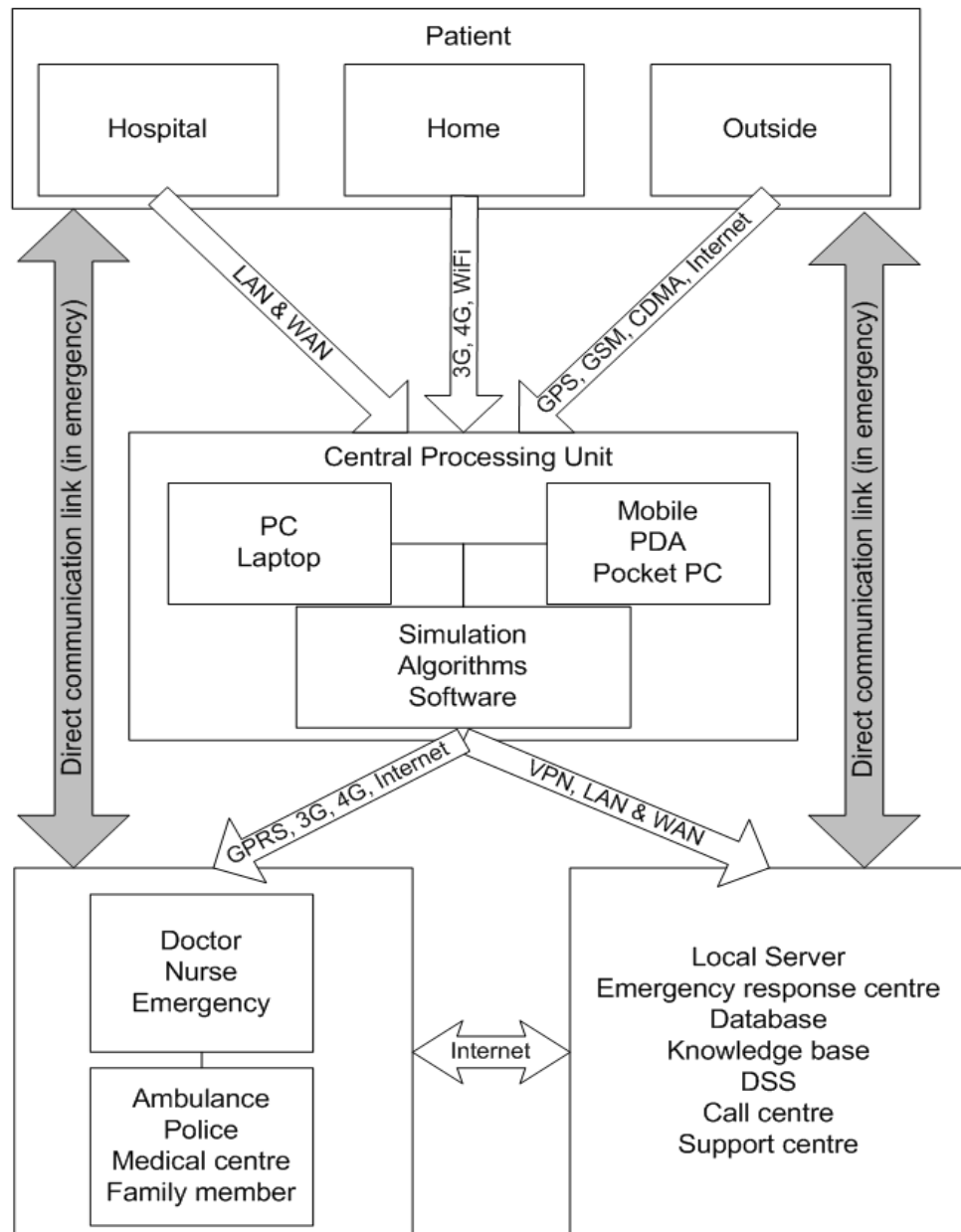
Figure 1.2 Overall architecture of smart health monitoring systems.

A definition of the terminology associated with this advanced technology is necessary in order to understand these state-of-the-art devices and systems which are now

dominating and revolutionising PMS. In this context, PMS refers to the smart systems which monitor, collect or process data on remote/wireless platforms. Wireless sensor area network (WSAN), wireless body area network (WBAN), wireless sensor network (WSN), body area network (BAN) and personal area network (PAN) are terms for wireless wearable telehealth monitoring systems for the collection of vital signs from patients by attaching sensors directly to the body or via a garment (e-textile). Figure 1.3 shows the networking of PMS in a five-layered structure. This model has been developed after studying the design concepts of various PMS from the literature. The next section introduces the vital sign monitoring systems and their components.
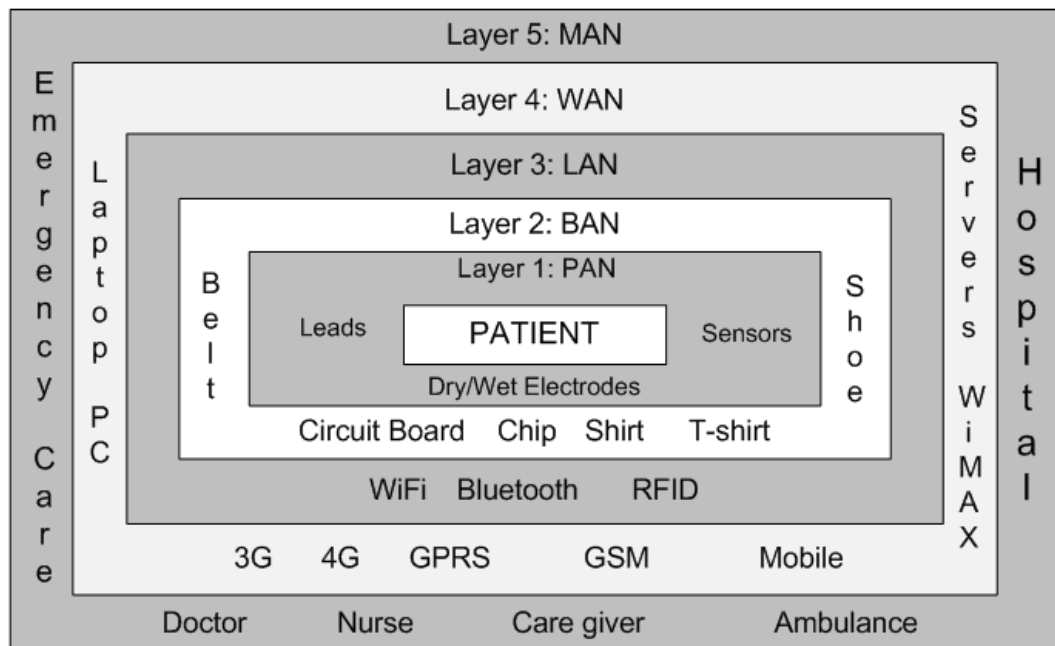
Figure 1.3 Overview of five layered smart patient monitoring system, where PAN represents personal area network, BAN is body area network, LAN is local area network, WAN is wide area network and MAN represents metropolitan area network.

1.4 Vital Signs Monitoring

Vital signs or physiological parameters are the critical factors to determine an individual's health status. For centuries, vital signs measurement has been the very first assessment, which includes counting the number of pulses in one minute and checking forehead palpation for body temperature manually. The monitoring of vital signs has been an important and critical procedure to gain information about the health status of patients in any given scenario. There have been continuous improvement and enhancement of the vital signs collection equipment, transmission protocols and

graphical presentation to the clinician in an informative and easy to understand approach. Often, vital signs are considered important in the early detection of health related issues only if they are collected and presented accurately [36].

Today, vital signs are incorporated in every basic health assessment plan, as the simple measurements of physiological parameters that represent a set of objective data used to determine general parameters of a patient's health and viability. These values influence the medical professional's interpretation of a patient's overall condition and affect the course of treatment for each patient individually. Although vital signs monitoring is one of the most commonly performed task in healthcare, most of the literature has reported that the frequency of obtaining vital signs depends on hospital policy, nursing judgment or physicians' written instruction and is commonly based on the patient's health complaint. For example, acute stroke units have guidelines that require vital signs monitoring every 15 minutes during the acute phases of care and most intensive care units require a minimum of hourly records of vital signs [37].

Motivating factors for engineers, medical professionals and scientists towards continuous enhancement and development of advanced vital signs monitoring systems are: high healthcare costs, increasing worldwide population, increase of older adult population, adoption of mobile phones (smartphones) and the trend of 'being online' and 'always connected'.

The latest, advanced, sophisticated vital signs monitoring systems are useful in early detection and early warning in cases of health deterioration [38-43]. These alerts can be followed-up by medical professionals with prescribed medical procedures to investigate further. One study found that more than half of the 3160 admissions to five acute hospitals had at least one recording of early signs of critical illness (e.g. SpO2 < 95%) [44]. A recent review recommended that every patient should have a documented plan for vital signs monitoring that includes: physiological parameters to assess, time, duration and plan [45]. In order to identify and monitor acutely ill patients such systems should be used more frequently in clinical settings because critically ill patients frequently demonstrate signs of deterioration and that early intervention often reduces grave consequences.

A common example of using vital signs monitoring for early warning generation is a widely adopted scoring mechanism called Early Warning Score (EWS). Derangement in

any of the parameters is assigned a number and the sum of these is used to calculate an overall EWS [46]. There has been rapid growth in techniques and methods to assist healthcare professionals in achieving better healthcare delivery for older adults [16-18] and people with disabilities [47].

Figure 1.4, shows the current trend of vital signs monitoring systems in different types, connectivity, categories and places including online integration [48-51].
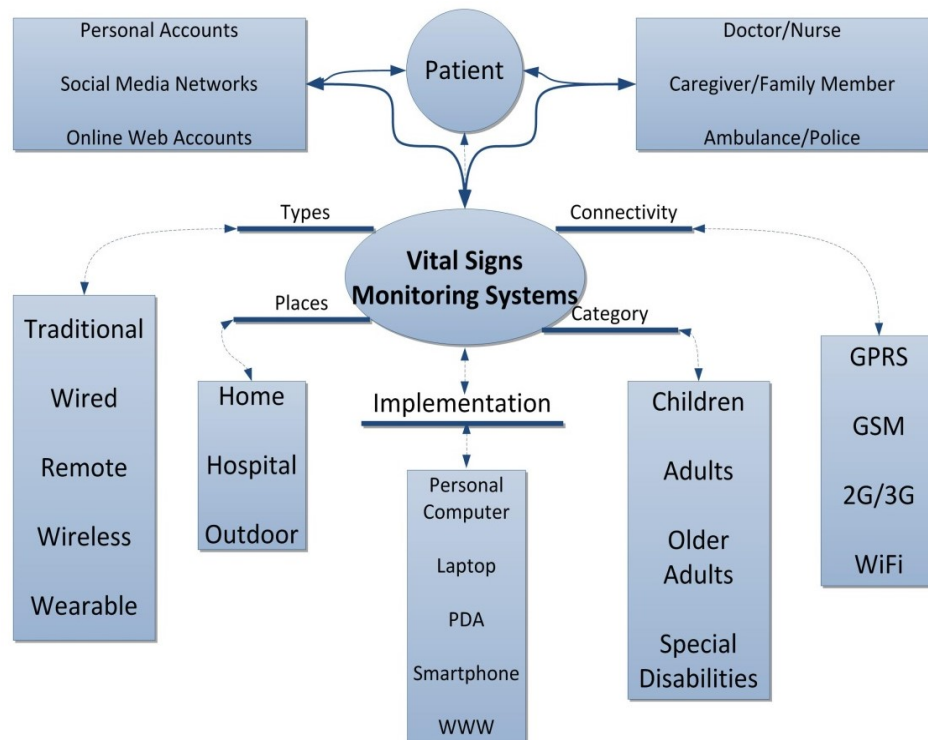
Figure 1.4 Current trend and integration of vital signs monitoring system.

1.4.1 Blood Pressure

Blood pressure (BP) refers to the pressure exerted by blood against the arterial wall. BP is an important physiological parameter to measure the reflection of blood flow when the heart is contracting (systole) and relaxing (diastole) [52]. In the acute medical setting changes or trends in BP often give the medical professionals an early indication to start appropriate medical treatment. For example, a drop in BP has been found to be a common sign in patients prior to cardiac arrest [52]. The importance of measuring BP accurately cannot be over-emphasised and yet it is one of the most inaccurately measured vital signs. If a BP measurement consistently underestimates the diastolic

pressure by 5mmHg, it could result in two thirds of hypertensive patients being ignored for preventative treatment [52].

BP was first measured using a device in the late 18th and early 19th centuries [53]. Since then, there has been a steady improvement in BP measuring devices. Figure 1.5, shows the evolution of BP measurement devices; Figure 1.5(a) shows a traditional manual sphygmomanometer which requires a stethoscope to measure the pressure [54]. This device is usually used by trained medical practitioners in a quiet environment. Figure 1.5(b) shows an automatic Boso-medicus prestige BP monitor, a wireless Bluetooth (BT) device which measures BP and HRand wirelessly transmits the recorded data via Bluetooth (BT) [55]. It can record the BP data at user-defined time intervals using a simple user interface feature. Similar devices have been used in many clinical trials with clinically accurate and reliable measurements [56]. Figure 1.5(c) shows the latest automatic wrist BP monitor [57] which has a large memory to store the recording, but lacks wireless transmission. It is reported that such devices are often at the clinical validation and medical trial stage and therefore the adoption of these devices in clinical settings is likely to occur in the 'near future'. The patient's mobility would be limited using most devices due to the cuff inflation feature, which makes the arm immobile. There has been some progress in the design of cuff-less BP monitors, such as a wrist BP monitor as shown in Figure 1.5(c).

Figure 1.5 (a) A manual sphygmomanometer [54], (b) An automatic Boso-medicus prestige BP monitor [55] and (c) A latest HL-168B automatic wrist BP monitor [57].

1.4.2   Pulse (Heart Rate) and Oxygen Saturation (SpO2)

Pulse is defined as the palpable rhythmic expansion of an artery produced by the increased volume of blood pushed into the vessel by the beating of the heart [58]. Pulse rate is the number of pulses recorded in one minute. In most clinical circumstances pulse rate is identical (very similar) to heart rate. Critical factors that affect the pulse rate are: age, existing/on-going medical conditions and medication. The duration of pulse monitoring for achieving an accurate reading of pulse is a debatable topic often reported in the literature as 15 sec or 30 sec or longer [59]. It is reported that counting the pulse for 30 seconds or less is potentially problematic as an irregular pulse may not be detected during this interval. Moreover, the contradictory findings of studies reported on the relationship between the length of pulse assessment and accuracy [60]. It was also suggested that some other factors such as irregular pulse or if the person is cold, play a significant role in the inaccuracy of reading [61].

Pulse oximeters usually use red and infrared lights to measure SpO2. These devices apply light near to a finger or body part and measure the amount of light received by a sensor under the body part. The difference of the absorbed signal can be mapped to a SpO2 value. This also provides a plethysmographic signal, from which heart rate and further blood flow information can be derived. In the busy medical environment, medical professionals are often loaded with many patient specific tasks and often there is a chance of missing a critical physiological measurement [62]. Therefore, using an accurate pulse oximeter to measure a physiologic parameter often increases the chance of early detection of illness or other underlying health issues. It gives medical professionals the opportunity to identify and perform further clinical assessments.

Figure 1.6(a) shows a traditional-manual way of pulse measurement which is still considered to be a gold standard because of its 100% accuracy and this is usually performed by health practitioners [63]. Figure 1.6(b) shows an accurate hospital grade portable hand-held pulse oximeter [64] and Figure 1.6(c) shows a Nonin's Onyx II finger clip oximeter. It is a wireless Bluetooth device which records and transmits the pulse (HR) and oxygen saturation continuously to any BT enabled machine [65].
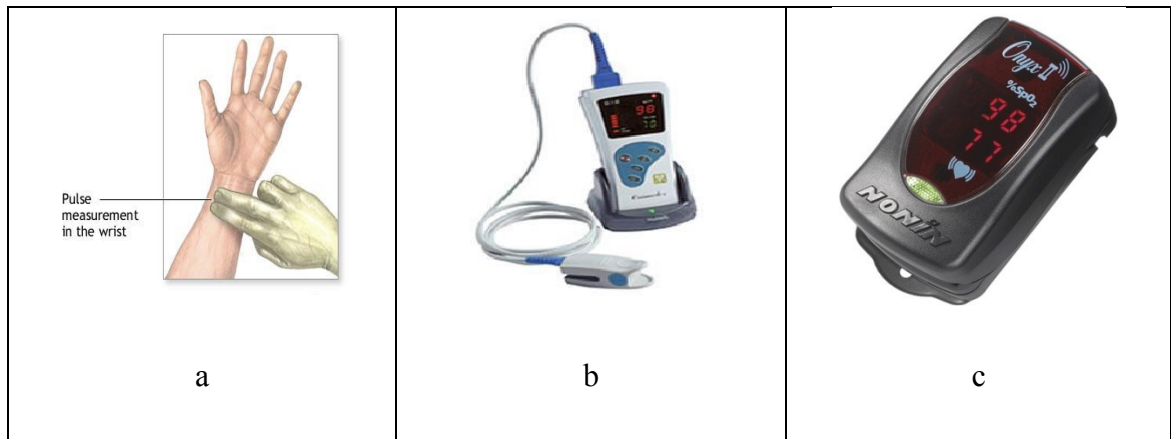
Figure 1.6 (a) A manual way of pulse measurement which is still considered as a gold standard because of its 100% accuracy [63], 2 (b) A hospital grade portable hand-held pulse oximeter [64] and 2 (c) A Nonin's Onyx II finger clip Bluetooth oximeter [65].

1.4.3 Body Temperature

The balance between heat generated and heat lost is represented as the body's core (internal) temperature. Core temperature is technically difficult to measure (except by an anal reading which is distressing for the patient) and in most clinical circumstances it is acceptable to approximate core temperature by measurement of peripheral body temperature in the mouth, ear (ear drum = tympanic membrane) or skin. Factors that may not affect the body's core temperature but can contribute to the inaccuracy of these peripheral measurements are consumption of hot or cold fluids, vasoconstriction of the peripheral arteries (e.g. cold hands) or wearing warm clothes. There are several factors that need to be considered in order to have an accurate and reliable peripheral temperature measurement. One study found significant differences in the accuracy and consistency of several commonly used devices for measuring temperature including tympanic, oral disposable, oral electric and temporal artery [66]. Figure 1.7 shows the evolution of temperature measurement devices over the past years. Figure 1.7(a) shows mercury in a glass thermometer which is treated as a gold standard measurement [67]. Figure 1.7(b) shows the Omron's instant ear thermometer measurement device which is an instant, reliable and compact ear temperature device and is now in use in many healthcare facilities [68]. Figure 1.7(c) shows the G-plus wireless remote body temperature used for continuous body temperature measurement which transfers the temperature readings remotely to its base unit [69].
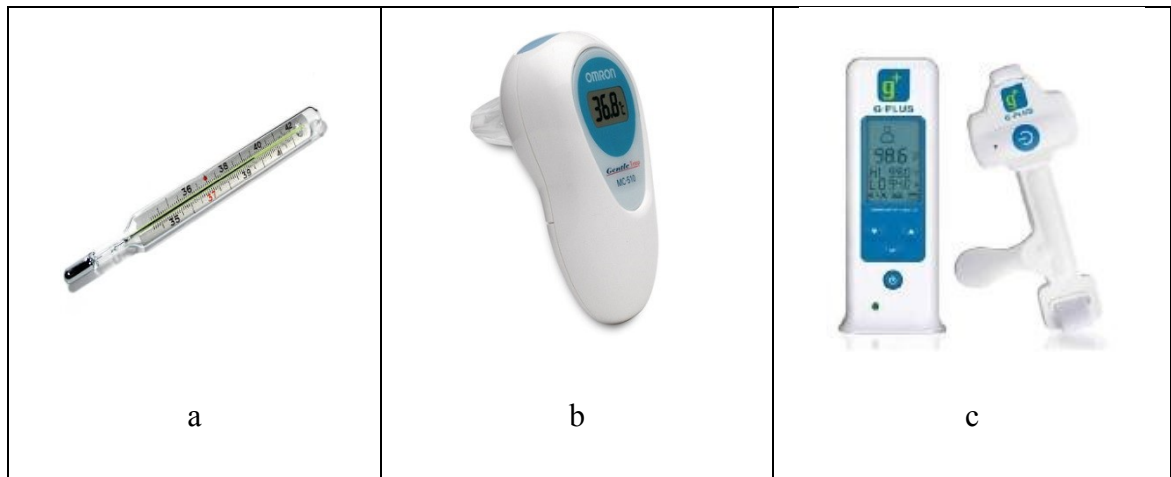
Figure 1.7 (a) A mercury in glass thermometer [67], (b) The Omron's instant ear thermometer measurement device [68] and (c) The G-plus wireless remote body temperature used for continuous body temperature measurement [69].

1.4.4 Respiratory Rate

The number of breaths taken in a given time (usually 1 minute) is known as the respiratory rate and among all the vital signs, the respiratory rate, in particular, is often not recorded and/or neglected. This is in spite of the fact that an abnormal respiratory rate has been shown to be an important predictor of serious events such as cardiac arrest and admission to an intensive care unit (ICU) [70]. It is also considered as one of the most sensitive (and early) indicators of critical illness [71]. An increase from the patient's normal rate of even three to five breaths per minute is an early and important sign of respiratory distress and potential hypoxaemia. In the acutely ill patient, it is recommended that the respiratory rate should be counted for a full minute, rather than 30 seconds [72].

1.5 Motivation

The emergence of PMS applications can address key issues or challenges such as: the increasing worldwide healthcare related costs, the increasing populations of older adults, the high usage of ubiquitous devices (smartphone, tablet, laptop, PDA or PC) in our daily lives and enhancing overall healthcare delivery. Some of the key reasons that motivate this research towards better healthcare delivery are discussed here:

1.5.1 Worldwide Healthcare Costs

According to US Bureau of the Census [73], within the next decade, annual U.S. expenditure on healthcare is projected to reach $4 trillion/year, or 20% of the gross

domestic product [74]. During this period, all United States healthcare spending is projected to grow at an annual average rate of 5.8%, 1.1 percentage points faster than expected growth in Gross Domestic Product (GDP). By 2020, healthcare spending is projected to be 19.8% of GDP, increasing from 17.6% in 2010. All healthcare spending will reach $4.64 trillion in 2020 [75, 76]. Health monitoring systems can play a significant role in reducing hospitalization, the burden on medical staff, consultation time, waiting time and overall healthcare costs.

1.5.2 Increasing Older Adult Population

In the last two decades, the rapid increase in the older adult population (those aged 65 years and over) has proved to be a major challenge in healthcare. The number of patients now requiring continuous monitoring has risen proportionally with this increase in population and, by 2025, this (65+) group will number approximately 1.2 billion. By 2050, there will be 2 billion in this age group, with 80% in developing countries [77]. Moreover, in developed countries, older adults will constitute nearly 20% of the overall population according to the population reference bureau [78]. According to the French National Institute of Statistics and Economic Studies (NISE), 24.4% of the French population is in the older age group (65+) [79]. In 2006, in the UK, the 75+ age group accounts for 41% of the population of state pensionable age. However, by 2056, with the increase in age for state pension entitlement, this group will account for 67% of the pensionable population [80]. In June 2010, there were 3.01 million people aged 65+ in Australia [81] and, in New Zealand, by 2031, one in five New Zealanders will be aged 65+, compared to one in eight in 2009. It is projected that the proportion of older adults aged 65+, in New Zealand will increase from approximately 13.5% in 2011 to 22.3% by 2031 and 26.3% by 2051 respectively [82].

1.5.3 Use of Ubiquitous Devices

Today the world is witnessing an increase in the use of ubiquitous devices (smartphones, tablets, laptops, etc.). A smartphone generally includes advanced functionality beyond making phone calls and sending text messages. Users will have plenty of personal computer features in their handheld smartphone, accessible with the touch of a button or swipe of a finger. The rapid growth of smartphone medical and health applications demonstrates that developers/researchers see a current market for mobile health [83].

1.6 Issues and Challenges Facing Wireless and Remote Monitoring Systems

A number of critical issues considered important in this research are discussed here.

1.6.1 Reliability, Efficiency and Acceptability

With the ever growing wireless/mobile based PMS, end-user acceptability is becoming an important aspect in the design of such systems. There is still an open research question to be addressed and the opportunity for research to address a particular question such as: Do wireless/remote/mobile based patient monitoring systems make a difference to the patient's (end-users) well-being? To answer this important question, many researchers have included the views of patients as well as of medical professionals at every stage of the design and development [84]. The acceptance of any system in the healthcare industry depends on the user awareness and acceptability. The adaptation of a device within the clinical field is diminished if it is negatively perceived. User-centred design is essential in order to incorporate these perceptions into the product, especially at the earlier stages of the project development. When analysing the user's needs, contextual inquiry and the user's profiling, the designer should consider a number of factors such as task analysis, surveys, interviews and focus groups to address the user acceptability [85]. This thesis supports the proposal of Steele et al. [86] that future studies should document any attitudes, perceptions and concerns of users. It is known that highly sophisticated technology and data analysis techniques become irrelevant if the users do not wear the sensor systems for the allocated periods of time [87].

The reliability of monitoring systems is an important and open research question which is often considered as a critical parameter for the acceptability of the system. In the context of reliability and efficiency, the main purpose is to connect the patient monitoring systems to the user within their activity area (range) and model the regular activities. An alert is not triggered when the person is outside the coverage area or a specific range of more than a predefined threshold. Several methods are proposed for determining when an alert/alarm should be triggered [88]. Bergmann and McGregor [40] carefully considered several systems and have recommended the best and most efficient body-worn sensor design. Current trends in wearable PMS applications have

produced an innovative and versatile approach to wearable textile-based monitoring systems using smart shirts [89], T-shirts [90], electrode-embedded textiles [91, 92], worn at home [18, 22, 31], in bed [93, 94] in the form of headgear [95], or footwear [96]. Innovative methods for improving physiological signal processing have also been developed [97]. These include, neural networks [98], fuzzy logic [99-101], principal component analysis and independent component analysis [102]. In brief, PMS must provide reliable and efficient vital signs and algorithms for evaluating the patient's needs. The system should be simple, reliable and user-friendly.

1.6.2   Platform Variability and Cost Effectiveness

The software platform is becoming a drawback to the development and implementation of mobile based PMS due to its multiple/different operating systems. The development environments for handsets cover a wide range of operating systems including: Microsoft Windows Mobile, Symbian, Blackberry, Palm OS, Mobile Linux, J2ME, Apple's iOS and the Android platform by Google. Another issue with the use of mobile platforms is variability and compatibility between the programming language and application environment. At present, efforts to make m-health systems fully functional in all available (common) platforms are slowly improving the situation [103]. The involvement of healthcare professionals in the development of such systems and their participation in the policy discussions is important in order to achieve the full potential of such applications [104-106]. Another barrier is the mobility of data as most of the mobile PMS transfer patients' vital data and/or key physiological parameters via mobile communication links, such as: GPRS, 2G, 3G, 4G and 5G (under development) networks. Costly mobile phone contracts and expensive termination fees could create a barrier to accessing for a specific service such as medical data processing [107].

1.6.3   Energy Usage and Battery Life

It is very important to have a low energy consumption device especially for battery operated systems, such as a smartphone, tablet or laptop. There is a long lasting debate on the effect of cell phone radiation on the human body, which is beyond the scope of this research. When a device transfers a considerable amount of raw data to the central processing unit of a stationary computer, a large amount of energy is required which is normally supplied by a battery. For example, a blood pressure measurement every 10 minutes requires 35 mA/h (consider data transmission, valve and microcontroller). In

this case 1000 mA/h or AAA batteries are required and these batteries will last for a day or so. These applications require a high quality of data to be sent to multiple ubiquitous devices in real-time [108]. Long term use of such systems can pose a serious threat to a device's battery life and seriously compromise the transmission of essential data [26, 109, 110]. Researchers are actively developing new low-power, low-energy consumption sensors which can be used for long time monitoring and provide more battery life [111-114]. A proper frame work has to be developed to address the energy consumption issue, which can be a serious threat to the mobile/remote PMS [115]. In emergency situations where the patient collapses and has poor connectivity (especially in rural areas), or when device is switched off, then self-automated alert systems should be activated by the device's in-built chips [116].

1.6.4   User Interface and Quality of Patient's Medical Data

From the user's (clinician and/or patient) point of view, the graphical user interface (GUI) is one of the most appealing functions that should be easy to use, simple and functional. Such features can be difficult to develop for different types of users including the older adult and people with disabilities. Today, mobile devices offer simple and easy processes to download an application (by looking at 3-4 screen shots shown by the manufacturer). Thus, there is a possibility that if the user dislikes the application or finds it complicated then the application will be removed as easily as it was downloaded. Therefore it is essential to have a user-friendly application for all common mobile platforms.

Using high quality data (according to medical standards) in remote applications is important for reliable communication. Various techniques have been applied to collect high quality data [16, 93, 117]. However, in some studies short-time data measurement was worrisome [93, 118, 119], because, either the data quality was substandard [120] or high false positive alarm rates were reported [121]. It is necessary for the vital sign monitoring systems to capture and transfer data of the highest possible quality. For example, ECG signals were far more accurate when gel electrodes were used [92] and those measuring devices without gel proved to be inaccurate [48]. It is found that in the early stages of system development, a theoretical framework should be set in combination with data (simulated or trial) to manage physiological parameters. At each

stage of the development, the feedback of medical professionals should also be considered and discussed in every possible aspect in relation to the end user (patient).

1.6.5 Security and Privacy

Security and privacy are the most important functions of any healthcare system and often these areas are neglected in the development of wireless/remote PMS; and often security is considered as a concept similar to the safety of any system. As transmission of data in remote/mobile PMS is wireless, it may result in various security threats. Security issues in wireless sensor networks have been a major area of research in recent years and many researchers have specifically addressed security issues with respect to healthcare applications [122-127]. Some of the security and privacy issues are discussed here along with some recommendations for improvement.

The security issues can be classified into two categories: system security and information security. Ng et al. [128] have classified threats and attacks into two major categories—passive and active. Kargl et al. [129] have mentioned attacks in health monitoring in detail such as: modification of medical data, forging of alarms on medical data, denial of service, location and activity tracking of users, physical tampering with devices and jamming attacks. Security and privacy vulnerabilities are discussed in detail by Williams [130]. Some of the key points mentioned are: ease of network formation, complexity of interactions, duplicitous users and leakage to third party servers and shared content.

A number of security and privacy frameworks have been developed, designed and tested for their reliability; 22 free web based personal health record privacy and security policies have been analysed by Carrion et al. [127] and they reported a high level of user's security with applications such as Google Health, ZeabraHealth, Keas and Microsoft Health Vault. Al Ameen et al. [125] divided security and privacy into two aspects; firstly, system security, which includes administrative, physical and technical level security and secondly, information security, which includes data encryption, data integration, authentication and freshness protection [122-125].

A strong and robust privacy-preserving scheme against global eavesdropping for e-health systems called SAGE, works with multiple layer security transit relationship to make current remote/mobile healthcare (m-health) safe and secure [124]. It is also

essential to consider policymakers, certification bodies, manufacturers, public-key infrastructure, distribution and management in order to develop a successful health monitoring system. Some of the most reliable security and privacy frameworks considered are discussed in detail by Kotz et al. [123] and Avancha et al. [131] which include: office of the national coordinator national framework; health privacy project's (HPP) best principle; HPP best practices; Markel's foundation's 'connecting for health' common framework; and the Certification Commission for Healthcare Information Technology's Certification criteria.

A trust based security framework using encryption and decryption [26], a framework designed to secure wireless-networked sensors with a middle ware component to deliver sensing data and retrieve patient monitoring information securely using a two tier architecture [132], a robust and secure system built on three main functions: data protection on the device, secure authentication and data encryption [133], design consideration for the long term monitoring of vital signs, and a work presented at [134, 135] are some of the recent developments carried out by the researchers in addressing the most common and vital security and privacy issues. It is advised that, if any of the above discussed framework(s) is adopted then the system can be considered to have basic security standards. In time to come there will be more and more advancement in this area because m-health is attaining high acceptance in the general public and development of more secure and reliable applications are under development or already available on the market [8, 110, 115, 136-139].

1.7 Scope and Bounds of this Research

1.7.1 Scope of Research

The research presented in this thesis deals with three main concepts: wireless monitoring; falls detection and prediction; and early detection and interpretation of abnormal vital signs - these are interrelated and interconnected as illustrated in Figure 1.8. Moreover, this research investigates various techniques in order to support/justify the proposed system. They are: (1) Evaluation of user's acceptability, mobility, usability and comfort of the wireless medical devices [140]; (2) Testing of an early warning systems to detect hypotension and hypertension [141]; (3) Implementation and testing

of a mobile telehealthcare system [142]; and (4) Web-based vital signs PMS's theoretical framework and design modelling and their issues [143, 144].
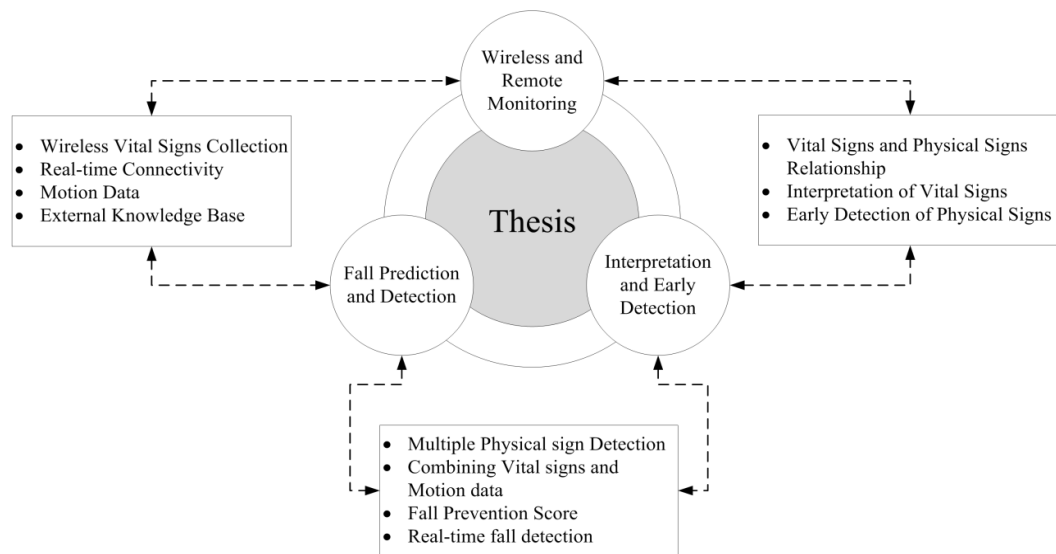
Figure 1.8 Scopes of research as described in the thesis.

1.7.2   Bounds of Research

This research had to limit its scope in several aspects, without compromising its creditability, because of the long period of time required for each intervention for validation in a real-time clinical trial. This research specifically focuses on older adults (65+) in hospital ward settings. Thirty patients could be recruited in order to allow enough data set collection for each patient so that changes in their vital signs could be recorded, which is critical for this research. The falls prediction model has been tested and evaluated using data from 20 patients (developed first by using data from 10 patients) but 'true clinical' (prospective) evaluation could not be carried out due to the time constraint. Monitoring of falls-related hospital admission for 30 recruited patients would require at least several months (depending on the falls incident rate).

Another important aspect of this project is the use of wireless medical devices. Wireless devices available on the market have been considered after extensive market research for cost, reliability, accuracy and availability. The main reason for this is to save time by not developing/investigating the hardware side for the system (which is beyond the scope of this thesis).

1.8 Original Contributions

The original contributions of this thesis are summarised as follows:

- Development of a wireless vital signs recording and monitoring system: Medical devices' connectivity and real-time vital signs transmission have been directed towards improving platform interoperability.

- Development of a vital signs interpretation model
  The proposed system is currently capable of identifying seven physical signs that may occur during a patient's stay in a hospital ward. It has been tested using the recorded data from 20 patients at two hospital's geriatrics wards. The proposed system has achieved accuracy of 96%, sensitivity of 100%, specificity of 93.75% and predictability of 90.38% in compare with the interpretation by a medical expert for the same physical signs. 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 author is not aware of any such system available or in use in New Zealand hospitals. There are few monitoring systems based on threshold setting for generating similar alarms. The proposed system is superior to other systems due to the fact that it is used for individualised monitoring, evidence based reasoning, fuzzy templates and weighted scoring parameters for detection, 'diagnosis' and interpretation of multiple physical signs.

- Development of a falls detection and prediction model
  The use of accelerometer based falls detection is not new. However, the research presented in this thesis utilises the above model with motion data to detect directional falls (backward, forward, right and left-side falls). The proposed detection model has achieved an accuracy of 98%, sensitivity of 96% and specificity of 100% when detecting directional falls. In falls risk prediction, the model uses real-time vital signs, motion data, falls history and type of medications to predict the low, medium or high falls risk in hospitalised older adults. The proposed model was compared with the manual falls risk scoring tool called Morse Falls Scale [145], used clinically on the hospital wards. The

proposed system achieved accuracy of 85%, sensitivity of 100% and predictability of 100% when compared with Morse Falls Scale assessment for the same patients.

- Designing of an integrated healthcare system framework

  The other major contribution documented in this thesis is the development and design of an integrated healthcare monitoring system. The most important components required for understanding the current situation/complaint of a hospitalised older adult are incorporated into the integrated healthcare system including; physical observation, vital signs, motion data (walking patterns), medical information and history. The main idea behind the integrated system is that the system should seamlessly integrate with other existing/available systems or work as a standalone system. Currently, the proposed system can present the information about patient's real-time vital signs, types of medication, falls history, clinical notes/medical information, data trends, statistical analysis, historical trends, multiple physical signs detection and falls risk prediction.

1.9   Justification of Methodology Adopted

- This thesis has identified problems in using two fuzzy models for two different priorities. Specifically when using two fuzzy models for the same data, fuzzy logic provides no guidance on how to structure diagnostic rules, nor what form of fuzzy operators should be used, and it does not provide certainty of information that is necessary in priority 1 and priority 2 categories. This research has identified expert C based rules combined with the fuzzy model as an appropriate way to provide completely different outcomes (P1 and P2). The use of evidence-based reasoning has a close analogue in fuzzy logic models but forces the use of certain operators and rule structures. In addition, it allows the system to convey more (relevant) information to the operator.

- A multilayer outcome has been adopted to address some critical issues such as identifying the underlying knowledge of early detection, to achieve low false alarms and allow more flexibility to clinicians in deciding on interventions. There are certain facts that this work has identified in terms of early detection; the P2 warning is the early detection of physical sign(s), explained in detail in

section 5.4.5. The two priorities, P1 and P2, do not overlap each other for incoming data, which gives each priority its uniqueness in generating the outcome. Expert rules were found to be very effective in detecting P2 warnings due to the fact that they consider the individual's historical data pattern as well as real-time vital signs, whereas P1 is based on fuzzy logic variables and is well known for its flexibility and accuracy in such settings where data is usually incomplete or partial.

- The design, development and evaluation of the proposed system in three phases have proved very effective in terms of accuracy, sensitivity, specificity, predictability and overall reliability in the real medical environment. Consultation with clinicians throughout the development of the proposed system enables the incorporation of their views and requirements in order to assist them skilfully.

1.10 Thesis Outline

This chapter presents an introduction to different types of monitoring systems, vital signs monitoring, motivations, issues and challenges and contributions of the research.

Chapter 2: Literature Review: gives an overview of the state-of-the-art patient monitoring systems, methods of vital signs monitoring and diagnosis with issues and challenges. Different vital signs monitoring techniques and methods are reviewed in order to establish the research gap and its associated research problems.

Chapter 3: Wireless and Remote Monitoring System: presents design functionalities, methodology behind the proposed system and links between clinicians and patients using the wireless and remote systems.

Chapter 4: Data Collection and Protocols: gives details about the hospital data collection process and protocols adopted. Data statistics and related information including data transmission, wireless medical devices and data analysis are described. The important relationship between vital signs and physical signs is also discussed.

Chapter 5: Vital Signs diagnosis and Interpretation: presents fundamental concepts of crisp and fuzzy set theory that pertain to developments in the second part of the proposed interpretation engine. Fuzzy modelling in general and fuzzy logic methods of

inference for diagnosis are discussed, particularly with regard to linguistic and relational fuzzy models. Discussion on the effects of various design parameters is given along with some examples. This chapter also discusses the interpretative ability of the diagnostic structure. The main development in this chapter is that of vital signs interpretation, which may be used for early detection of multiple physical signs.

Chapter 6: Falls Prevention and Detection: describes the development of the falls risk prediction model with various key components. Also discussed are different approaches used in falls risk prediction. The vital signs and motion data based falls detection model is also explained, which accurately identifies backward, forward, left and right-side falls.

Chapter 7: Results and Validations: detailed proposed system performance evaluations are presented. Kappa analysis is carried out to assess the overall agreement between the system and the medical expert when interpreting physical signs. Falls risk prediction has been compared with the hospital based falls risk scoring tool.

Chapter 8: Discussion and Conclusions: provides summaries of the major aspects examined in this thesis and is intended to also place these findings in a wider environment.

CHAPTER 2   Literature Review

2.1   Introduction

This chapter divides the literature related to patient monitoring systems into: (1) types – smart (wearable and wireless), remote and mobile based solutions; (2) target specific – home, hospital or people with disabilities; (3) methodology/technique based approach – expert systems, artificial networks or fuzzy logic based systems; and (4) PMS - specifically addressing fall detection and prevention. Therefore, this classification gives the much needed baseline understanding of this research and its related areas.

2.2   Types of Monitoring Systems

2.2.1   Smart Monitoring Systems

A smart vest [48] is essentially a wearable physiological monitoring system incorporated in a vest. A variety of sensors integrated into the garment's fabric simultaneously collects bio-signals in a non-invasive and unobtrusive way. The parameters measured by the vest include ECG, photoplethysmography (optically obtained volumetric measurement of blood volume changes) (PPG), HR, BP, body temperature, and galvanic skin response (measuring the electrical conductance of the skin) (GSR). Furthermore, it is reported that ECGs can be recorded without using gel, and is also free from baseline noise and motion artefacts due to hardware-implemented high pass, low pass, and notch filters. Moreover, BP is calculated noninvasively via PPG. Results from validation trials confirm the accuracy of measured physiological parameters. LOBIN [92], an e-textile wireless healthcare monitoring system to record ECG, HR and body temperature, is a wearable wireless sensor. Similarly, Blue Box [50] is a novel hand-held device capable of collecting and wirelessly transmitting key cardiac parameters such as ECG, PPG and bio-impedance. It also measures RR intervals (R wave to R wave interval - R wave is equal to the time between systoles i.e. pulse rate) and QRS duration, HR, systolic time intervals as well as assessing their values in correlation with cardiac output measured by an echo-doppler. An in-shoe device has been developed by Saito et al. [96] to monitor plantar pressure (measurement between the plantar surface of the foot and a supporting surface) under real-life conditions. A pressure-sensitive conductive rubber sensor measures

plantar pressure and validation is performed by an f-scan system. SMARTDIAB [146] is a platform designed to support the monitoring, management, and treatment of patients with type 1 diabetes mellitus (T1DM) which incorporates the patient unit (PU) and patient management unit (PMU). The pilot version of the SMARTDIAB has already been implemented and evaluated in a clinical setting. TELEMON [147] is an electronic-informatics-telecom and scalable system that allows automatic, complex and real time tele-monitoring by mobile communications for monitoring vital signs of chronically ill older patients. It employs a WristClinic™ device which is connected to a radio interface with a MiniGate™ USB (max radius 100m) and then to a vital parameter monitor wrist unit (MiniClinic™). It is concluded that such systems are gaining acceptance into the healthcare settings in home or hospital due to their high reliability and accuracy. The technological use of such systems suggests some advance in this area but lack of validation and evaluation in a real clinical environment seems to be one of the main drawbacks.

2.2.2 Remote and Mobile Monitoring Systems

Remote health monitoring systems (RHMSs) are defined as the use of electronic information and communication technology to support and enhance the quality of healthcare when distance separates the healthcare professionals and patients. RHMSs usually transmit the patients' vital data from a remote location to the clinicians in real-time using advanced information and communication technology. RHMSs are combined with mobile communication systems and wearable monitoring technology. This technology has many advantages and provides innovative solutions to deliver healthcare by remote monitoring of patients.

A reliable, intelligent, secure monitoring and management system has been developed to focus on efficient communication, improvement in the reliability of data communication and effective management of wearable medical devices' energy [26]. Another project developed an embedded mobile ECG monitoring system [16] based on client–server architecture where the server (normally located in a hospital) stores ECG signals from the patient through a patient monitor (located in the patient's house) or an RFID reader. This embedded system communicates between the medical sensor network and the mobile GPRS interface and Prognosis [148] is defined as a physiological data fusion model for multisensory WHMS. The latter is based on fuzzy

logic for the generation of prognoses for health conditions by identifying the causal relationship between various disorders and symptoms.

Remote monitoring systems not only monitor vital signs but also detect abnormalities and transmit the data in real-time to healthcare professionals. Frequently, these systems send data with a delay either due to the processing of real-time data and/or wireless data transmission. However, a significant threat to these systems is data security and privacy, in terms of patient identification and confidentiality of medical information. These issues have not as yet been completely addressed and there is room for improvement in the design and structure of the system so that it complies with medical and ethical standards.

Mobile monitoring systems are beginning to emerge as a useful technology for healthcare delivery. For example, by using a basic cell phone calling service or short message service (SMS), people with type 1 diabetes mellitus were assisted in self-management, by sending a text message on their mobile phone. This method has produced favourable changes in diabetes self-efficacy and adherence to treatment [149] and behavioural changes [150]. There is also an effective and positive response from smokers, smoking being one of the world's current major problems. This is done through mobile phone based projects such as 'Text2Quit' and 'txt2Stop' [151, 152]. Today such applications are available in many areas of healthcare such as: physical activity [153], anti-obesity [154], diabetes self-management [42] and asthma self-management [155].

A multi-agent architecture comprising intelligent agents for cardio and weight monitoring, based on mobile technology (GSM), has been developed to collate patient data. Intelligent agents collectively send diagnostic information and recommend medical interventions in a mobile environment. Software was developed using a Symbian operating system, Java 2 Micro Edition (J2ME) as mobile programming and Java 2 Enterprise Edition (J2EE) for server-side agent programming [110]. Self-powered WSN [156] monitors ECG, pulse-oximeters and BP from a remote location. Crossbow MICAz motes were used to design a robust mesh network that routes patient data to a remote base station within a hospital via a router node. The latter consists of an energy harvesting circuit board and solar panel set up which is located near overhead 34W fluorescent lights [156]. Another system [157] whereby a call from a mobile

phone to a server computer initiates transmission of a graphical chart via the mobile phone was developed specially for older adults. This system uses low power sensors and tri-axis accelerometers for mobile phones' graphical display charts.

A clinically validated and flexible framework, performing real-time analysis of physiological data to monitor patient health conditions has also been developed [121]. Physiological parameters were collected by sensors and analysed by means of data mining techniques. Real-time processing was performed on mobile devices (pocket PCs and smartphones) and a suitable alert could be triggered in emergency situations. A system design has been conducted using clustering algorithms, simple K-means (KM), farthest first (FF), and expectation maximization (EM) algorithms (default algorithm was simple KM), with different sampling intervals and time windows. Deploying advanced algorithms to improve the results has been reported. However, the processing impact of these computationally intensive algorithms on the mobile devices such as battery life and delay in data transmission can be considered as a significant shortfall. In a unique approach [120] to measure the heart rate by a non-contact and non-invasive device, a CCD camera was employed in a trial of 14 Asian participants. A 30-second time-lapse imaging of the body surface was acquired whilst HR was measured by a pulse oximeter and RR by a thermistor. A combination of a time-lapse imaging from a hand held video camera and PC-based image processing software, indicated a 30-second average HR and RR based on changes in the brightness of the region of interest (ROI). These changes in brightness or movement of ROI play a critical role in the accurate measurement of HR.

M-PMS would benefit many patients and medical professionals by providing rapid access to health information, especially in emergency situations. This technology is continuously being enhanced, but there are still challenges to improve its clinical application. For instance, raw data can be transmitted efficiently from a mobile device but the analysis and processing of that data is still a major concern. This is due to the high impact that data processing can impose on the device's battery runtime and the generating delay in the transmission of data. The model of data transmission in M-PMS can be presented in two transmission types and three steps as shown in Figure 2.1. In type 1, patient data is collated by a mobile device and then transmitted to a remote server for processing. Then the data is transmitted to the clinician's mobile device directly or via the patient's mobile device. In type 2, the patient data is sent directly to a

remote station for processing and then transmitted to other devices. In some cases, only the results or alerts will be transmitted. Both types can generate delays in producing results. As indicated in Figure 2.1, there will be a direct link between the patient and the clinician (dashed line). Continuous data transfer both through sending and receiving by mobile devices significantly reduces battery life. A brief description of similar systems using the latest technology is presented in Table 2.2.
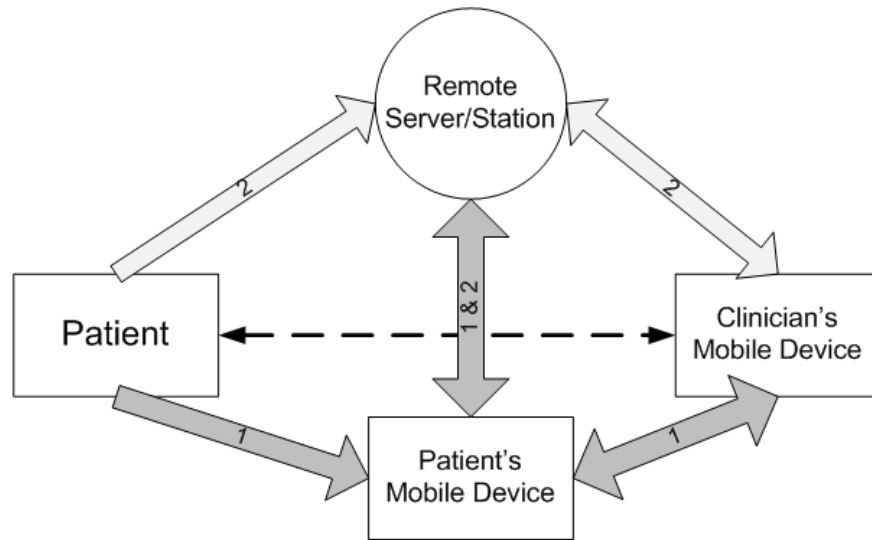
Figure 2.1 Data transfer structure for mobile health monitoring.

Wireless body area network (WBAN) is the essential part of the wireless PMS. A WBAN allows the integration of intelligent systems, miniaturized components and low-power sensor nodes attached to the body for monitoring physiological activities. For instance, ECG data collection has advanced to the extent where several studies have successfully investigated contactless [158] and leadless ECG monitoring [159]. Concerns around the adverse effect of electrodes on the human body are also addressed [160] with recommendations for the best electrode locations [161]. In recognition of obstructive sleep apnoea, a low-cost, real-time monitoring system MedAssist has been developed [162]. Using shimmer WSBN mote, a low complexity energy-efficient ECG compression has been developed for compressed sensing and signal acquisition and compression [163]. Continuous and real-time monitoring and recording of a patient's ECG signals have been developed using a Holter-based portable ECG monitoring system as well as two smart phones for cardiovascular diagnosis [106]. The issue of accuracy and power has been solved to some extent by using lightweight, power-saving

and RFID based wireless or USB ECG devices [164], but still there is a constant threat of data security [20].

Several feature extraction models based on wavelet transform were developed [137] including a BSN based context aware QRS detection [165], an image guided ECG signal detection [166] and an e-technology in a unified DICOM format [167]. Such systems which are completely mobile based are offering advancement in the technology and processing capacity in a mobile environment. A new physiological multi-parameter remote monitoring system based on the browser/server model has been developed. The system consists of a server monitoring centre, Internet network and PC-based multi-parameter monitors on the world-wide-web, using MMS (multimedia messaging service), GPRS (general packet radio service) and global positioning system (GPS) to transfer ECG data acquired and stored in the Holter monitor via the Internet.

A medical embedded device for individualized care (MEDIC) was developed [168] based on an innovative software architecture for enabling sensor management and disease prediction using a conventional personal digital assistant (PDA) or a cell phone [168]. HeartSaver, a mobile medical device was developed [169] for real-time ECG monitoring and automatic detection of several cardiac pathologies. This is an Android mobile based application software that sends a text message related to the patient's condition and location to a physician. An attachable ECG adhesive bandage sensor was implemented for continuous ECG monitoring system by using Planar-Fashionable Circuit Board technology. It uses a low cost sensor chip which is bonded on fabric, wirelessly powered for safety, has dry electrodes for less skin irritation and is suitable for long term monitoring [170]. Wireless ECG monitoring using low data rate ultra wideband transmission was also developed. It is currently under consideration for a newly formed WBAN group (IEEE 802.15.6) to develop a standard for wireless vital sign monitoring [171].

Table 2.3 showing mobile/wireless ECG monitoring systems clearly indicates that system stability is high when implemented on PC or PDA and is usually low for mobile devices (smartphones). However, the cost of a mobile device is low when compared with a PC and a time delay is also observed when using a mobile device as compared with a PC.

Figure 2.2 shows the wireless/mobile based architecture of a wearable system. Most of the reviewed systems in this section represent a similar design in communication and transferring of a patient's physiological data. A common telemedicine network mesh consists of: patient, physician, caregiver, nurse, emergency response unit, local station for data processing either locally or remotely, analysis and storage. Usually communication will be carried out by wired or wireless using mobile broadband or the internet.
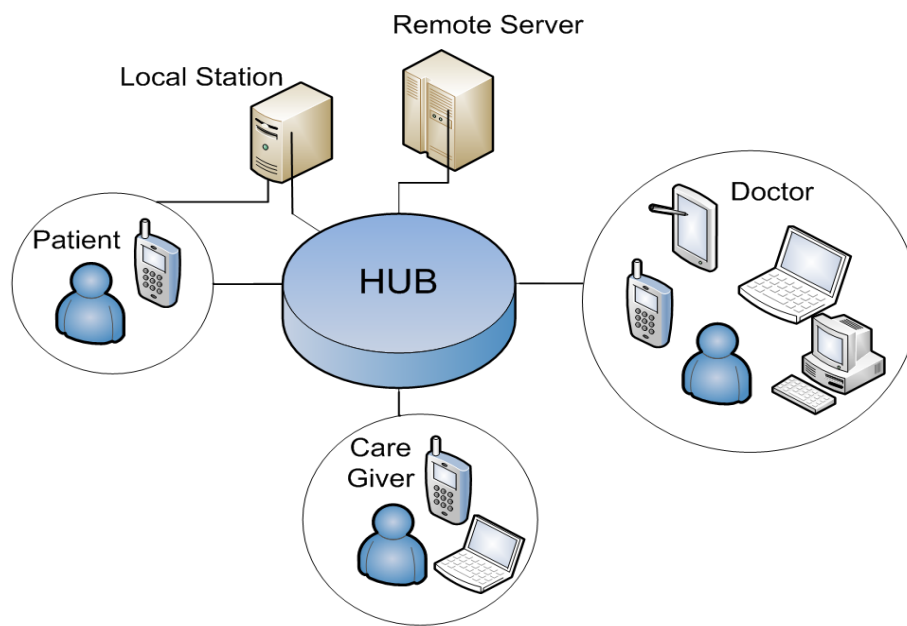
Figure 2.2 Communication networking of wireless/mobile wearable systems.

2.2.3 Mobile based Vital Signs Monitoring Systems

Collection and processing of physiological parameters using mobile devices for patient monitoring is discussed here. Airstrip Technologies [103] has developed an innovative patient monitoring solution, using the AppPoint^{TM} software development platform, which is compatible with most handheld smartphones, tablets and PCs. Figure 2.3(a) shows the Airstrip Technologies' remote continuous vital signs monitoring via iPhone. According to Topol [172] acceptance of mobile phones in healthcare is possible because of ever-growing use of smartphones, enhanced bandwidth with third and fourth generation (3G and 4G) mobile data networks and smartphones with computing power equal to that of a personal laptop computer. Ren-Guey et al. [51] have developed a smartphone based healthcare system with an alert mechanism using unified modelling

language (UML) via the Nokia 7610 phone. This system detects an abnormal parameter and alerts the clinician via SMS using mobile internet data shown in Figure 2.3(b). The system achieved R-wave detection of 95% and this rate can be further increased by reducing false alarms. This system uses a smartphone as the main processing platform, which connects to external hardware/sensor and transmits the alert via mobile data. For the purpose of continuous monitoring, the mobile communication link should be ON all the time, which is often considered costly and will also have a huge impact on the mobile's battery life.

By integrating the Holter monitor (which allows continuous ECG recordings) with a mobile phone, Oresko et al. [173] have developed a smartphone based cardiovascular disease detection system called 'HeartToGo'. The system employs Windows mobile operating system 5 and 6 for smartphones, and MIT-BIH database to test its performance. Its core model is built using C++, C# and detects QRS signals with quite high accuracy as shown in Figure 2.3(c). The accuracy of this system was analysed by a three-way cross-validation method which helps to minimise variations due to random sampling of finite-size data samples. It is also reported that the dataset was partitioned for each class randomly into three disjoint subsets of approximately equal size. A similar system called 'Blue Box' [50] has been developed as a novel hand-held device capable of collecting and wirelessly transmitting key cardiac parameters: ECG, PPG and bio-impedance (Figure 2.3(d)). It also measures RR interval and QRS duration, HR, systolic time intervals and assesses their values in correlation with cardiac output measured by an echo-doppler. In ECG measurement a 30-60 seconds time delay has been reported. Another common issue reported in literature is the simulation or testing of the system by using a small sample size and healthy subjects often give low accuracy results when tested in real-time [50, 174]. Figure 2.3(e) shows a wrist-worn integrated health monitoring device (WIHMD) developed by Kang et al. [175]. WIHMD consists of six vital signals; a fall detector, a single-channel electrocardiogram, non-invasive blood pressure, pulse oximetry (SpO2), respiration rate, and body surface temperature measuring units. It is essential to mention that the size of the WIHMD is 60 × 50 × 20 mm, except for the wrist cuff, and the total system weighs only 200 g, including two 1.5-V AAA-sized batteries. The system has achieved high accuracy and works on low power consumption, and has been tested using 150 simulated cases and five human subjects.

The majority of vital sign monitoring systems use built-in Bluetooth technology to receive information from various devices and use mobile internet or WiFi to transfer information. This typical setup limits the mobility of the user to its Bluetooth (BT) range only and continuous use of BT often reduces battery life.

Figure 2.3 (a) Image courtesy of AirPort Technologies [103], (b) A mobile healthcare system with alert mechanism developed by Ren-Guey et al. [51], (c) HeartToGo – a cardiovascular disease detection system developed by Oresko et al. [173], (d) A remote patient monitoring system for heart failure patients called 'Blue Box' [50] and (e) Wrist-worn integrated health monitoring device (WIHMD) developed by Kang et al. [175].

Today's smartphones not only serve as key computing and communication mobile devices of choice, but they also come with a rich set of embedded and advanced sensors, such as an accelerometer, digital compass, gyroscope, GPS, microphone and camera. Collectively, these sensors are enabling new applications across a wide variety of domains. Tackling diabetes is likely one of the major concerns for the global public health community where smartphones can play an effective role. Smartphones using GPRS, 3G, 4G and 5G (under development) for data transfer are a technically attractive solution in establishing a reliable communication link between patients and clinicians. Nowadays smartphones can transmit and receive data in real-time, using their widescreen graphical display of data and the keyboard to allow entry of additional data.

A brief summary of mobile PMS and its potential benefits is presented in [29, 113], where some successful case studies in the areas of electronic patient records, emergency telemedicine, tele-radiology and home monitoring are discussed. Various scenarios of mobile PMS for managing emergency circumstances can be found in [176]. Recent studies and surveys on advancements in this domain are given in [7, 113, 177, 178]. Table 2.4 summarises some of the discussed mobile PMS. The most successful and widely adopted mobile technology networking architecture is shown in Figure 2.2-4. Similar architecture is also adopted by many researchers such as: Liu et al. [136], Lane at al. [177], Kumar et al. [176], Alemdar and Ersoy [113], Ming et al. [122], Mughal et al. [132] and Kulkarni and Ozturk [88]. The standard wireless communication protocols used in the above wireless/wearable HMS are listed in Table 2.1.

Table 2.1 Wireless communication protocols in wearable health monitoring systems

Technique/Parameters	Range	Data Rate	Cost	Frequency
Bluetooth	10-100m	1-3 Mbps	$3-$5	2.4 GHz
Zigbee	10-75m	20 Kbps 40 Kbps 250 Kbps	$2-$3	868 MHz 915 MHz 2.4 GHz
Infrared	1m	16 Mbps	$2	-
Ultra wideband	2m	500kbps	$3-$5	400 MHz
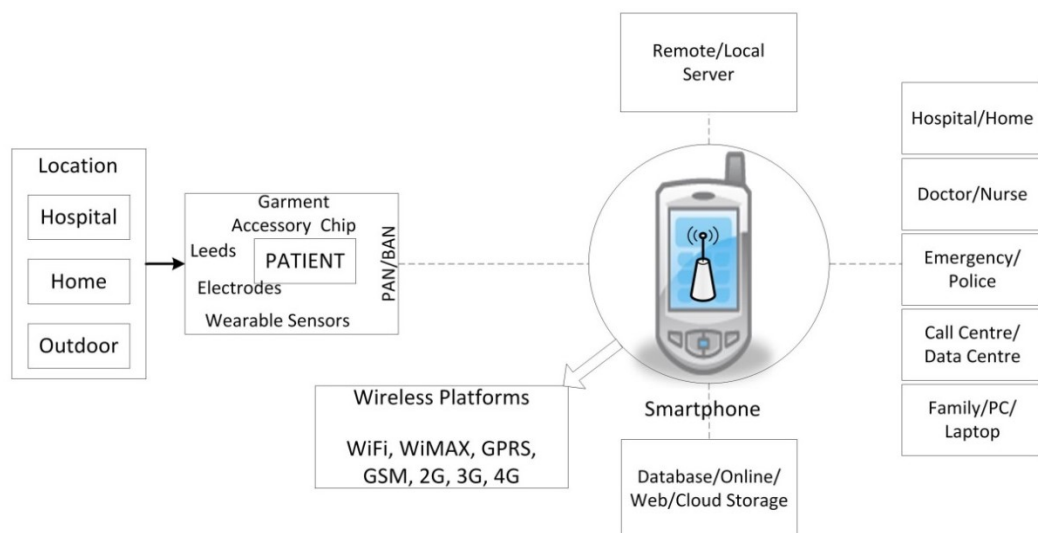
Figure 2.4 Widely adopted mHealth technology networking architecture.

2.3 Personalised Monitoring Systems

2.3.1 Overview of Current Systems

There are several approaches towards assisting the older adults who live independently. A smart home for the older adult has been developed, using HR, BP and sensors to measure weight, light, temperature, the presence of gas or smoke, falls risk and moisture throughout the home. A digital IP camera transmits data via an IP-based Rabbit microcontroller with a built-in small web server, and information is accessed via a secure web [179]. Although this method has achieved a higher accuracy, it incurs higher costs as more sensors need to be deployed around the home setting. Patients exhibiting symptoms of cardiac infarction, sleep apnoea or hypopnea were successfully monitored by body weight and during sleep [118]. Similar work was also carried out by an ECG monitor on patients in the bath [15] or bed [93, 119] without direct skin contact. Respiration and pulse were monitored by an air mattress sensor [180], and body temperature and movement by a thermistor [181]. A BP monitor [182] installed in the toilet seat and a respiration and cardiac beat monitor fitted under a pillow, using vinyl tubes, filled with silicon-oil, has also been explored [183].

Another smart home system for older people developed by the TAFETA group [184] provides a framework for the processing and communication of extracted information by using intelligent sensors such as magnetic switches, thermistors, accelerometers, RFID, infrared motion sensors, microphone array, smart grab bars, pressure sensitive mats and electronic noses. Extended duration of monitoring is achievable through various sensors without interfering with activities of daily living (ADLs). Another framework, ANGELAH [18], integrates the sensors and actuators required for monitoring and detecting potential acute situations. It also alerts medical professionals to respond to emergency cases. An RFID reader is used for entry-exit and a camera for computer vision based emergency detection. Likewise, LAURA [185] performs localization, tracking and monitoring of indoor patients with an average localization error rate of less than two metres in 80% of cases. In another study, specific to disease detection in a simultaneous measurement of ECG and plethysmography (pleth) involving 29 subjects, the pulse rate variability extracted from finger photo-pleth waveforms can be a substitute for heart rate variability derived from the RR intervals of ECG signals during obstructive sleep apnoea [117].

2.3.2 People with Dementia

Dementia is the most common form of chronic disease in older adults worldwide and absolute number of people affected is predicted to increase incrementally as the life span of the population increases. Currently, there are an estimated 24 million people diagnosed with some form of dementia [186] and many research studies are focusing on improving their quality of life. In 2006, a wireless healthcare service system was developed [19], which integrated the following technologies: RFID, GPS, a global system for mobile communications (GSM), as well as a geographic information system (GIS) to construct a stray prevention system without interfering in daily life activities. It was specifically designed for indoor, outdoor, emergency and remote monitoring and mainly employs resident motion sensors and rescue locators attached to the body. In 2008, this work was further developed by the same researchers [20], with the use of eXtensible-Markup-Language (XML) with RFID technology in disease assessment and safety monitoring of people with dementia. The tame transformation signatures (TTS) algorithm encrypted tag IDs to preserve confidentiality. Participants willingly wore light tags and clinical trialling of the system indicated that the indoor RFID reader had a response time of 0.5 seconds with 40 tag sensors, whereas the outdoor reader gave a sensing time of approximately 5 seconds due to power save mode being used.

2.3.3 People with Parkinson's Disease

MercuryLive [23] is a web based home monitoring system for people diagnosed with Parkinson's disease. It consists of a central server which collates data and stores it for web access, as well as a live video streaming (provided by Red5). It also runs on the central server, the patient host computer and a body sensor network (BSN) called Mercury. Based on the SHIMMER sensor, Mercury includes multiple body worn sensors connected to a base station (laptop) and clinician host computer, as well as a web based GUI, which collates the data via video conferencing using 40% video compression. A similar system has been developed for the detection and assessment of the severity of symptoms in patients with Parkinsonian dyskinesia [24] by using small, accurate and robust accelerometers and gyroscopes. A pilot study has been conducted to estimate the severity of tremor, bradykinesia, dyskinesia and motor complications in Parkinson's patients using a support vector machine (SVM) classifier [25]. Both systems achieved encouraging results when tested in real-time.

2.3.4 People with Alzheimer's Disease

The Escort System [21], a safety monitoring system for those with Alzheimer's Disease uses a unique approach known as 'Talking Lights'. This system gives optical location information and transmits lights to the patient receiver device via a ZigBee network and an alert (SMS) can be sent to a mobile device. In the monitoring of patient safety, Ho et al. [22] employed Bluetooth access points (APs) situated in each room of the house. All Bluetooth APs are connected to a local database which stores and sends data to another server. This Bluetooth-enabled monitoring device should be carried by the patient for location updates and monitoring [22]. Therefore, it is the patient's responsibility to carry the device at all times and should the patient not do so or move out of the range, then the system fails.

2.3.5 Review and Critical Analysis

Smart Vest [48] and LOBIN [92] share a similar approach as wearable physiological monitoring systems in terms of using wearable textile, wireless monitoring and patient tracking. Smart Vest uses wireless transmission from the textile to a remote station and LOBIN uses wireless transmission boards and distribution points in patient living areas (indoors). Results show that both systems satisfy medical and usability conditions. Despite the advantages of such systems in health monitoring, there are some concerns with the smart wearable devices as they must be worn continuously and be restricted to a specified range. Moreover, the quality of the data collected by these devices is usually poor. Patient comfort is another concern as they may find wearing garments with wireless or wired sensors physically uncomfortable, restrictive and even irritating. Therefore, further research is required to improve the characteristics of wearable devices as well as their real time clinical features.

The TAFETA [184], ANGELAH [18] and LAURA [185] groups employed a similar approach to the health monitoring of older adults by using application specific sensors. The TAFETA group utilised nine different sensors in a home setting and collected useful data whereas ANGELAH employed RFID technology and LAURA focused on the localisation and tracking as the main method for subject monitoring. These three systems provided an acceptable performance in assisting older people in their daily activities in the long term.

Although home-based health monitoring systems can contribute to the advancement of healthcare, the level of intelligence of the sensors, area of application and internet or mobile data dependency for connectivity require further research and development. Where the subject moves out of range, evades sensor contact or is behaving contrary to the system, a false alarm will be generated even though he/she is engaging in normal daily activities. Furthermore, a delay in the internet connectivity will also result in a subsequent delay in real-time monitoring.

In the advanced technology sphere, LOBIN [92] and MOPET [187] face the most common challenge of ECG signal quality and electrodes drying out. In addressing the issue of electrodes drying out, a textile integrated active electrode as opposed to a commercial wet Ag/AgCl electrode has also been developed and tested with the signal integrity during a five-cycle washing test [91]. Blue Box [50], an e-chair [188] and a wearable belt [189] are systems that are an advancement in the present state of the art e-health technologies, monitoring vital signs with high real-time accuracy. Such applications addressed some of the common issues of this technology. In the real-time scenario, vital data transmission often had some data processing and network delays. Some of the systems [190, 191] have produced good results when tested in simulation environment, but reported delays when tested in real time.

Mobile PMS is considered as one of the best ways to have the vital signs from the remote/mobile location, but apart from the advantages there are some drawbacks of this fast-emerging technology. The most common issues with mobile-based systems are delays in providing the results, alerts due to data loss or buffering delay, network delays, monitoring delays or processing delays [87]. These systems were mainly developed for a specific setup (home or hospital), a fixed place or a small area to meet patients' specific needs but the majority of such systems lack self-learning capability [16]. Mobile monitoring systems using 3G data suffer from connectivity problems, signal strength issues, short battery life and low transmission speed, thus resulting in delays or low quality data for a short time or a high data transmission cost. The next section will provide an insight into the latest ECG signal processing, algorithms and software tools used for better monitoring and diagnosing.

Wireless and mobile PMS often create data security and low battery life issues. To address the data security problem, a cross-layer framework has been developed based

on unequal resource allocation to support secure wireless ECG data encryption and transmission [114]. The low battery life issue occurs due to continuous connectivity of smart phones with Bluetooth, WiFi or 3G systems using the OS platform for network connectivity. Moreover, if the power supply is not an issue then the mobility of the device will become problematic.

Continuous data transmission by mobile devices can significantly reduce battery life. This scenario in particular is more challenging when compared to poor signal strength or in the case of data transmission charges or delays. Another critical challenge is the security and privacy of user data, especially in remote monitoring systems. These systems not only monitor vital signs but can also detect abnormalities and transmit data to healthcare professionals in real time. However, a significant threat to these systems is data security and privacy in terms of patient identification and confidentiality of medical information. These issues have not yet been fully addressed and there is a need for improvement in the design and structure of these systems to comply with medical and ethical standards. However, M-PMS may impact positively on clinical staff in the common areas that support some important activities such as patient schedule changes, and discussions related to professional feedback and quality control. This impact in a surgical department however was found to be negative and additional socio-technical mechanisms may be required to overcome these issues [192]. Table 2.5 summarises the above mentioned vital signs monitoring systems.

2.4 Processing Techniques for Monitoring Systems

2.4.1 Vital Signs Processing Methods

Computerised signal processing and analysis play a significant role in remote and wireless monitoring systems. However, it needs to be improved in terms of diagnosis to reduce false alarms and afford extended continuous monitoring. The two major concerns related to these wireless systems are processing time and power consumption. Battery powered portable wireless devices can be designed to perform most of the signal processing locally and transmit results remotely but transmission, in itself, normally consumes more power than processing. Innovative methods for improving vital sign(s) processing have been developed [97]. Most wireless communications between a fixed base station and mobile stations take place within a certain coverage

area with an acceptable signal-to-noise ratio. By reducing the implementation complexities of the mobile station receiver, the power consumption in a mobile terminal can also be decreased. However, this reduction often conflicts with lowering the signal-to-noise ratio threshold value. Furthermore, the receiving mobile station should follow standard medical protocols for diagnosis accuracy. In the following section, algorithms and software related to vital sign(s) processing are discussed [112].

A novel unbiased and normalized adaptive noise reduction system to suppress random noise in ECG signals has been designed. This system includes a two-stage moving-average filter, an infinite impulse response comb filter, an additive white noise generator to test the system's performance in terms of signal-to-noise ratio [193], low cost online acquisition of ECG signal using Matlab and LabView and time-plane feature extraction from digitized ECG samples using a statistical approach [194]. A mobile based ECG detection and analysis algorithm [195], ARTiiFACT, a software tool for processing ECG data [196], ECG signal processing and digital filtering on 8-bit microcontroller [197] and a mean shift based self-adaptive model [198] are some of the latest systems developed for ECG signal classification and analysis.

2.4.2   Signal Compression and Enhancement Techniques

A vital signal processing method using a quad level vector, consisting of compression and classification flow has been designed. This software enables both flows to achieve better performance with a lower computation complexity. The compression algorithm is performed by using ECGskeleton and Huffman coding [199]. Five levels of discrete wavelet transform were applied to decompose the signal into six sub-band components from higher order statistics [200]. A new wavelet-based signal compression algorithm has been developed where each signal frame was first transformed by a DWT and then the transform coefficients were quantized with a uniform scalar dead-zone quantiser [201]. Vital signal compression techniques, using wavelet packets and an embedded zero tree wavelet [202] as well as a novel system-on-chip using CMOS technology for signal compression have been developed [203] for faster processing and transmission.

Annotated ECG data is publicly accessible to support research through different resources such as Physionet data bank (http://www.physionet.org). It offers ECG data from Medicalgorithmics which has successfully developed an innovative solution PocketECG as one of the leading mobile arrhythmia diagnostic technologies

(http://www.medicalgorithmics.com/). This research uses the Physionet data bank for off-line testing of the proposed system and has been found helpful for initial stage testing and especially for a trial and error approach. Various methods and techniques have successfully been adopted for ECG signal enhancement using adaptive Kalman filtering [204], nonlinear Bayesian filtering [205], adaptive filtering [206], discrete Fourier transform (DFT) [207] and wavelet transform [105] which resulted in high accuracy and reliable outcomes. Among other techniques used are artificial neural networks [174], Lyapunov exponents [99], fuzzy wavelet and fuzzy c-means clustering [191], self-organising maps [208] and independent component analysis [209].

Table 2.6 shows the selected algorithms or software based vital signs PMS and shows the real-time data transfer with accurate results when using PC based applications (Matlab and LabVIEW) compared to mobile/smart phone based applications.

Advanced signal processing algorithms for faster processing, low power consumption, low cost and less complexity have been developed. Such algorithms are often tested by simulation or under fixed conditions. Implementation of these algorithms in the wearable, remote or mobile monitoring environment led to poor results due to an increase in processing time and delays. A medical grade remote monitoring system with a reliability exceeding 99% has been developed but a 2.4 second initial buffering delay [210] as well as a small processing and network delay were indicated. On the other hand, some algorithms aim for faster and/or secure diagnosis [211].

2.5 Fall Detection and Prevention Models

2.5.1 Overview

Falls among older adults are very common and their incidence increases with age. The proportion of people who sustain at least one fall over a year varies from 28% to 35% in the over 65 age group to 32% to 42% in the 75+ age group, with 15% of older people falling at least twice a year. Incidence rates in hospitals are higher and, in long-term care settings, approximately 30–50% of people fall each year, with 40% falling recurrently [212]. Stevens et al. [213] conducted a study which estimated the cost of fatal and non-fatal falls amongst older adults, and reported direct medical costs totalling 0.2 billion dollars per annum for fatal and 19 billion dollars for non-fatal injuries in the US. Of the non-fatal injury costs, 63% ($12 billion) were for hospitalizations, 21% ($4

billion) were for emergency department visits and 16% ($3 billion) were for treatment in outpatient settings in the US.

In New Zealand this problem is more serious and needs immediate attention. The Accident Compensation Corporation New Zealand (ACC) webpage states that, "If you are over 65, you have a one in three chance of falling this year and, if you are over 80, you have a one in two (50%) chance of falling this year" [214].

According to the Health Quality and Safety Commission's report 'Serious and Sentinel Events Report 2010/2011' falls accounted for 52% of all serious and sentinel events reported in hospitals in 2010/2011 compared to 35% in 2009/2010 [215]. Hence, there is a clear need for a falls detection, prediction and avoidance system to be in place, particularly in hospitals to avoid these incidents and reduce the consequences.

Hauer et al. [216] provide a comprehensive, non-exclusive fall definition that identifies a fall as 'an unexpected event in which the participant comes to rest on the ground, floor, or lower level'. Injuries sustained from falls to older adults include fractured bones (hip fracture is common), subdural hematoma ('brain' haemorrhage), soft tissue damage, cuts and also serious wounds [217]. In order to predict falls, it is important to incorporate falls risk factors and related contributors. Some of these risk factors are described in the next section.

2.5.2 Fall Detection Systems

It has been reported that clinical balance assessment scales can assess falls risk. A quantitative fall risk assessment [218] using a timed-up-and-go (TUG) test that was developed by Mathias et al. [219] and a Berg balance scale (BBS) [220] employs the SHIMMER sensors and Matlab for processing raw accelerometer and gyroscope data. Systems results indicated that the manual TUG test had an accuracy of 60.6%, BBS an accuracy of 61.4% and the mean test, an accuracy of 76.8% when estimating the falls risk in 349 older adults. Another fall detection system was developed [221] as a server based approach where the data was collated from biomedical sensors for control and processing. A linear autoregressive (AR) Burg spectrum estimation was applied as a fall detection algorithm. The results from the system reported 100% sensitivity, 95.68% specificity with an overall analysis time of four seconds.

The two most common falls 'detection' (or response) approaches are: automatic falls detection (using sensors, accelerometers and video cameras) and personal emergency response systems [222]. The latter works with a pendant-like device with an alert button which needs to be worn by the user at all times. In case of a fall/accident, the device automatically sends a signal to a base station or users have to press the alert button manually. Such devices need to be within a certain range from the base unit [223]. The push-button pendant system is not efficient because it is often difficult to differentiate between a real and false fall [224], the constrained range and also a high rate of false alarms [225]. In addition, in clinical experience, many older people fail to wear them, or even when wearing them at the time of a fall, are unable or unwilling to activate the alarm.

Tri-axial accelerometers or video cameras have been employed in the majority of work in the area of fall detection. However, there was one significant problem related to the use of cameras as they only function in a given view angle and in certain lighting conditions. Moreover, should the subject move beyond these settings then the system cannot record accurately and distinguish a real fall. Even under normal conditions (no fall), if the subject moves, a false alarm will be generated due to the lack of other fall related parameters such as vital signs. Therefore, it is aimed to integrate motion and balance measurement of older adults in the proposed system to improve sensitivity, accuracy and responsive balance testing in clinical practice [226]. Figure 2.5 shows a generic working model adopted for the proposed system.

For example, a false alert may be generated if the monitored person makes an unpredicted movement which the video camera reports as a fall [227]. Vital signs and cognitive function can also be considered as falls-related factors/predictors. This research intelligently combines four main vital signs (heart rate, blood pressure, oxygen saturation and skin temperature) with motion data to predict falls by early detection and/or prevention.
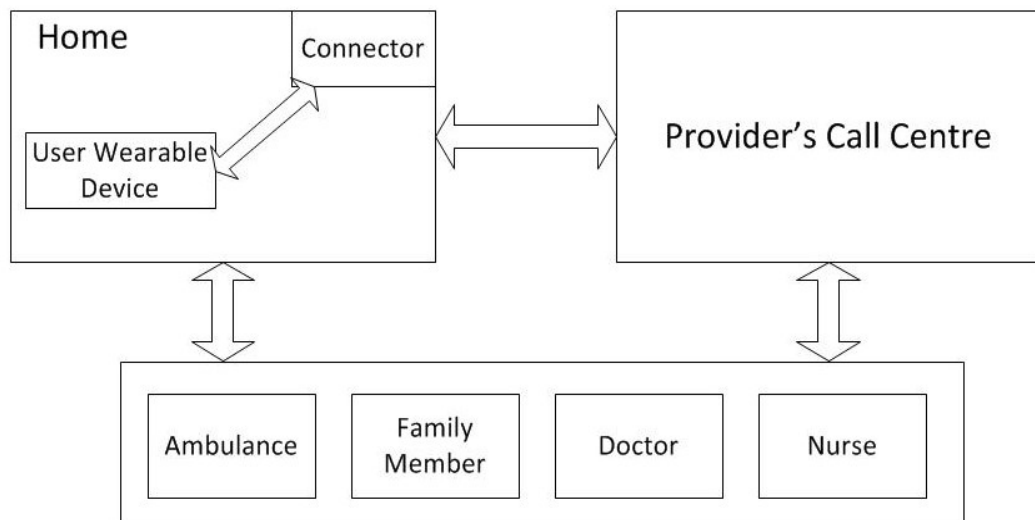
Figure 2.5 Falls alert system working model.

2.5.3 Case Studies

The most effective strategy in the prevention of falls is to involve a multi-disciplinary, holistic and patient-specific approach. Measures should take into account the person's medical condition, social circumstances and psychological factors. [228] cites four types of successful, published fall prevention trials.

a) Single factor, single intervention such as the treatment of syncopal falls with cardiac pacing.

b) Multiple factors, systems intervention: a population group of older people with different medical histories who were admitted to the emergency department was individually assessed by a hospital fall assessment system. Then they were advised of appropriate treatments using the resources available to the hospital and a significant decrease in the risk of further falls was achieved.

c) Multiple factors, specific interventions: a range of clearly defined interventions were employed in combination to prevent falls in a population group experiencing falls from multiple causes.

d) Multiple factors, single interventions, for multiple aetiological factors, a single major risk factor can be very effective for a single intervention such as strength and balance retraining. Single intervention trials can also identify effective components for multifactorial public health programmes for fall prevention.

The results from meta-analyses of trials with the same or similar interventions showed that the most effective intervention in reducing falls in older adults is assessment and multifactorial interventions with a 95% confidence interval of 0.75 (0.65 to 0.88) [229]. In addition, a total of 37 randomised controlled trials for those in rest homes and hospitals (both long term care and acute) were identified [229]. Twenty-nine of the trials were carried out in long term care facilities on 17,291 residents, 13,481 women, 3,765 men, 45 gender not specified, and the remaining eight trials were conducted in hospitals on 2,862 inpatients: 1,716 women, 1,146 men. A total of 41 interventions were tested:

- 4 multiple intervention programmes (not tested in hospitals)
- 26 single factor interventions (6 tested in hospitals)
- 11 multifactorial programmes (3 tested in hospitals)

Three trials of multifactorial interventions indicated a high success rate in residential care facilities in Europe [229]. Interventional factors included instituting exercise programmes, creating a suitable environment, employing assistive technology, educating staff on fall prevention, reviewing prescription drugs, providing free hip protectors and initiating post-fall problem solving training. Furthermore, it was found that falls in hospitals occur three times more than in community living. The findings of meta-analyses from trials with the same or similar interventions showed that effective interventions can be implemented to reduce falls in older adults, both in residential and hospital settings.

2.6 Summary of Reviewed Systems and Methodologies

This section summaries the literature review section into types, categories and functionality of the above reviewed PMS into their respective tables.

Table 2.2 Selected health monitoring systems.

Title or Author	HW/ SW	Module	Parameters	Medical Application	Place/ Type
TAFETA [184]	Pathway & Austco DCS-2000	Online	9 sensors	General Monitoring	Home/ Sim
LOBIN [92]	E-Textile	PAN	ECG, HR, M, T, L	WSNM	Hospital/ Tested
Smart Vest [50]	E-Textile	Remote	ECG, BP, T, PPG, GSR	General Monitoring	Outside/ Sim
Blue Box [50]	Hand-held device	Remote	ECG, PPG, Bio-impedance	Congestive heart failure	Remote/ Trial
Lin et. al [20]	RFID	Online	Activity	Dementia	Home/ Trail
The Escort System [21]	'Talking Lights'	Remote	Activity	Alzheimer's	Home/ Trail
Mercury-Live [23]	Sensors	Remote	Activity	Parkinson's	Home/ Trail
LAURA [185]	Localisation	PAN	Tracking	General monitoring	Home/ RT
TELEMON [147]	E-health services	Mobile	ECG, HR, AP, OS, R, T	Chronic illness	Pilot

*Systems trialled or implemented on patient, home or hospital, HW/SW=hardware/software, Sim=simulation, RT=real-time, M=movement, T=temperature, L=location, PAN=personal area network, WSNM=wireless sensor network monitoring, SOFLC=self-organising fuzzy logic controller, SAP=systolic arterial pressure, DOA=depth of anaesthesia, DDMS= diabetes data management system, AP=arterial pressure, OS=oxygen saturation, R=respiration.

Table 2.3 Selected wireless/mobile based systems

Title or Author	HW/SW	Modules	Medical application	Implement-ation	System Stability	Cost
MedAssist [162]	SVM	Smartph one	Sleep apnoea	Simulation	N/A	Low
MEDIC [168]	WSN	PDA	Individual care	Home/RT	High	High
HeartSav-er [169]	Microcontr oller	Mobile	Cardiac Diagnosis	Simulation	N/A	Low
Oresko et al. [106]	LabView/M atlab	Real-time	Cardio vascular disease	Simulation	N/A	High
Dilmagh-ani et al. [87]	SimpliciTI	Remote	Chronic Diseases	Home/Proto col	High	High
Dong-Her et al. [16]	RFID	Mobile	Older persons Monitoring	Home/Trial	Medium	Low
Tan et al. [49]	Linux based	Portable	Signal measurement	Simulation	N/A	High
Hsieh et al. [167]	XML	Mobile	ECG and Image	Hospital/Tri al	Medium	Low
Bansal et al. [230]	Matlab	PC/Wirel ess	Digital processing and monitoring	Real-time	High	High

SVM represents support vector model, WSN wireless sensor network, PDA personal digital assistant, RT real-time, RFID radio frequency identification, XML represents extensible markup language and simulations are N/A due to high stability when compared with real-time testing.

Table 2.4 Smartphone based healthcare delivery systems

Name	Purpose	Device	Wireless Technology	Language
Ren-Guey et al. [51]	healthcare system with alert mechanism	Nokia 7610	Bluetooth class 2 application programming interface, JAVA,	Borland C++ 6.0 Active X data objects
HeartToGo [173]	Cardiovasc-ular disease detection System	Windows Mobile 5 (Amoi E72) and 6 (HTC)	Blue tooth class, Matlab and LabView	C#, C++, .NET and used MIT-BIH database
Blue Box [50]	Heart failure patient monitoring system	Handheld device	low-power Bluetooth module	converter (AD5934)
kang et al. [175]	Wrist-worn integrated health monitoring device (WIHMD)	Samsung smartphone	Personal area network, ad hoc networking	QRS detection algorithms, microcontroller (ATmega103L, Atmel, USA
Farmer et al. [231]	Phone based telemedicine system for type 1 diabetes	Motorola T720i phone,	Bluetooth, GPRS (2.5G)	JAVA programming
Tatara et al. [232]	Self-help tool for Type 2 diabetes	HTC P3450	Wireless data transmission	Software application
Breslauer et al. [233]	Clinical microscopy	Nokia N 73, (with 3.2 megapixel CMOS camera)	N/A	sophisticated algorithm

Table 2.5 Expert systems for vital signs monitoring

Name	Type/Technique	Data Used	Application	Rules
EMUTEM [234]	Fuzzy logic	Vital Signs, audio and sensors	Older adults	26 with 20 scenarios
Centinela [235]	Naïve Bayes, Neural networks and Bayesian networks	Vital signs and acceleration data	General	Eight classification algorithms and three window sizes
FLOGERA [236]	Fuzzy inference system in wireless sensor networks	Vital signs and environment sensors	Event detection	19
Fuzzy CARA [237]	Fuzzy logic	Vital signs, medical history and activity	Emergency situation detection	Fuzzy rules, medical conditions and medical history
FuzzyARDS [238]	Fuzzy rules	Vital signs and blood glucose	ARDS	Eight

ARDS= Acute Respiratory Distress Syndrome.

Table 2.6 Selected algorithms/software for wearable health monitoring systems

Name	ECG	Technology/Software	Technique	Platform	Time
Xin et al. [239]	Processing	CMOS/ASIC chip	Wavelet Transform	Wearable	Delayed
Vullings et al. [204]	Enhancement	Matlab	Adaptive Kalman filter	PC	Real-time
Sufi et al. [211]	Compression	MMS & SMS Protocols	Algorithm	Mobile Phone	Delayed
Oster et al. [205]	Denoising	Matlab	Bayesian Filtering	PC	Real-time
Capua et al. [240]	Measurement	LabView	Algorithm	Mobile/ Web based	Real-time
Kim et al. [199]	Compression & Classification	Holter System	quad level vector	PC	Delayed
Marco and Chiari [105]	Delineation	32 bit integer Online Processing	Wavelet Transform	Web Based	Real-time
ARTiiFACT [196]	Artefact Processing	Matlab	Detection Algorithm	PC	Real-time
Tseng [101]	Signal Analysis	Windows OS	Fuzzy Wavelet	Mobile /Remote	Delayed

CHAPTER 3   The Proposed Wireless and Remote Monitoring System

3.1 Introduction

Telehealth is one of the emerging areas of today's healthcare for the delivery of health information remotely. The worldwide acceptance of telehealth solutions is due to the use of the internet and related services, being 'online' at all times and the ease of communication anytime and anywhere. Moreover, the need for telehealth is increasing in older adults worldwide, for the purpose of reducing the cost and enhancing the quality of healthcare delivery. After in-depth market analysis, in this research we have collaborated with Medtech Global Limited [241] for the delivery of the advanced healthcare solution called VitelMed [242], which acts as the base medium for the proposed research project in order to have an overall integrated system: vital signs collection and monitoring, video conferencing and multiple physical signs interpretation. Telehealth is often considered as the extension of telemedicine and is defined as: the use of information, computing, electronics and telecommunications technologies to provide healthcare delivery when patient and clinician are separated by a distance [243]. Moreover, it employs advanced telecommunications technologies for the exchange of medical information via the electronic medium for the delivery of healthcare [244]. Telehealth technologies range from simple text messaging and phone calls to advanced remote patient monitoring and to the innovative real-time monitoring of vital signs and video consulting (two-way video conferencing) [245]. It uses the combination of digital video cameras, simple-online questionnaires, medical measurement devices and/or sensors.

The telehealth care solution is capable of enhancing the quality of patient care while reducing the cost [5]. It is categorised into three types: remote (home) monitoring, video conferencing and store and forward. Some of the telehealth services which are already in use are:

- E-prescription: One of the commonly used services which enables clinicians to send prescriptions directly to the pharmacies and eventually helps in reducing prescribing errors [62].

- Messaging: Simple text messaging improves the communications (appointments, reminders and notes) between clinicians and patients and saves time and cost [246].

- Medical Imaging: The waiting time and hospital cost is reduced by accessing high quality digital images by various specialists and/or departments such as radiology and cardiology.

- Remote monitoring and video consultation: This technology allows clinicians and patients to interact virtually (using physiological data and audio/video) and efficiently.

- Email: The increasing use of internet related services enables the integration of basic communications such as electronic mail in the healthcare settings which is proved to be a low cost, fast and effective medium of communication.

- Electronic Health Record (EHR): Access, store or transfer of patient's EHR, high resolution images, consultation notes, medical documents and patient's background history are some of the competent telehealth care services currently in use [247].

The basic functionality and working structure of the selected telehealth system can be described from the patient's and clinician's points of view. The patient's side consists of a wireless transmission unit, medical peripherals for data collection and a video camera (not very common at present) for the transfer of vital signs and video data via the internet. The clinician's side consists of a software application installed on a personal computer or laptop with audio/video capabilities. The VitelMed telehealth care solution includes medical standard features and technology for better healthcare. Also, it gives the patient their own environmental freedom of staying at home while their healthcare services continue.

3.2 Current Healthcare Solutions

The majority of work in the area of wireless remote patient monitoring can be divided into two types of systems: body attached sensor-based monitoring (wired or wireless) and medical device-based wireless monitoring. The development of the 'Electronic Doctor's Bag' [109], with a mobile communication link, is an example of the latter for

home medical services. This system has been tested in two clinics and one hospital with three medical doctors and two nurses. It measures physiological data such as ECG, BP and blood sugar level as well as performing ultrasonic diagnosis of the patient with compressed and coded video images. A case study has been set up with a pilot trial of the system in integrating tele-healthcare and decision support in the patient care management of chronic obstructive pulmonary disease and chronic heart failure [248]. The system was able to identify the risks incurred when an individual's measurements exceeded the predetermined or adaptive thresholds limits. This process was performed by its core decision support system and knowledge-base. Up to 24 hours of constant monitoring of older adults was proposed with a possible extension to a longer term of monitoring and detecting abnormal events and emergency cases. Such events can be reported to the relatives or healthcare professionals by telephone, SMS and e-mail. Moreover, these systems should be able to deal well with security and privacy issues [108].

A computer-aided bedside vital signal monitoring system consisting of a bedside monitor and a central monitor based on an industrial standard has been developed [249]. The central monitor allows real-time access to the bedside data via standard software interfaces to facilitate the communication between the devices. This system performed well in a robust and real-time handling of up to 16 bedside monitors.

McLean et al. [250] conducted a research to identify the technological impact of wireless remote patient monitoring systems on people living with prolonged medical conditions and also people living in remote areas with limited mobility. It is reported that such systems are cost-effective and can offer significant enhancement in healthcare delivery. These systems are evidently useful in early diagnosis [251]; they are low cost [252] and in some cases can reduce hospitalisation [139]. Therefore, accuracy, reliability, removing delay in communication, security and privacy are some of the challenges facing wireless remote patient monitoring systems. More attention to the user's acceptance and feedback should be considered in the design and development of such systems.

TeleHealth Emergency (THE) system has been developed by Minesh et al. [253] based on the 'locate-diagnose-move' technique. THE system is presented in the form of a Wearable Tele-Bio watch which consists of: an alert button for abnormal physiological

parameters (BP, HR and body temperature), a speaker for audio services, a manual call button to connect to the call centre, a display for time, BP, HR and temperature via two navigation keys and a Bio-Belt to collect BP, HR and body temperature. It also contains a global system for mobile (GSM)/ a general packet radio service (GPRS) unit for location and data transfer. Although, THE concept is innovative, it lacks the key tele-health standards in the reported model, the physiological parameters often vary when a person is at rest and/or in activity, hence there is a fair chance of a false alarm generated by a wrist-worn watch with delayed data transmission.

KeepInTouch, a low cost system developed by Angius et al. [254] is constructed in two sections: the patient's side and the clinician's side. The patients' side is a combination of a set-top box to collect medical data and a TV-connected user interface (UI). The clinician's side is a web based application which enables access to audio/video and data from the patient's unit using digital video broadcasting terrestrial technology. The proposed system is easy to operate on the patient's side by removing the PC connection, and using a TV as the medium. However, medical peripherals are limited to only three only specific models/devices. A similar TV-based solution called MOTIVA has also been developed by Philips [255] which does not include any medical data collection device.

A low cost, high accuracy and wide availability system, which obtains a patient's key physiological data from a remote location is proposed by Yan et al. [256]. In case of emergency, when set parameter limits are exceeded, the clinician will receive an alert via the web or SMS. The clinician will then reply with the appropriate measures via the same medium. The data quality is reported as high, but time-delayed results can occur due to the web and mobile data interfaces and the strength of these. Secondly, it is quite difficult for such a system to be implemented in medical settings due to the fact that it uses crisp threshold limits for the alert generation, which is one of the biggest contributors to false alarms [257].

Figure 3.1 shows the basic understanding of four-way (multiple) video conferencing managed by a single server for online use of healthcare consultation in real time. The four blocks with dotted lines are the external/internal data processes performed on the same server simultaneously. The architecture model is adopted from the literature which uses similar concepts. Such tele-communication systems are reported useful in the fields

of heart disease [258], wound care [259], mental health [260], diabetes management [261] and dermatology [262].
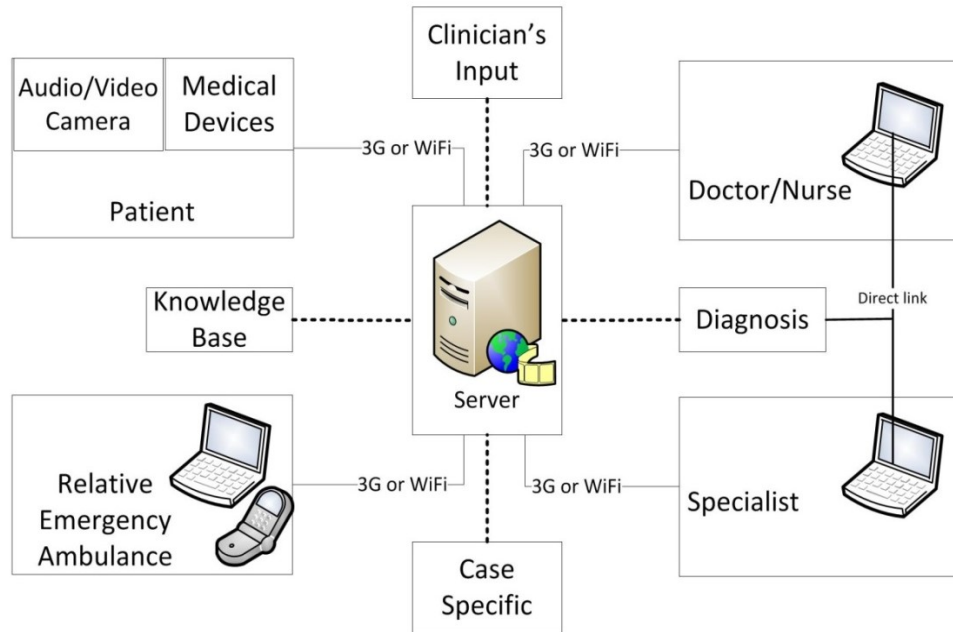
Figure 3.1 Adopted architecture for multiple video consultations for real-time applications.

3.3 Overview of the Proposed System for Application in this Thesis

The system consists of an advanced set-top box, which runs the VitelMed software application providing connectivity with a wide variety of medical devices. A special feature of VitelMed is the one-touch button, for easy and instant connectivity. Users press a button to automatically connect to a call centre or their medical professional. A TV or other screen can be connected to enable two way video/audio tele-visiting (conferencing) using a high resolution camera. It collects vital signs via wired or wireless medical devices and sends that information to the medical professional in real time without any delay. In parallel, a medical professional can have two-way video conferencing, as a virtual face-to-face clinical consultation, using a tilt, pan, zoom high resolution camera. VitelMed is fully operational and efficient in several essential points of healthcare (places): in emergency care (ambulance), in secondary care (hospital) in primary care (medical centres) and also in homes and aged care facilities.

Figure 3.2 Doctor and patient consultation using VitelMed solution [242].

3.4 Connecting Patients and Clinicians

The simple and easy-to-use patient's side of the VitelMed system enables the patient (user) to quickly become familiar with the solution. Using the one touch button, the patient can instantly connect to a call centre, nurse or doctor. In a home setting the system is usually connected to a TV (with remote) to give the user a familiar technological advantage, without the drawback of using a PC or advanced software which may be rejected by older adults due to lack of technological interest or understanding. Fully customised medical parameters for the collection of information, clear and large multi-media keys and on-screen navigation and control settings gives the patient personalised and individual healthcare delivery. The medical professional is provided with a software application, which can be installed on any PC or laptop with audio and video features, with access to the patient's electronic health record and medical history. A clear, easy to understand and user friendly graphical display helps clinicians to provide medical care to the user. On the clinician's side, the application can have two-way video conferencing with real-time physiological data from the patient's side and remote control of the camera at the patient's end.

Figure 3.3 Medical professionals access to VitelMed software application [242].

3.5 Interoperability in Medical Devices Connectivity

VitelMed offers connectivity to a large number of medical devices for patients' physiological data collection. It connects the latest medical devices from almost all medical device manufacturers, providers and vendors. The medical devices which are fully compatible with VitelMed and available in the market to buy over the shelf are: heart rate monitors, ECG monitors, blood glucose monitors, vital sign monitors, peak flow meters, blood pressure monitors, weight scales, pulse oximeters and foetal monitors. This provides for a wide scope of patient monitoring, especially patients with diabetes, congestive heart failure, chronic obstructive pulmonary disease and chronic skin ulcers, the early detection of which allows early intervention to avoid potential hospitalisation.

Figure 3.4 VitelMed Solution kit showing medical devices, speaker, microphone, integrated camera and touch screen [242].

3.6 Technical Capabilities

Some of the advanced technical capabilities which make the VitelMed solution a reliable, cutting edge and advanced telehealth care solution are:

- Communication protocols - audio/video with adaptive bandwidth of 16-2048KBps
- Network communications - LAN, WAN, IP addressing (static, DHCP or PPPoE), TCP/IP protocols
- Data ports - two RS-232, four USB, one SD card connector, IR remote control and Bluetooth class 2

- Communication Security-XML based messaging, first key exchange and streaming encryption

3.7 Basic Design Functionalities

Figure 3.5 shows the overview of the system design and its working model. The system consists of two components: a set-top box at the patient's side and PC based software at the medical professional's side. The key components and some of the features of VitelMed are discussed below.

3.7.1 Set-Top-Box

The set-top-box is a technologically advanced and reliable machine which can be easily connected to TV or screen. It wirelessly connects to medical devices and receives the patient's physiological data as well as audio/video with adaptive bandwidth of 16-2048 Kbps. This may give a high acceptance rate among patients, especially older adults, who are less interested and/or not technically sound enough to use sophisticated computer based software program.

3.7.2 Physiological Data

The system is fully compatible with more than 20 medical devices. This includes almost all vital sign collection devices: ECG, heart rate monitor, BP, P, blood glucose meter, etc. This enables the monitoring of patients with several diseases such as diabetes, heart diseases and chronic obstructive pulmonary disease. This monitoring can have the advantage of early detection of exacerbations and thus may reduce the rate of potential hospitalizations.

3.7.3 Audio/Video Functionality

A high resolution camera, with pan, tilt and zoom transmits high quality data to medical professional in real-time. The medical professional can remotely control the patient's side camera which gives them a realistic and face-to-face consultation experience with the patient and eventually helps to assist in much detail. It uses advanced network communication such as: LAN, WAN, IP addressing (static, DHCP or PPPoE) and TCP/IP protocols.

3.7.4 User-friendly Approach

The VitelMed system offers patient a one-touch button for direct connectivity to the clinician in case of emergency. A single touch button will connect to the medical professional's PC based software and an instant audio/video conference call takes place with real-time physiological data available at both ends. It also gives clear on-screen information to the patient, which is very useful in system (technology) acceptance and reliability.

3.7.5 Data Security

The VitelMed box has a number of data ports for wired connectivity such as: RS-232, USB, secure digital card connector and Bluetooth class 2 for wireless connectivity. Security and privacy of medical data and the patient's personal identification is secured by using XML based messaging, first key exchange and streaming encryption. The collected data is assigned a unique identifier linked with the patient's medical devices and profile. Patient data is encrypted before transmitting over the web-based services and data can only be accessed by a unique login and password. Additional firewall/port settings were also enforced, to protect patient's data. Each patient profile is linked with a patient-assigned medical device (serial number and MAC address) only to receive the wireless medical data directly into the specific patient profile. Additional evaluation and validation has been performed to test each and every module of the system, including data loss, data accuracy, transmission time and overall reliability of the system.

3.7.6 Clinician's Side

The clinician has a PC based software application which can be installed on any PC, with audio/video functionality such as microphone and webcam. During a video visit (video-conferencing), the clinician can access the patient's physiological data in real time similar to a face-to-face consultation. Much consideration has been given to the clinician's acceptance of this technology by providing informative, easy and simple to use graphical user interface.
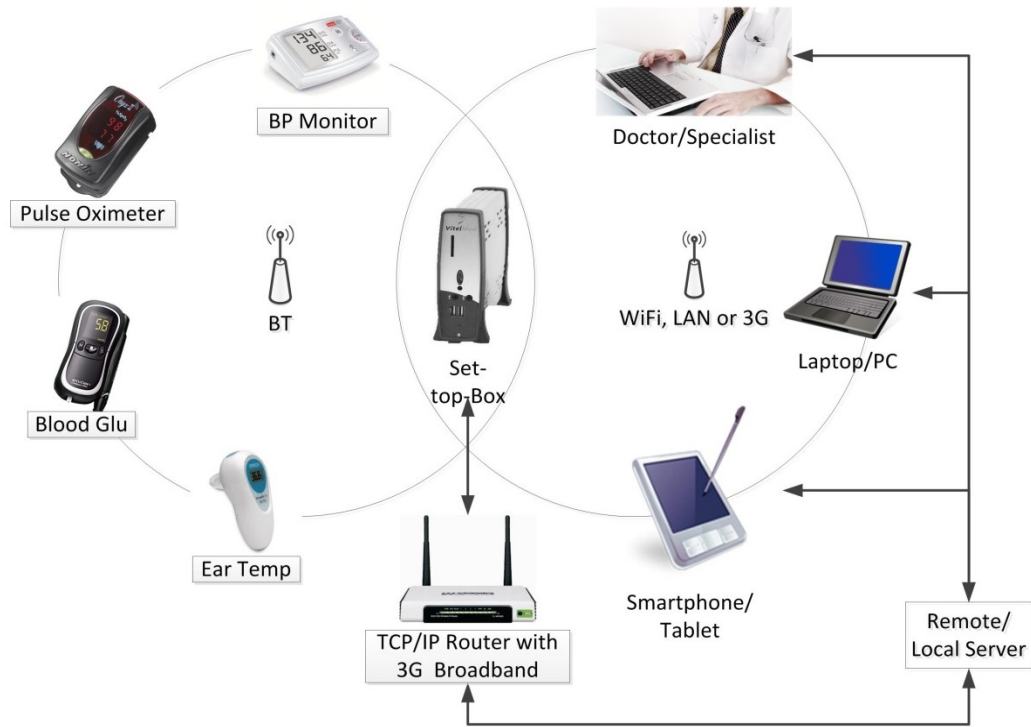
Figure 3.5 Overview of proposed system design, communication and working model

3.8 Overall Integrated Healthcare System Model

Integrated healthcare system plays an increasingly important role in current healthcare reform efforts [9, 46, 263]. Economic, political and socio-demographic forces are moving the modern healthcare system beyond the largely reactive acute care paradigm to a more holistic paradigm emphasizing optimization of the population's health [264]. Many healthcare providers believe that an integrated healthcare system will lead to higher quality care at a lower cost while maintaining or improving the recipients' health and satisfaction. Integration of healthcare system can facilitate the optimisation of patient data being shared for common services and it minimise the under-use, overuse or misuse of patient data [264]. However, monitoring the progress potentially associated with the efforts being made, and the gathering and dissemination of evidence-based knowledge is hampered by the lack of integration of patient's information being shared among healthcare organisations [265]. One of the main aims of this research is to achieve the integrated healthcare system depicted in Figure 3.6 which currently contains four main modules (observational, physiological, motion and diagnosis) and has the capability to add more similar healthcare services modules, such as medication, history, etc. Integration of the proposed system into the existing electronic health records

systems in primary and secondary healthcare is being investigated and initial results suggested that it is highly possible to integrate the system.

3.8.1 Video Conferencing/Telehealthcare (Physical Observation)

Among other advancements of telehealth service is the use of video conferencing between the patient and the clinician. This technology is likely to enhance current healthcare. The use of video communication in companies (teleconferencing), academic institutions (educational videos) and personal or social use (video chat) has enabled the technology to be integrated in the medical environment and provide innovative healthcare services. Today telehealth systems using video consultation is emerging as a cost-effective and efficient platform for the healthcare sector. The efficiency of this technology is constantly evaluated in the research studies and literature review. A comparison between face-to-face and closed circuit television (CCTV) interviews with 85 psychiatrically disordered people has found no significance differences between the two interview methods [266]. A similar comparison in neuropsychological assessment of 98 patients by Schopp et al. showed no significant difference and reported the videoconferencing approach is proven to be cost-effective [267].

A research study on the use of equipment in telehealth care has reported that a cheap computer with basic components including audio/video capabilities is enough to carry out the video consultation for basic treatments but suggested more sophisticated equipment is required for advanced treatment via video consultation [268]. The system is tested for the audio/video conferencing of up to four people. This module of the system is not tested in a clinical environment due to the ethical and policy issues restricting the use of video in a hospital. Therefore, the methodology, working model and testing results are not emphasised in this research. Moreover, this module is beyond the scope of the research and it is tested in non-hospital settings only in order to check the working and integration of the whole system (other modules). Instead this study has adopted the traditional face-face observation method to collect the physical observational data, which is inserted manually into the patient's profile containing other information such as vital signs, motion data and medications.

3.8.2 Wireless and Remote Vital Signs Monitoring (Patient Monitoring)

Observational data combined with vital signs helps the system to accurately interpret the possible physical signs. Wireless and remote vital signs monitoring (described in this chapter) allows the clinician as well as the patient to access vital signs information at anytime and anywhere in real-time. It is reported that the accurate observation of vital signs in real time (without long delays) can help reduce grave consequences [29, 36, 43, 178].

3.8.3 Falls Prediction and Detection (Predictive Model)

The falls prediction and detection module combines the patient motion data with real-time vital signs and related observational notes in order to help predict falls risk. Instead of falls detection this research focuses on falls prediction to avoid falls and their related disabilities in hospitals. Currently hospital falls are one of the major healthcare concerns worldwide because of the ageing population. Current observational data and vital signs gives the critical information related to the patient's physiology, and motion data provide an additional tool in falls detection/prediction. These data combined with the patient's medical history potentially gives the interpretation model high information accessibility to predict falls risk (described in detail in the next chapter).

3.8.4 Interpretation and Diagnosis (Decision Support)

The next chapter discusses the proposed interpretation model in detail including methodology adopted and the framework developed for interpretation of physical signs. Early detection of physical sign(s) is also tested and evaluated.
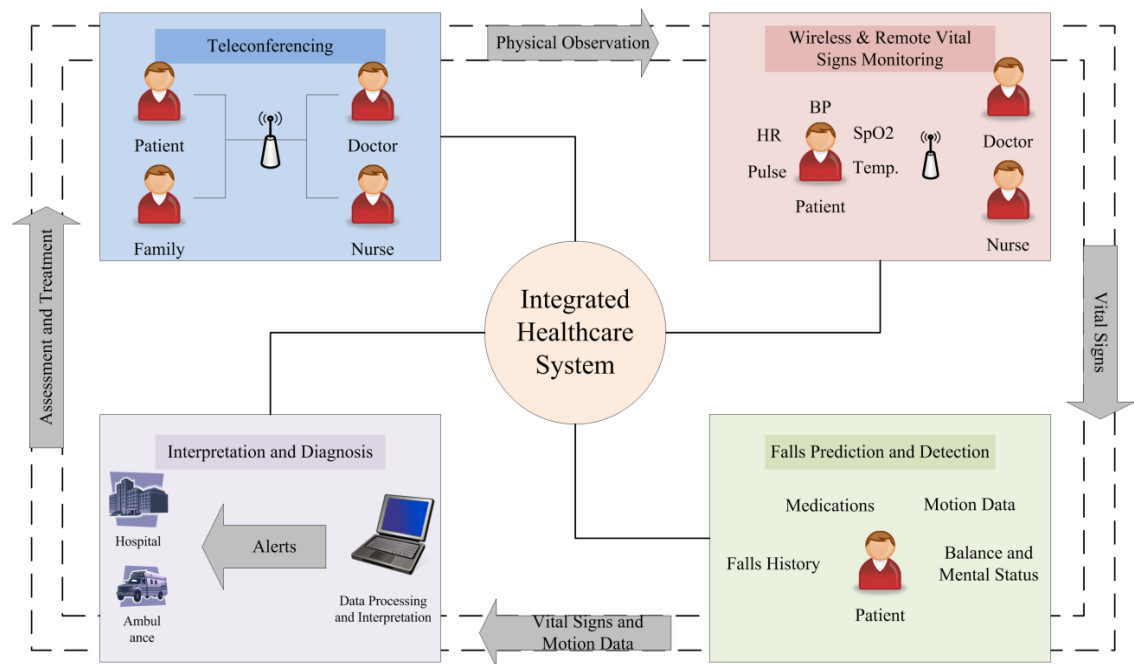
Figure 3.6 Overview of the integrated healthcare system of this thesis described in four main modules.

3.9 Summary

This chapter described the remote and wireless vital signs monitoring module of the proposed system of this thesis and its key components. The web access is emphasised in order to address the accessibility issue of the patient's vital data over the web to the patient as well clinicians in real time. Security and privacy are also addressed to the extent that the system can be considered secure for vital data collection and transmission.

The proposed system incorporates physical observations as text input because, at present, hospitals (North Shore Hospital and Waitakere Hospital) do not have any computerised ward-monitoring outside the intensive/cardiac/emergency clinical situations. Real-time vital signs are the critical inputs that contribute to the multiple physical signs interpretation as well as falls risk prediction. Motion data potentially aids falls risk prediction in terms of low, medium and high risk.

This chapter also introduced the overall methodology used to conduct hospital clinical trials. The next chapter will discuss the data collection process and protocols adopted to collect real-time patient's vital signs in hospital, including data statistics and analysis.

CHAPTER 4   Data Collection and Protocols

4.1 Introduction

The managerial aspect of providing health services to patients in hospitals is becoming increasingly important. Hospitals want to reduce costs and improve their financial assets on one hand, while they seek to maximise the levels of care and patient satisfaction on the other. One unit that is of particular interest to this research is the older adults' wards. In fact, health professionals have to anticipate the increasing demand in healthcare services caused by the ageing population [269]. These factors clearly emphasise the need for efficiency, and the necessity for further enhancements in the hospital wards. The past few decades have witnessed a real improvement in the ward setup and patient monitoring equipment; this benefits both the clinician and the patient. Even patient monitoring while they are being transported to the hospital provides data on such vital and complex parameters as electrocardiography (ECG), oxygen saturation by pulse oximetry (SpO$_2$), heart rate, and blood pressure [270], which helps with early treatment and makes the clinician's work easier.

One of the important areas related to this research is the patient's vital signs, on this the whole development is based on. This chapter in-detail discuss the data collection methodology, adoption of data collection (including ethical approvals) and discusses the test-bed prepared for the real-time hospital clinical trial.

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 vital data record 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 care.

The electronic health record (EHR) is a generic document that is used for a wide variety of assessments and procedures. An ideal record system is expected to contain relevant patient information: procedure, evaluation, intra-operative events/complications, medications, history, observation charts, known issues and other instructions. This record can be, and has been, used for post data analysis, fault detection, development of

monitoring systems, development of warning systems and also in a number of different areas of related studies.

The rapid development of telecommunication and information technologies has accelerated development in the EHR [271]. This work also explores the possibility of realizing a reliable and efficient remote monitoring system and the development of a decision-support system to function in a smart alarm capacity and manage the complexity of modern healthcare procedures. Wireless patient monitoring systems in the hospital ward not only increase the mobility of patients and medical personnel, but also improve the quality of health care [272]. With respect to the remote monitoring of patients, many groups have demonstrated the transmission of vital signs using: GPRS, 2G, 3G, 4G and 5G (under development) networks [107]. Some researchers have used cellular phones to transmit vital signs from the ambulance to the hospital, either in store-and-forward mode [273] or in real-time mode [274]. In the following sections of this chapter, the details of patients' data collection are discussed, followed by data acquisition devices and protocols.

4.2   Ethics Approvals and Process

The collection of vital signs from humans (patients) is considered as s 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. [275]'

The research described in this thesis has successfully obtained ethics approvals in order to conduct the hospital clinical trial in New Zealand from the following authorities:

- Universal trial number obtained from World Health Organisation (U1111-1126-9410).
- The proposed clinical trial has been registered at Australia and New Zealand Clinical Trials Registry (ANZCTR) – APPENDIX A1.
  (https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=347922)

- Northern X Regional Ethics Committee approval number – NTX/12/EXP/073, approved March-2012 - APPENDIX A2.

- Waitemata District Health Board's (WDHB) Maori Research Review Committee, Awhina Research & Knowledge Centre – APPENDIX A3.

- Auckland University of Technology Ethical Committee (AUTEC) approval number – 12/117, approved May-2012) - APPENDIX A4.

4.2.1 Sample Size

For sample size calculation it is assumed that the significance level is 0.05, power of 0.95, the effect size of 0.6 (mean difference 1.2 and SD 2). The calculation returned the sample size of 30. This was also consistent with previous research experience (Anaesthesia monitoring [276-279] using 30 patients). The above calculation is carried out using G*Power 3.1.3 [280].

4.2.2 Patient Inclusion and Exclusion Criteria

Patients on Assessment, Treatment and Rehabilitation (AT&R) wards of North Shore Hospital and Waitakere Hospital are all over the age of 65 (male and female). Those who refused informed consent (see below); Hodkinson AMT 7/10 or less [281], patients deemed unsuitable by medical or nursing staff, terminally ill patients and patients on any other monitoring device were excluded from the study.

4.3 Patient Recruitment Protocol and Process

Ward-based medical staff identified appropriate patients and approved the patient information sheet (APPENDIX B1) that was given to the patient with a verbal explanation 24 hours prior to obtaining consent. An approved patient consent form (APPENDIX B2) was used to obtain written patient consent, signed by the participant and the ward clinician (physician). A ward-based trained registered nurse helped with data collection.

4.4 Hospital Setup

One of the critical aspects of data collection was the device optimization and maintaining the appropriate distance between the set-top-box and the wireless (BT) devices. Figure 4.1 shows the hospital ward nursing station where the setup was installed. The distance was within the BT range from all corners/rooms to the nursing

station as the nursing station is almost in the centre of the ward, connecting all the rooms and walk ways. The distance and location of the data collector was critical in order to avoid any data loss due to the BT connectivity. This was identified and remedied during the pre-hospital trial setup and testing of devices. In the view of this research, Figure 4.1 shows the practical setup for the real-time test bed during a real-time data collection and testing session at the Waitakere Hospital (WDHB). The goal of the real-time data collection was to capture the vital signs and related patient information/observation with the correct time-stamp, and to evoke suggestions from the clinicians for making the prototype alarm more ergonomic.
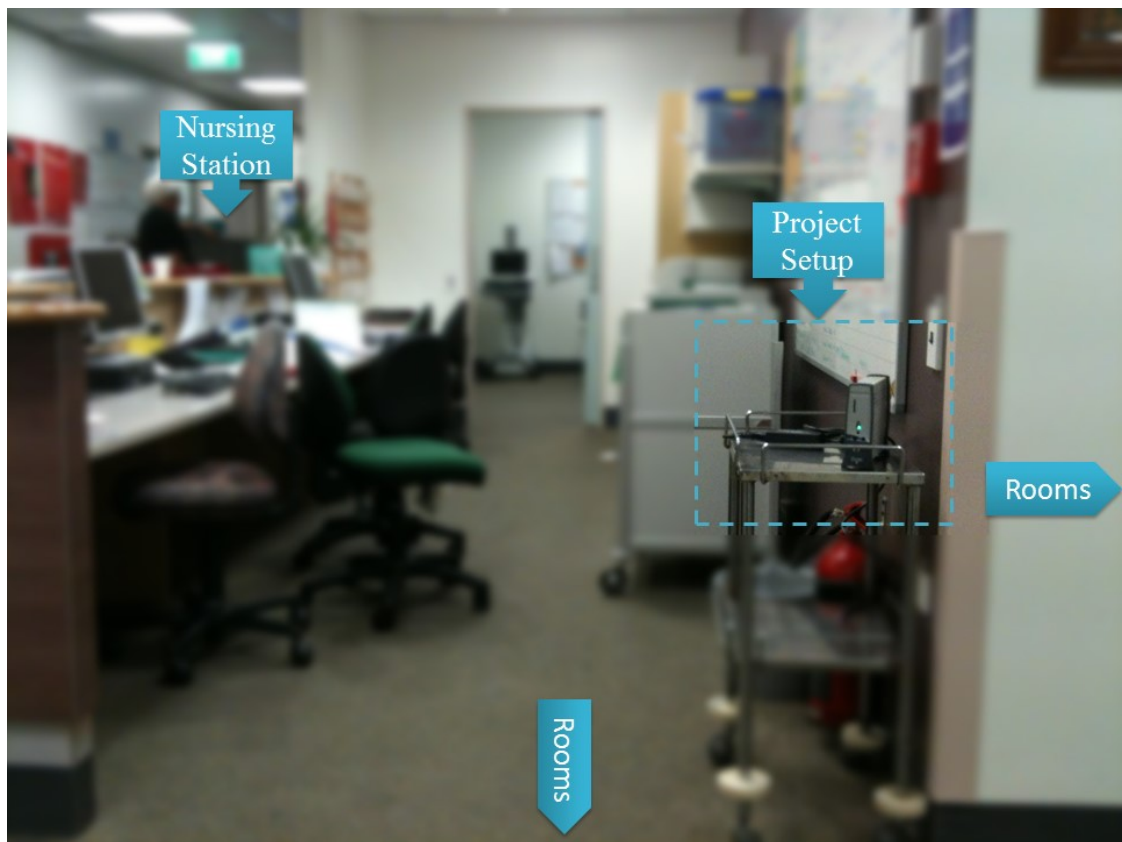
Figure 4.1 Hospital's project setup

4.4.1 Selection of Wireless Medical Devices

This research adopted market available clinically proven and validated wireless medical devices that were incorporated into one system. Development of wireless medical devices 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 wireless in-hospital patient monitoring system. The

selection of medical devices 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 4.1 describes the features/functionalities considered in each device before the device selection. Device features are divided into five categories; wireless (project theme), reliability (for use in hospital), transmission (seamless data transmission to other machines), size/power/cost (end user's ease and affordability) and operational usability.

Table 4.1 Features identified for inclusion of medical devices.

Categories	Features
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

4.4.2   Wireless Medical Devices

Figure 4.2 show the wireless medical devices used in this research after satisfying the above selection criteria. The system has the capability of collecting multiple data simultaneously from multiple patients. A brief description of the devices shown in Figure 4.2 is given below (number 1-8 refers to the medical device shown in Figure 4.2);

1. **Set-top-box**: It runs the software application which receives the patient's physiological data from different medical devices and transmits it in real-time over the secure internet connection to the personal PC or laptop.

2. **Blood pressure monitor**: Boso-medicus prestige blood pressure monitor [55] is a wireless Bluetooth device. It measures blood pressure (systolic and diastolic) and pulse, records at user defined time intervals and is easy to operate.

3. **Pulse Oximeter**: Nonin's Onyx II finger clip oximeter [65] is a wireless Bluetooth device which records oxygen saturation and heart rate continuously.

4. **Blood glucose meter**: Accu-Chek Compact plus blood glucose meter [282] is wireless infrared connected device which records the blood glucose level.

5. **Ear temperature**: Omron's instant ear thermometer [68] is an accurate and fast ear temperature measurement device.

6. **Body temperature**: G-plus wireless remote body thermometer [69] is a continuous body temperature wireless device.

7. **Spirometer**: nSpire's Piko-6 meter [283] is a wireless infrared connected device which gives FEV6 and FEV1/FEV6 readings.

8. **Accelerometer**: Gulf Coasts Data Concept's accelerometer/Magnetometer Data Logger X8M-3mini [284] is a compact, continuous data collection device used for falls detection in this project.

Figure 4.2 Wireless medical devices used for the proposed patient monitoring system.

4.4.3 Medical Devices' Specification and Functionalities

Table 4.2 describes the specification and functionalities of the wireless medical devices described above.

Table 4.2 Medical device specifications and functionalities

Medical Device	Model	Connectivity/ Transmission	Size/Body position
Blood Pressure	Bosco-Medicus Prestige BT [55]	Wireless/ BT	Small/arm cuff
Pulse Oximeter	Nonin's Onyx-II [65]	Wireless/ BT	Compact/finger tip
Blood Glucose	Accu-chek Compact Plus [282]	Wireless/ IR	Small/ fingertip blood
Ear Temp.	Omron's Instant ear thermometer [68]	Wireless	Small/Ear
Body Temp.	G-plus Wireless body thermometer [69]	Wireless/ BT	Compact/ armpit
Spirometer	nSpire's Piko-6 [283]	Wireless/ IR	Small/ air blow
Accelerometer	8-XM3-mini [284]	Wireless	Compact/ chest

Where BT is class-2 Bluetooth and IR is infrared.

4.4.4   Data Transmission and Communication

The generic system architecture is illustrated in Figure 4.3. The set-top-box is capable of and responsible for vital data collection from all the wireless Bluetooth (BT) connected devices: audio/video (optional) recordings and transmitting the data in real time to the clinician's computer directly or via a central processing system where data analysis and fuzzy logic diagnosis was performed. High importance has been given to the security and privacy of the system due to the wireless and remote connectivity of the system. Security and privacy of patient information in remote monitoring systems is one of the biggest concerns and is considered to be a barrier to the adoption of this healthcare technology worldwide [125, 126, 133, 138].

The set-top-box has a secure gateway which allows data connectivity to the devices which are registered and linked to the specific patient profile including details of devices (serial number and MAC address). Data received at the clinicians' end can only be accessed by use of a unique username and password. This study purposely avoids

any public network connectivity due to the possibility of third-party access to the sensitive medical information and therefore mobile 3G data has been used via a secure router and firewall settings, which connect to the set-top-box and laptop (wired as well as wireless). The system can also work on other networks such as WiFi, mobile data (GPRS, 2G or 3G), LAN or UMTS.
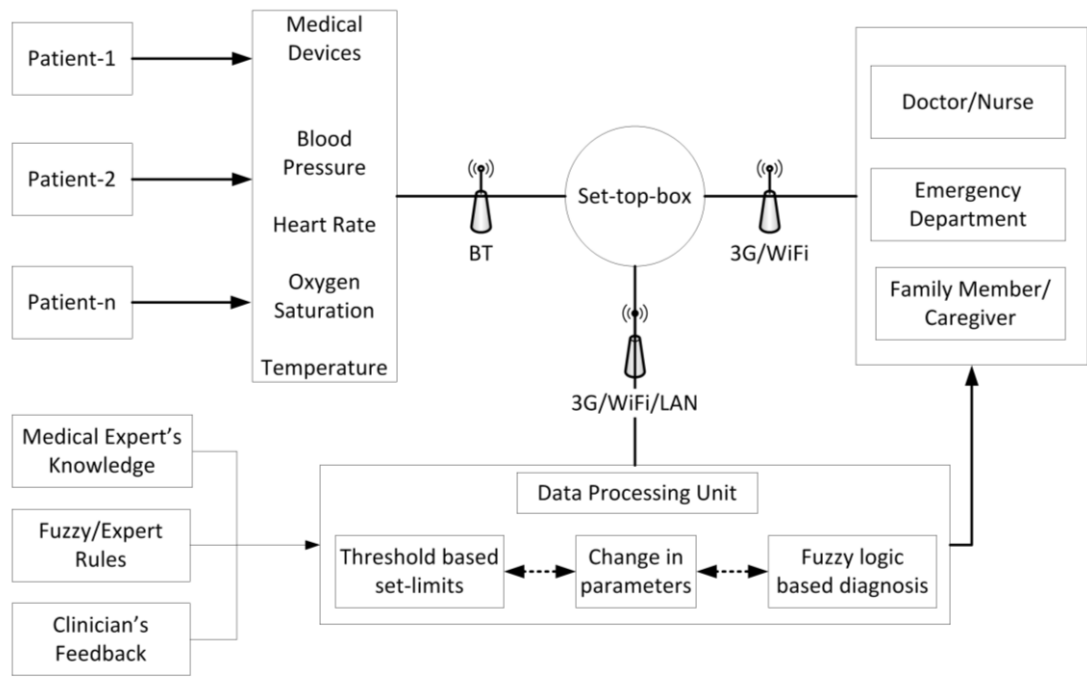
Figure 4.3 Generic system architecture of proposed monitoring and diagnosis system: three bold lines connecting the set-top-box shows the wireless connectivity and instant, real-time data transmission to other devices.

4.5 Data Collection

This study implemented a three-way cross validation data collection method: firstly, vital signs were collected by wireless medical devices and transmitted in real-time to the base machine (laptop); secondly, the trained registered nurse performed blind manual readings of the same parameters, using standard ward devices. Every measurement made by the medical devices was recorded manually by the researcher to check wireless transmission data loss, inaccurate data transmission, and transmission delay time. Every measurement transmitted wirelessly was stamped for real-time and date with the unique patient ID representing that patients profile and their connected device(s). Apart from the vital signs, the proposed system allows the clinician to enter additional clinical notes/comments, which is regarded as an advantageous feature because physical observation during the patient interaction and patient complaint is one of the best ways

to diagnose the real health issue. Observational notes such as: wounds, bandage, plaster, walking frame, gutter frame, pain complaints, activeness, response, visible mood and recent incident/improvement, restriction, special exercise/diet, irregular heartbeat etc, combined with real-time vital signs gave the interpretation model high accuracy and reliability. A screenshot of a typical patient file containing vital signs and observation notes used for advanced processing and interpretation is shown in APPENDIX C.

4.5.1 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 group is different from the 80+ age group. The difference is minor (Table 4.6) 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 4.3 below shows the variety of statistical information related to the patient data collected. In the tables below BP (Sys/Dia) is blood pressure (systolic/diastolic), 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 Temp is tympanic (ear) temperature in degree Celsius.

Table 4.3 Mean values of the whole patient data

Parameter	Mean Value
Number of Patients	30
Age	82Y 1M
Sex (M/F) %	57/43
BP (Systolic/Diastolic)	125.15/71.81
Heart rate	77.42 BPM
Oxygen Saturation	96.12%
Blood Glucose	134.79mg/dl (7.48 mmol/l)
Tympanic (ear) Temperature	36.56 ºC

Table 4.4 Statistical information of the whole patient data

Parameter	Age	BP (Sys/Dia)	HR	SpO2	B Glu	Temp
Maximum	93.7	205/118	130	100	236	37.5
Minimum	65.9	78/47	49	80	66	35.3
Range	27.8	127/71	81	20	170	2.2
SD	6.39	21.35/12.85	16.04	3.51	46.72	0.39
Median	83.80	122/70	75	97	111.5	36.6
Mode	72.9	118/70	74	97	101	36.5

Table 4.5 Statistical information of male/female

Parameters	Sex/Stats	Mean	Max	Min	Range	SD	Median
Age M=17&F=13	M	81.57	93.7	65.9	27.8	7.73	82.9
	F	82.74	88.6	72.9	15.7	4.62	84.11
BP (Sys/Dia)	M	123.6/67.4	205/94	78/48	127/46	21.4/9.1	121.5/67
	F	126.5/75.7	185/118	81/47	104/71	21.2/14.4	122.5/75.5
HR	M	75.73	128	49	79	15.69	74
	F	78.96	130	53	77	16.28	75.5
SpO2	M	96.15	100	80	20	3.722	97
	F	96.08	100	82	18	3.32	97
B Glu	M	151.73	236	86	150	49.60	157
	F	106.55	149	66	83	23.11	107
Temp	M	36.57	37.5	35.6	1.9	0.38	36.6
	F	36.55	37.5	35.3	2.2	0.40	36.6

Table 4.6 Statistical information for 65-79 and 80+ age groups

Parameters	Stats	Mean	Max	Min	Range	SD	Median
Age 65-79 = 9 80+ = 21	65-79	74.5	79.11	65.9	13.21	4.12	74.4
	80+	85.72	93.7	80.5	13.2	3.31	85.7
BP (Sys/Dia)	65-79	127.5/71.3	205/94	96/52	109/42	21.2/10.4	123/71
	80+	124.4/71.9	185/118	78/47	107/71	21.3/13.5	122/70
HR	65-79	76.90	128	53	75	14.53	75
	80+	77.58	130	49	81	16.52	74
SpO2	65-79	95.72	100	84	16	4.06	97
	80+	96.24	100	80	20	3.32	97
B Glu	65-79	162.57	210	91	119	50.07	181
	80+	123.35	236	66	170	41.48	110
Temp	65-80	36.5	37.3	35.6	1.7	0.40	36.6
	80+	36.5	37.5	35.3	2.2	0.39	36.5

The above statistical information is used to develop the basic outline of the proposed interpretation model, so that a multi-layered structure can be implemented i.e. multiple vital signs associated with multiple physical signs.

4.6 Data Associations

4.6.1 Input and Output Data

The relationship between the vital signs and physical signs is considered to be the core knowledge and theoretical framework for this research. The direct relationship between the vital signs and physical signs are shown in Table 4.7 shows the baseline in assigning the input-output parameter outlines. However, this study is based on multiple input/output data points.

Table 4.7 Direct association between vital signs and physical signs

Vital Signs	Interpretation model for multiple input and multiple output parameters	Physical Signs
Heart Rate		Tachycardia/Bradycardia
Blood Pressure (Systolic and Diastolic)		Hypotension/Hypertension
Oxygen Saturation (SpO2)		Hypoxaemia/Hypovolaemia
Respiration Rate		High / Low Respiration Rate
Temperature		Fever / Hypothermia
Body Movement		Falls & Accidents

4.6.2 Relationship between Vital Signs and Physical Signs

Table 4.8 shows the important relationship between the collected vital signs and their related possible physical signs. The relationship was established after consulting medical experts (Professor of Geriatric Medicine) and widely accepted literature [285]. This key relationship is adopted in the proposed vital signs interpretation model to detect various physical signs.

Table 4.8 Relationship between vital signs and physical signs

Physical Signs/Parameters	Heart Rate (HR)	Blood Pressure (BP)	Oxygen Saturation (SpO2)	Temp. (T)
Bradycardia	L	N/A	N/A	N/A
Tachycardia	H	N/A	N or L	N/A
Hypotension	L/N/H	L	N/A	N/A
Hypertension	N/A	H	N/A	N/A
Hypoxaemia	N/A	N/A	Often L	N/A
Fever	H or N	N/A	N/A	H
Hypothermia	L or N	L or N	N/A	L
Normal Range	60-90 bpm	100-140/60-80 mm/Hg	94%-99%	36.5-37.5 ^{0}C

Normal ranges are adopted from the literature [285] as well as a medical expert consultation, and the normal range may be different for some (when clustered into groups: age, and/or sex) but it is acceptable for the majority of the population. H = high, L = low, N = normal and N/A = not applicable.

4.7 Summary

Figure 4.4 shows the generic system architecture for the described scenario. Physiological biosensors constitute the front-end components of the system employed to measure a variety of vital signals. These wearable physiological sensors available on the market consists of wearable devices, such as wrist devices, ear-lobe sensors, finger sensors, arm bands, chest belts, waist belts, etc. In the latter case, the distributed biosensors are capable of wirelessly communicating their measurements and thus constitute a body area network (BAN), which can be formed through Bluetooth-enabled devices. Basic signal conditioning operations such as filtering, amplifying, and

normalising - even basic feature extraction - are usually performed by dedicated hardware (central processing unit).

The central processing unit (personal computer) performs several key tasks, as follows:

1. Handling the communication with the on-body-distributed biosensors, which involves collecting physiological measurements and voice recordings, communication synchronization, sending control signals for adjusting sensors' parameters, e.g., sample rate, accuracy and receiving sensor status data.

2. Performing additional digital signal processing on the acquired signals for feature extraction.

3. Verifying the received data, e.g., checking the validity of the received data via an advanced algorithm and discarding those that are found to be erroneous.

4. Comparing the extracted features or values from each signal with the thresholds, limits, or patterns located in the local signal database, which may contain patient-specific information about abnormal states, in order to possibly detect any health risks (embedded decision support).

5. Generating alarm signals for the user.

6. Displaying the collected measurements on the GUI in real time.

7. Transmitting the extracted medical information about the user to a remote medical station, e.g., to a medical centre or to a physician's cell phone, either in real time or in the form of report forms upon request or upon detection of events.

The next chapter explores the proposed vital signs interpretation for early detection of multiple physical signs. The framework, system modelling and other key components are described. The methodology and techniques adopted for the proposed system are also explored.
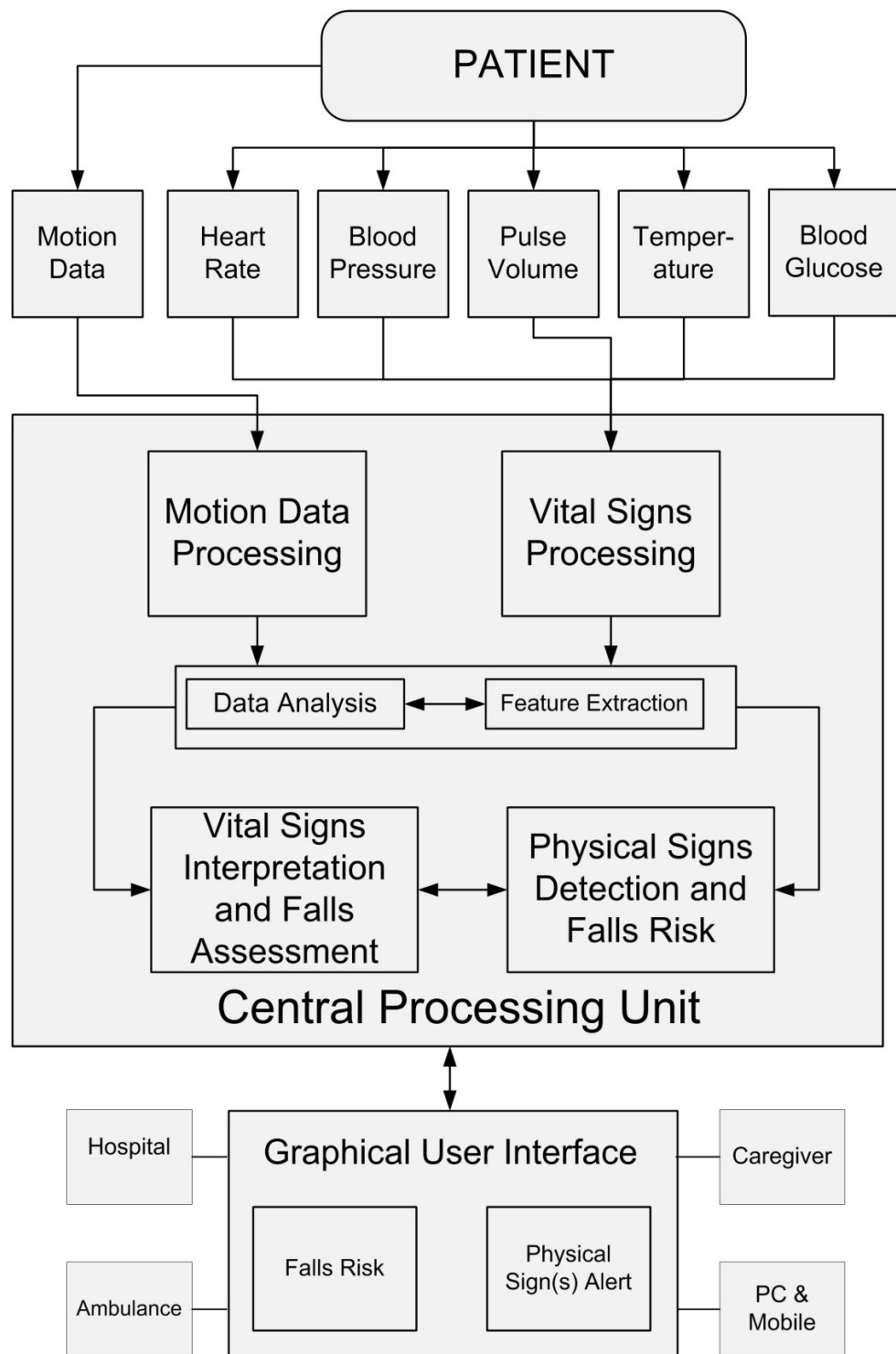
Figure 4.4 Data flowchart-block diagram view of the proposed model.

CHAPTER 5   Vital Signs Diagnosis and Interpretation

5.1 Introduction

Expert systems [286], clinical decision support systems [134, 248] and rule-based systems [287] have proved to be useful in medical diagnosis. These techniques have been established as expanding areas of research using their features and capabilities to turn 'data' into 'useful information' [178, 190, 288, 289]. Computer programs employing *fuzzy logic* are intended to imitate human thought processes in complex circumstances, but to function at greater speed [290]. Fuzzy logic-based expert systems have been developed in each and every area of healthcare delivery [100, 101, 208, 237, 291].

Fuzzy logic based vital signs monitoring systems mimic the expert's behaviour by executing a sequence of smart/intelligent algorithms which interpret vital signs in a meaningful manner fast and accurately. The expert knowledge systems for making the diagnosis are normally implemented using a form of linguistic rules. These rules are required to be converted into a programmable set of rules for the development of smart computer algorithms. Fuzzy logic based systems have the potential for implementing these linguistic rules into logical algorithms with high effectiveness and clinical usefulness. By using a fuzzy logic based algorithm, expert diagnostic systems can be developed to help the clinicians, as discussed by Grant and Naesh [290]. The proposed interpretation model uses the intelligent combination of a C language based classifier and fuzzy logic modelling with weighted parameters for vital signs interpretation and diagnosis of multiple physical signs.

5.2 Fuzzy Logic and its Application to Patient Monitoring

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 [292]. Unlike classical logic which requires a deep understanding of a system, exact equations

and precise numeric values, fuzzy logic incorporates an alternative way of thinking, which allows modelling complex systems using a higher level of abstraction originating from our knowledge and experience. It allows the expression of this knowledge with subjective concepts such as very hot, bright red and a long time, which are mapped into exact numeric ranges. Fuzzy logic has been gaining increasing acceptance during the past few years. There are over two thousand commercially available products using this logic, ranging from washing machines to high-speed trains. Nearly every application can potentially realize some of the benefits of fuzzy logic, such as performance, simplicity, lower cost and increased productivity.

5.2.1 A Fuzzy Pattern

Fuzzy logic is a logic that arrives at a definite conclusion based on vague, ambiguous or imprecise input information. When applying mathematical concepts to our daily lives it is often difficult to adhere to the logical constraints of traditional set theory because of the vagueness of the real world. The fuzzy logic enables an object to belong to a set with a certain degree; unlike traditional logic, it addresses the complexity of the world. It can also be used practically to aid systems in decision making. For example, the statement, 'Today is sunny' may have different degrees of truth. It may be 100 percent true if there are no clouds, 80 percent true if there are a few clouds, 50 percent true if it is hazy and 0 percent true if it rains all day. Now, let us observe how it aids in decision making. Consider the statement 'If today is not too hot and not rainy then I will go out to play'. This suitable condition of the statement can be reached by using basic fuzzy propositional logic. It analyses the degree of the suitable condition based on the sets designated, i.e. hot and rainy, obtains a crisp value, and then finally outputs a definite result [293].

Today, computers have a brilliant capacity for decision making for crisp processes. However, this is limited to systems which have a mathematical interpretation without human reasoning. Computers use binary logic and, prior to Zadeh, could only allow for values 1 for true and 0 for false. Statements like 'this car is not fast enough' or 'this person is quite smart' are rather vague statements which cannot be interpreted by classical logic. To handle this vagueness, fuzzy logic provides an extension from the classical logic [294]. Fuzzy logic starts, and builds on, a set of user-supplied human language rules. The fuzzy systems convert these rules to their mathematical equivalents.

This simplifies the job of the system designer and the computer, and the results are a much more accurate representation of the way systems behave in the real world.

The concept of Adaptive Neuro Fuzzy Interference system (ANFIS) [295] 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) [296]. The following sections will present and develop ideas such as sets, membership functions, logical operators, linguistic variables and rule bases.

5.2.2   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.

5.2.2.1   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.

5.2.2.2   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:

$$A = \{x \mid x > 3\} \qquad (5.1)$$

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:

$$A = \{x, \mu A (x) \mid x \, \varepsilon \, X\} \qquad (5.2)$$

Note that in the above expression μ 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 5.1 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.
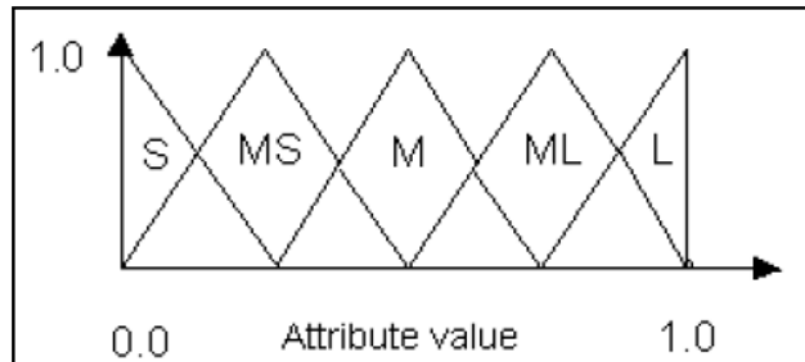
Figure 5.1 Example of Fuzzy Set. S is small; MS is medium small; M is medium, ML is medium large; L is large.

Figure 5.2 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.
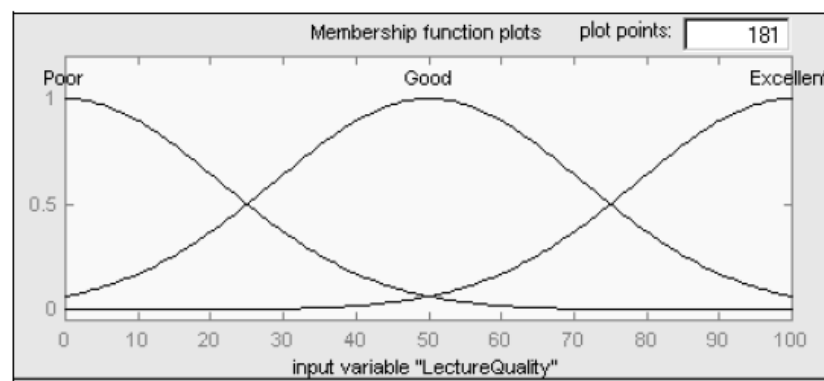
Figure 5.2 Example of a three-part Gaussian shaped MF.

5.2.2.3   *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. For this functionality, the functions min, max and additive complement (1-A) will have to be used.

5.2.3 Linguistic Variable and Rule Bases

Linguistic variables are values defined by fuzzy sets. The conditional statements that make up the rules that govern fuzzy logic behaviour use these linguistic variables and have an IF-THEN syntax. These IF-THEN rules are what make up fuzzy rule bases.

An IF-THEN rule can contain multiple premises or antecedents. For example,

- IF speed is high and the road is wet and brakes are poor THEN….

Similarly, the consequent of a rule may contain multiple parts.

- IF the temperature is very high then the fan is on and throughput is reduced THEN

Rule bases involve a number of distinct steps such as:

1. Firstly, the inputs must be fuzzified to a degree of membership between 0 and 1. This means that if the antecedent is true to some degree of membership, then the consequence is also true to that same degree.
2. Secondly, fuzzy operators are applied for antecedents with multiple parts to get a single number between 0 and 1.
3. Thirdly, the result is applied to the consequence. This step is also known as implication. The degree of support for the entire rule is used to shape the output of a fuzzy set.
4. The outputs of fuzzy sets from each rule are aggregated into a single fuzzy set output. This final set is evaluated (or defuzzified) to get a single number.

The process of fuzzifying a single crisp input, applying fuzzy operators and then defuzzifying it to produce a single crisp output is known as fuzzy inference. This progression of modelling is discussed in detail in Section 5.4.

5.3 Current Expert/Decision Support Systems

Environmental Multimodal for Tele-vigilance Medical EMUTEM for home monitoring has been developed [234]. It consists of three subsystems: the Anason [234] subsystem includes a set of microphones that allow sound remote monitoring of the acoustic environment of the older adult; the RFpat, a wearable device that can measure physiological data, such as heart rate, activity, posture and a fall; infrared sensors called Gardien [234] which detect the presence of the person. The EMUTEM fuzzy inference engine is developed using two groups of fuzzy IF-THEN rules: the output variable localization and the output variable alarm according to all inputs. As a result the system has achieved 95% accuracy for alarm generation and 97% accuracy for localisation. Centinela [235], a mobile phone-based sensing device combines acceleration data with vital signs to achieve highly accurate activity recognition. Centinela recognises: walking, running and sitting. After an extensive evaluation on statistical, structural and transient features, using eight classification algorithms, and three different window sizes, the system achieved the highest overall mean accuracy of 95.7% with a window size of 12s (including vital signs and acceleration data). It is also reported that the vital signs combined with acceleration data can be useful for recognizing certain human activities more accurately than by considering acceleration data only [235].

FLOGERA [236] has been developed with a special focus on accurate and reliable event detection in wireless sensor networks (WSN) using the fuzzy inference system (FIS), implemented in a TelosB [236] mote for a wide range of communication protocols. The system has achieved high rule verification for the FIS with 85% success rate when two out of five inputs were tested but the system performance was poor when more than three inputs were given. This poor performance is a concern for vital signs monitoring system with three basic inputs: HR, BP and P. Fuzzy CARA [237] has been developed to detect four real life situations: 'normal', 'abnormal', 'dangerous' and 'emergency' using vital signs and activities of daily life (ADLs). Real-time vital signs are collected from wearable Bio-Harness sensors while environmental sensing is simulated by an Android operating system. The system achieved higher accuracy by

using a fuzzy logic based classification model for using 12 fuzzy set inputs when compared with seven in a simulation environment. This system combines medical history and the current medical condition.

An intelligent on-line monitoring system for patients with Acute Respiratory Distress Syndrome (ARDS) has been developed using fuzzy logic - FuzzyARDS [238] and GlucoNotify [238]. This fuzzy knowledge-based hyperglycaemia control program was established as a real-time application in an Intensive Care Unit (ICU). The system can identify severe ARDS patients based on the fuzzy set theory, which is useful to evaluate patients for ARDS-therapy. Two reported issues with this system are the consideration of idle and delay functions and the lack of a combination of different vital data. To improve this approach MobiFuzzy [291] has been developed as a fuzzy remote patient monitoring mobile decision support system using Java micro edition fuzzy library.

5.4 Proposed Model Overview

A unique yet clinically successful model has been designed and developed. High importance has been given to the accuracy and reliability of the overall system. Figure 5.3 shows the model overview with its key modules. This section discusses in detail the core modules (methodologies) integrated into the interpretation engine.
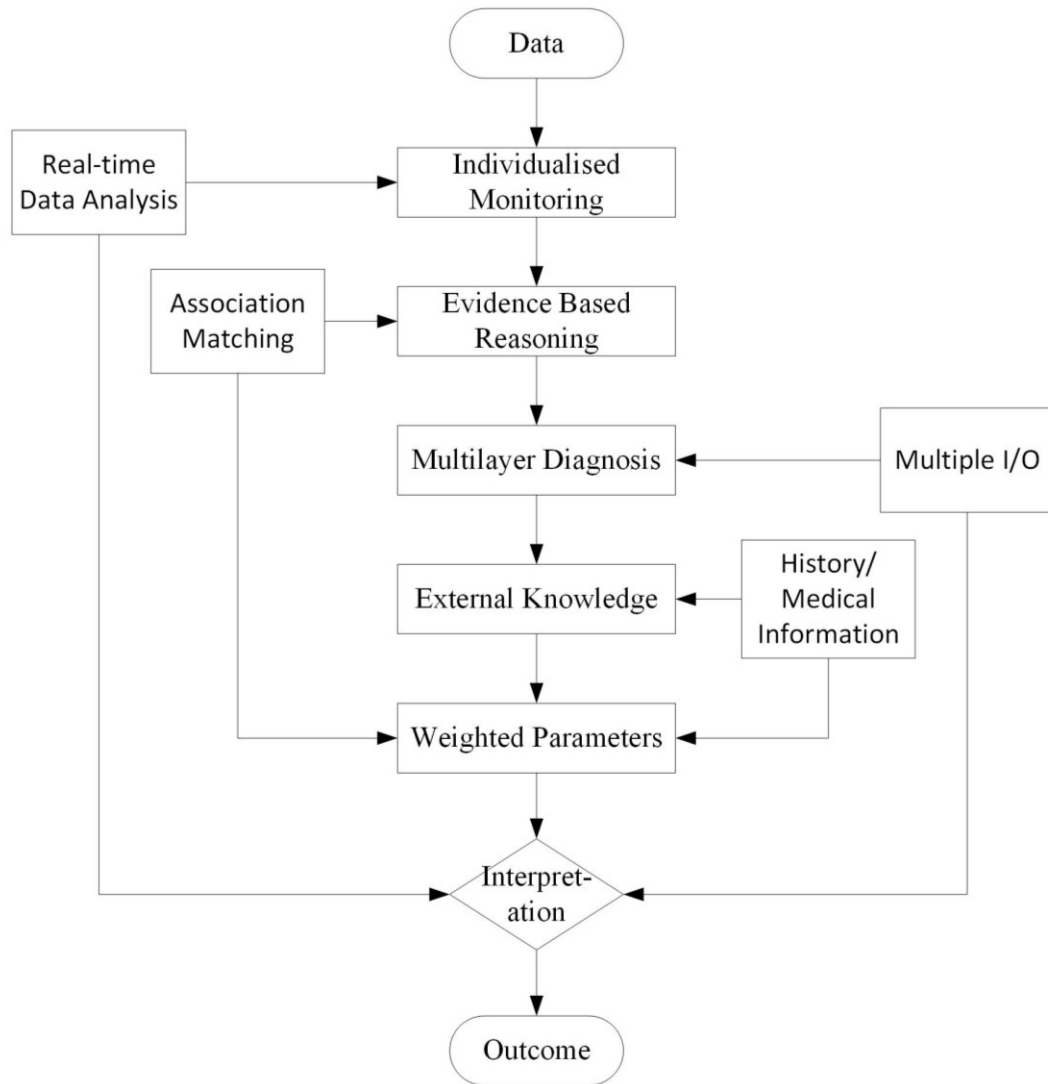
Figure 5.3 Overview of interpretation model.

5.4.1 Individualised Monitoring

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) [111, 255] and/or particular illness/health issue(s) [21, 297]. The proposed (thesis) model has adopted individualised monitoring because of the fact that physiological parameters are different in each individual, hence threshold or SD based monitoring models often give high false alarms [34] eventually reduce the reliability of the overall system. Table 5.1 shows the blood pressure statistics for the whole data vs. randomly selected patient data (patient #10 from the current thesis).

Table 5.1 Blood pressure statistics of whole data vs. patient #10

BP (Systolic/Diastolic)	Whole Data	Patient #10	Difference (%)
Mean	125.15/71.81	128.72/66.63	2.85/7.21
Maximum	205/118	151/75	26.34/36.44
Minimum	78/47	106/56	26.41/16.07
SD	21.35/12.85	12.37/7.55	8.08/13.24

The implementation of the threshold or SD range based model would have definitely given high false alarms due to the difference between the mean, maximum and minimum values of patient #10 when compared to the whole data, especially the SD difference (last row) of 8.08/13.24 in systolic/diastolic blood pressure. The proposed model uses the individual data for the interpretation called 'individualised monitoring' and the whole data set only serves as the outline boundary of the framework for the whole age group. The unique feature of the individualised monitoring module is that its adaptive boundary limits will be changing throughout the monitoring phase. Every 10th 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 transient hypertension where BP will be high (higher than normal for that particular patient) and upon treatment (medication) BP may be normal, this doesn't mean that the patient will always have normal BP from now on. While set individual limits will detect the transient hypertension, 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 transient hypertension and upon continuous update of the limits, will have a higher accuracy for transient or persistent hypertension detection if that particular health issue persists in the future for that patient (iterative optimisation).

Figure 5.4 shows the systolic blood pressure sample taken randomly from a patient's data to show the working of individualised monitoring. For every 10 recordings there is a window to capture the adaptive limits as shown in Figure 5.4. For 11-20 recordings the 'MAX1' is the maximum limit update, at 'MAX1' the current maximum (cMAX) value is checked against the maximum value for the last 10 recordings and any considerable changes will be detected. Similar processing has been carried out for mean

(ME1 to MEn) and minimum (MIN1 to MINn) values. In the 21-30 recordings window there is a considerable change detected when calculating the difference between 'Max2' and current 'cMAX'. In this case the BP (systolic) time stamped data is sent to the next module (evidence based/features extraction) for further processing. The same process is followed for all the vital sign(s).
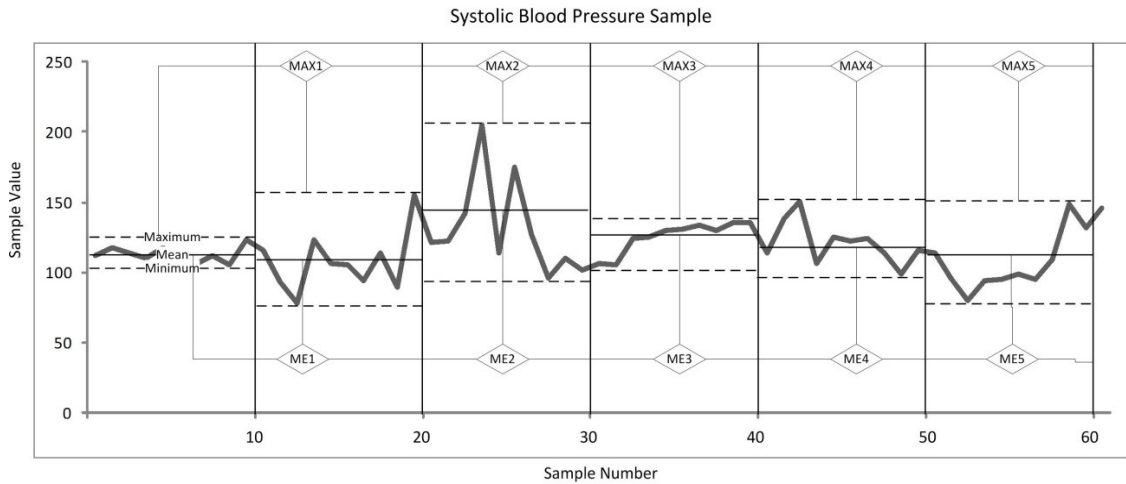
Figure 5.4 Systolic blood pressure sample for individualised monitoring

5.4.2 Evidence Based Reasoning

Evidence based reasoning (EBR) has become a successful technique for knowledge-based systems in this context. Briefly, EBR 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. EBR 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. Sometimes only a few substitutions are required, but in other situations the adaptation is a very complicated process.

In this context, evidence to support the event (outcome) is critical in order to achieve high accuracy and reliability. This module compares the current event (health issue)

within that patient's data for similar, former, solved or learned events. Figure 5.5 shows the outline of the EBR module. It can be said that this module works on the foundation of iteration optimisation for the repeated health events with in the same data pattern. 'The longer the use the higher the accuracy' can be claimed due to the continuous update-iteration cycle, which uses the extracted evidence for a data set and combines current as well as previous cases to match the best outcome association.
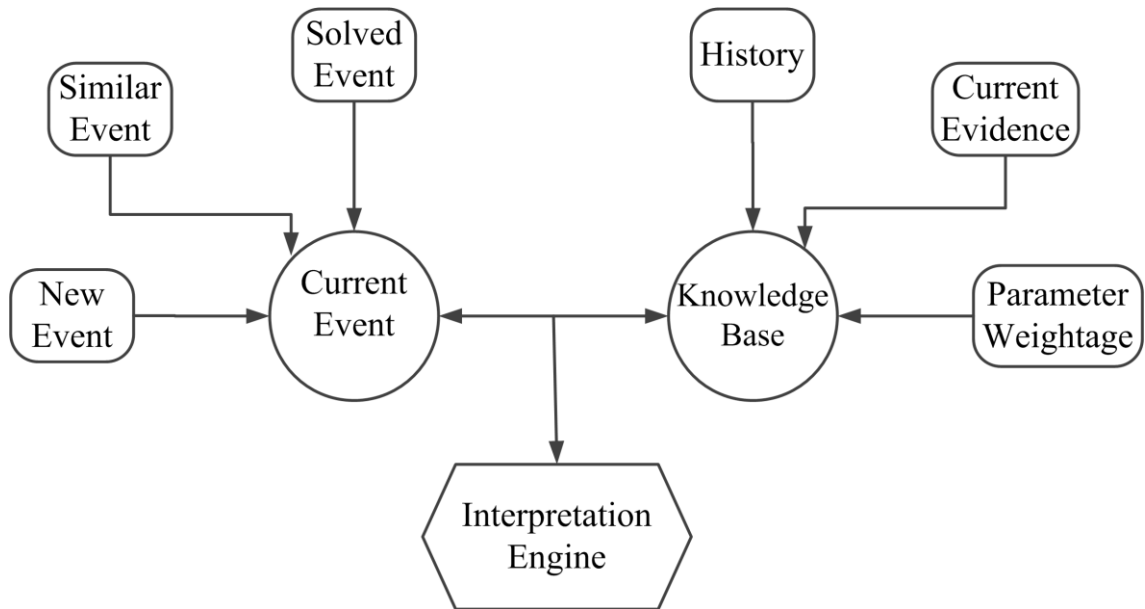
Figure 5.5 Similarity association matrix between current event and knowledge base.

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.

5.4.2.1   *Combination of Evidence*

Sources of evidence can be described as independent when they appear without any association to each other. A common example is the prime witness in the court of law or clinician providing a second opinion. If the evidence so provided can be stated as a body of evidence and equal weight is given to each source then Dempster's rule of combination can be used to calculate the consensus of opinion. Dempster's rule essentially calculates the joint probability distribution of two marginal bodies of evidence, and then normalises this result to ensure that the forming of the solution is itself a body of evidence. The formative work on the subject is [298], which is an expansion of [299]. In a finite discrete space, the Dempster-Shafer theory (DST) [298, 299] can be interpreted as a generalisation of probability theory where probabilities are

assigned to *sets* as opposed to mutually exclusive singletons. In traditional probability theory, evidence is associated with only one possible event. In DST, evidence can be associated with multiple possible events, e.g., sets of events. As a result, evidence in DST can be meaningful at a higher level of abstraction without having to resort to assumptions about the events within the evidential set. Where the evidence is sufficient to permit the assignment of probabilities to single events, the Dempster-Shafer model collapses to the traditional probabilistic formulation. One of the most important features of the Dempster-Shafer theory is that the model is designed to cope with varying levels of precision regarding the information and no further assumptions are needed to represent the information. It also allows for the direct representation of the uncertainty of system responses where an imprecise input can be characterised by a set or an interval and the resulting output is a set or an interval. There are three important functions in the Dempster-Shafer theory:

The basic probability assignment function (bpa or *m*), the *Belief* function (*Bel*), and the *Plausibility* function (*Pl*).

The basic probability assignment (bpa) is a primitive form of evidence theory. Generally speaking, the term "basic probability assignment" does *not* refer to probability in the classical sense. The bpa, represented by *m*, defines a mapping of the power set to the interval between 0 and 1, where the bpa of the null set is 0 and the summation of the bpa's of all the subsets of the power set is 1. The value of the bpa for a given set *A* (represented as *m*(*A*)), expresses the proportion of all relevant and available evidence that supports the claim that a particular element of *X* (the universal set) belongs to the set *A* but to no particular subset of *A*. Any further evidence on the subsets of A would be represented by another bpa, i.e. $B \subset A$, *m*(*B*), this would be the bpa for the subset *B*. Formally, this description of *m* can be represented with the following three equations:

$$m: P(X) [0,1] \tag{5.3}$$

$$m(\emptyset) = 0 \tag{5.4}$$

$$\sum_{A \in P(X)} m(A) = 1 \tag{5.5}$$

Where, P (X) represents the power set of X, $\emptyset$ is the null set, and A is a set in the power set $(A \in P(X))$.

From the basic probability assignment, the upper and lower bounds of an interval can be defined. This interval contains the precise probability of a set of interest (in the classical sense) and is bounded by two non-additive continuous measures called Belief and Plausibility. The lower bound *Belief* for a set A is defined as the sum of all the basic probability assignments of the proper subsets (B) of the set of interest (A) $(B \, Í \, A)$. The upper bound, *Plausibility*, is the sum of all the basic probability assignments of the sets (B) that intersect the set of interest (A) $(B \cap A \neq \emptyset)$. Formally, for all sets A that are elements of the power set $(A \in P(X))$,

$$Bel(A) = \sum_{B \mid B \subseteq A} m(B) \tag{5.6}$$

$$Pl(A) = \sum_{B \mid B \cap A \neq \emptyset} m(B) \tag{5.7}$$

The two measures, *Belief* and *Plausibility* are non-additive. This can be interpreted as not being required for the sum of all the Belief measures to be 1 and similarly for the sum of the Plausibility measures.

It is possible to obtain the basic probability assignment from the *Belief* measure with the following inverse function:

$$m(A) = \sum_{|B| B \subseteq A} (-1)^{|A-B|} Bel(B) \tag{5.8}$$

Where $|A\text{-}B|$ is the difference of the cardinality of the two sets.

In addition to deriving these measures from the basic probability assignment (*m*), these two measures can be derived from each other. For example, *Plausibility* can be derived from *Belief* in the following way:

$$Pl(A) = 1 - Bel(\bar{A}) \tag{5.9}$$

Where *A* is the classical complement of *A*. This definition of Plausibility in terms of Belief comes from the fact that all basic assignments must add up to 1.

$$Bel(\bar{A}) = \sum_{|B|B\subseteq\bar{A}} m(B)$$

$$= \sum_{(B|B\cap A = \emptyset)} m(B) \tag{5.10}$$

$$\sum_{(B|B\cap A \neq \emptyset)} m(B)$$

$$= 1 - \sum_{(B|B\cap A = \emptyset)} m(B) \tag{5.11}$$

From the definitions of Belief and Plausibility, it follows that *Pl* (*A*) = 1- *Bel* (Ā). As a consequence of Equations (5.8) and (5.9), given any one of these measures (*m* (*A*), *Bel* (*A*), *Pl* (*A*)) it is possible to derive the values of the other two measures. The precise probability of an event (in the classical sense) lies within the lower and upper bounds of *Belief* and *Plausibility,* respectively.

$$Bel(A) = P(A) = Pl(A) \tag{5.12}$$

The probability is uniquely determined if *Bel (A)* = *Pl (A)*. In this case, which corresponds to classical probability, all the probabilities, *P(A)* are uniquely determined for all subsets *A* of the universal set *X*. Otherwise, *Bel (A)* and *Pl (A)* may be viewed as lower and upper bounds on probabilities, respectively, where the actual probability is contained in the interval described by the bounds [298, 299].

5.4.3 External Medical/Historical Knowledge

The use of a patient's clinical information which usually consists of history, known health issues, allergies, medication and other related information to the interpretation of vital signs to predict/claim possible physical signs. There is a large amount of research currently ongoing in this area known as 'Big Data Analysis' (due to the huge amount of patient data available) [300]. In this context, the patient's clinical information is entered by the clinician as an additional input (text formatted) and the system assigns each input with its related vital sign so that the parameter weighting can be calculated and assessed.

For example, if the patient has a history of hypertension, this information will be entered by the clinician into the system via graphical user interface (GUI) text input spaces. To limit the complexity in this module only the above-mentioned history is linked to the corresponding vital sign(s) in order to support the outcome; all other information is displayed as 'observational notes'.

This module can be incomplete or partially complete; in that case the outcome result will not be affected and in the case where the clinical information is presented, then the confidence level of the predicted outcome will be higher. Therefore, the more information that is presented the higher will be the outcome confidence level. The extension of this module is used for the fall prediction score, which is explained in the next chapter.

Figure 5.6 shows the external clinical information incorporation into the interpretation engine. The clinical information inserted into the engine is looped into the execution (feedback-linking-estimate-evaluate) cycle. The linking of vital signs with the available information and estimating the possible physical signs are initiated with the continuous flow of information from the previous module (evidence based reasoning). Evaluation of gathered data will be linked to the next module (parameter weighting) in which each parameter is assigned weight (explained in the next section) depending on the information concerning similar health events assembled from various sources.
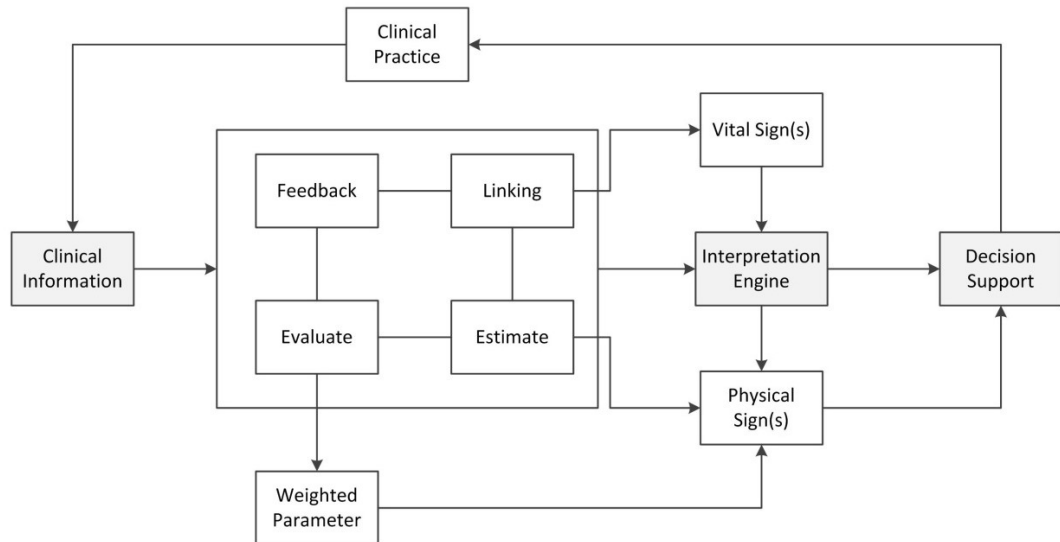
Figure 5.6 External clinical information flow and incorporation into interpretation engine.

Integration of the clinical information module with its learning capabilities into the interpretation engine will help engender a medical culture in which clinicians and engineers work together in a mutually supportive environment where cross-specialty communication is not only possible but intrinsic and continuous. The vision is for the development of an intelligent system consisting of "clinical informatics without walls" (Figure 5.6), in which the creation of evidence and clinical decision support tools is initiated, updated and enhanced by input from the clinicians. In this collaborative medical culture, knowledge generation would become routine and fully integrated into the clinical workflow. This module would use individual data to benefit the care of populations and population data to benefit the care of individuals.

5.4.4   Weighted Parameters

A robust scoring mechanism is proposed in this module (Figure 5.3), where information from various sources is grouped into the respective health event. Each time the information is collected from the credibly sourced evidence, a score is assigned to the corresponding health event. In this framework, there are primarily seven health events which are defined from E1-E7 where,

E1: Bradycardia.
E2: Tachycardia.
E3: Hypotension.
E4: Hypertension.
E5: Hypoaxemia.

E6: Fever.
E7: Hypothermia.

Let us consider hypertension, which is directly related to blood pressure (BP). Similarly all the other direct links are established based on the medical literature and standard vital signs and physical signs relationship (Table 4.8). Figure 5.7 shows the direct association between the vital signs and their related possible physical signs. The direct association bounds the core boundaries and sets each parameter into its respective group for the evidence-based weighted scoring.
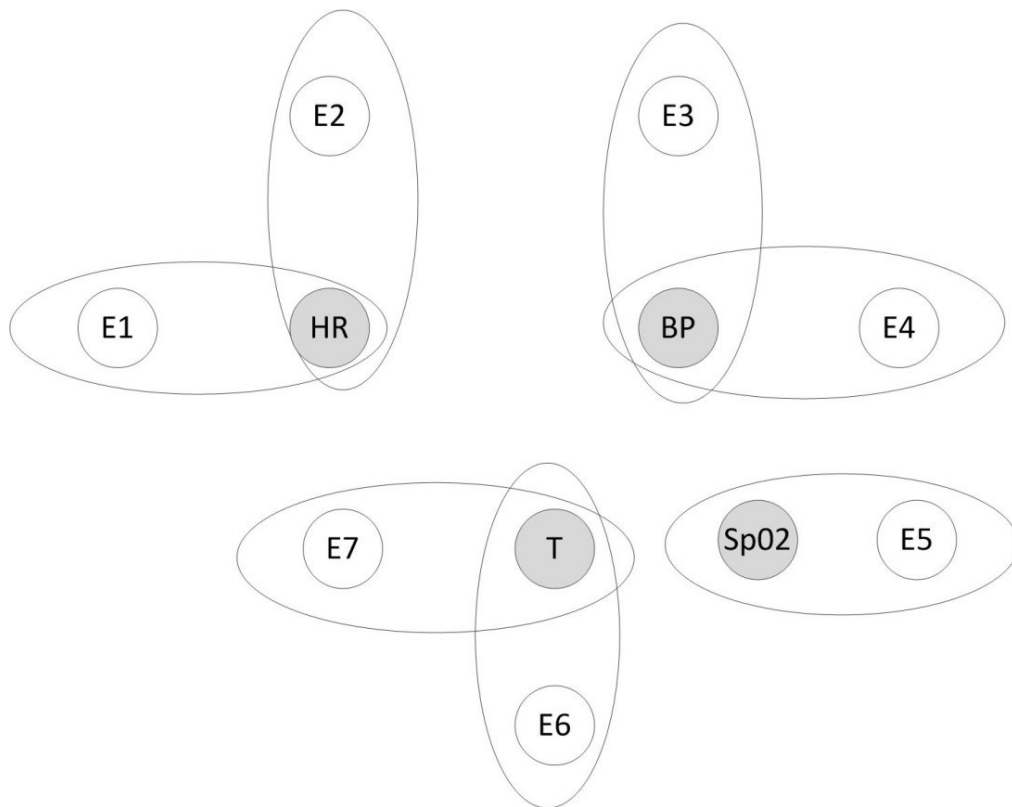
Figure 5.7 Direct link between vital signs and physical signs.

Figure 5.8 shows the second tier (indirect) linking between the vital signs and physical signs in the dotted ellipse. Let us consider the vital sign BP, for E3 (hypotension) and E4 (hypertension); BP is the direct association. From the gathered evidence of the above modules, the weighted scoring for indirect linking suggested that BP (at least in the in-patient setting) is also often associated with E2 (Tachycardia) and E5 (Hypoxaemia). In this case E2 and E5 has two layers of vital sign support, both direct (E2-HR and E5-SpO2) and indirect (E2-BP and E5-BP).
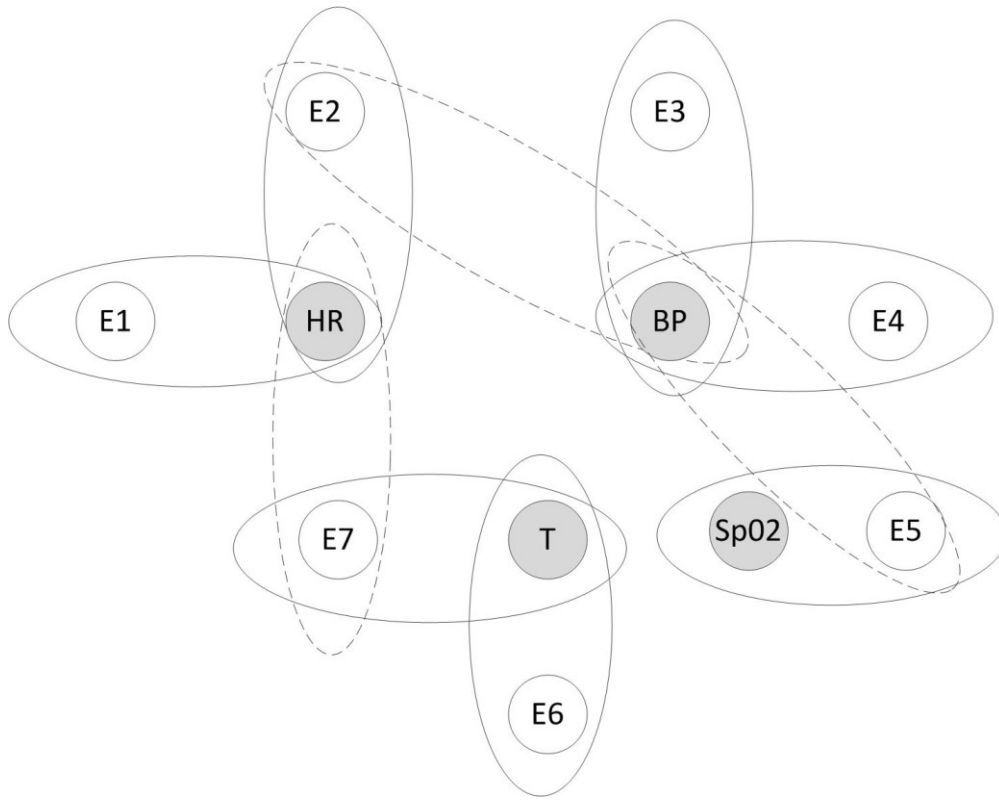
Figure 5.8 Second tier linking between the vital signs and physical signs.

5.4.5 Multilayer Diagnosis

Early detection of physical sign(s) can reduce adverse events [46, 288, 301]. The multilayer diagnostic module can improve the interpretation engine performance in the early detection of multiple physical signs by dividing the outcome into two priorities, instead of a simple 'yes' or 'no' classification. Figure 5.9 shows a sample of systolic blood pressure data selected randomly from a patient's data record to show the working of the multilayer priority model. The whole data set is completely divided into four states i.e. normal (pre-event), P2 (priority 2), P1 (priority 1) and Normal (post-event) states respectively. The sign of deterioration (P2) can be detected before the actual event (P1) occurs. In this case, the hypertension is detected in the area of 'P2' which is before the actual alarm point of 'P1'.
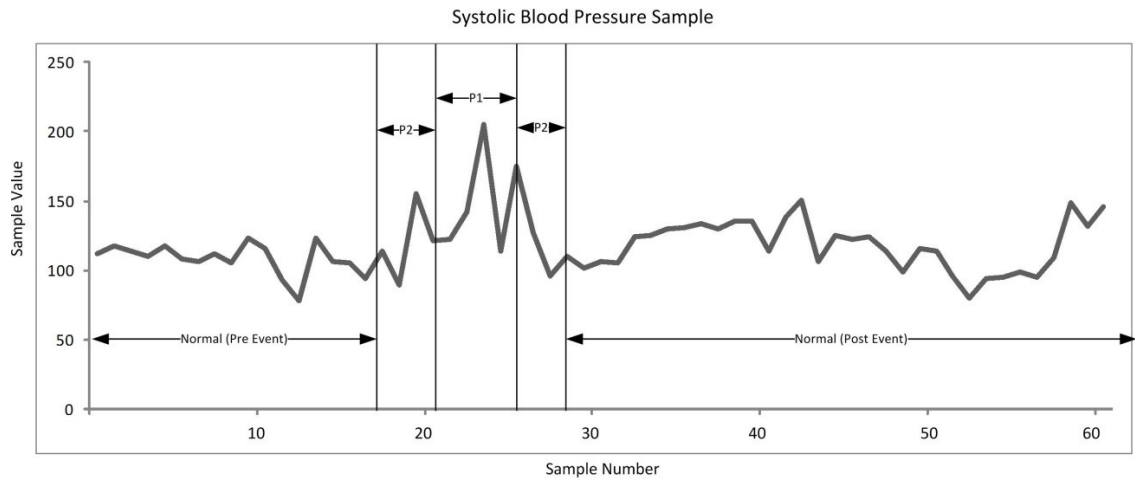
Figure 5.9 Multiple priorities based diagnosis.

The multi-priority approach is adopted using two different techniques; P1 alarm is a fuzzy logic based model, which employs the fuzzy inference model to detect the P1 level alarms while P2 warning is a C language based classifier, which uses expert rules with weighted parameters to detect the P2 level warnings.

Priority-1: For interpretation of seven different physical signs (Table 4.8) using four basic physiological parameters. Fuzzy logic modelling is used to map several degrees of membership functions from each vital sign to several physical signs. Due to its non-crispiness and flexibility, it can achieve low false alarms.

Priority-2: A C-based weighted parameter classifier; it has been optimized using standard deviation (SD) (calculated from each patient) either side of the mean value of physiological parameters. This mode can reduce false alarms by continuous changing of limits and boundaries (see section 7.5).

Both priorities use their own classification rule base to detect the respective priority (P1 or P2) using a different set of limits and ranges with no overlap as shown in Figure 5.10. Priorities are assigned with different alert mechanisms such as; messages/warnings and alarms that can be transmitted to the clinician's or nurse's devices. Table 5.2 shows vital signs handling according to the proposed two priorities.
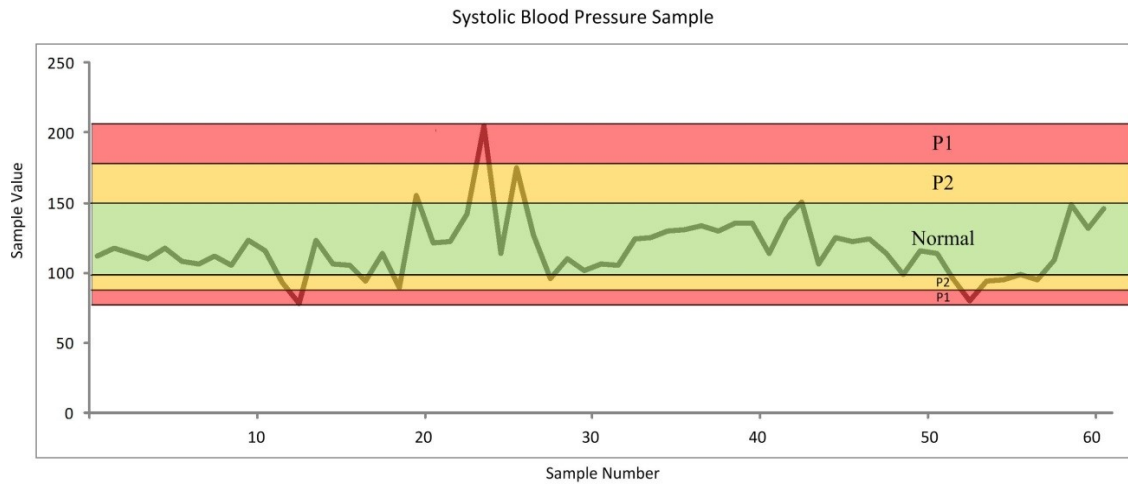
Figure 5.10 Priority based blood pressure sample.

Table 5.2 Vital signs data handling and classification using two priorities.

Priority	Type of monitoring	Type of Messages	Outcome Message*
Priority 1	Fuzzy logic based interpretation of physical signs	Alert	'Possible Physical sign(s)'
Priority 2	Change of SD with weighted parameter for each parameter	Warning Message No Alert	'Possible Physical sign(s)' with change in data

*Data represents the appropriate abnormal vital sign(s) and its related possible physical sign(s). Possible physical signs are: Bradycardia, Tachycardia, Hypertension, Hypotension, Hypoxaemia, Fever or Hypothermia.

5.4.5.1 Data Handling

The aim of the proposed model is to provide multiple combinations of extracted parameters in order to help clinicians with detection and estimation of health conditions and/or with early 'diagnosis'. Physical signs are classified as priority-2-warnings and priority-1-alarms. Priority 2 warnings are generated when the vital sign(s) changes above the set SD limit (individualised optimised limits). The vital sign(s) may be reversed to the normal state but if considerable changes are detected then the priority-1 type alarm will be generated. The proposed system is designed to reduce false alarms and to achieve high clinical reliability. Due to the nature of physiological parameters, which are variable and changing throughout monitoring, fuzzy logic is one of the best

approaches (see chapter 2 for other methods) in this type of monitoring and 'diagnosis' [302].

Figure 5.11 shows the proposed system flow chart. It effectively represents the acquisition and processing of linguistically described concepts using fuzzy logic. The main aim is to mimic medical specialists' views, i.e. reasoning based diagnosis with evidential support using multiple parameters for a robust health event indication. Another important aspect is the incorporation of medical knowledge into the model regarding how the occurrence of several events is related to a variety of physiological parameters and to what degree the presence of a specific health event under a certain context points toward a specific medical health condition. This is usually considered as external medical knowledge. A medical professional's input is incorporated into the system's basic design model to define the accurate relationships between each vital sign and its related possible interpretations.
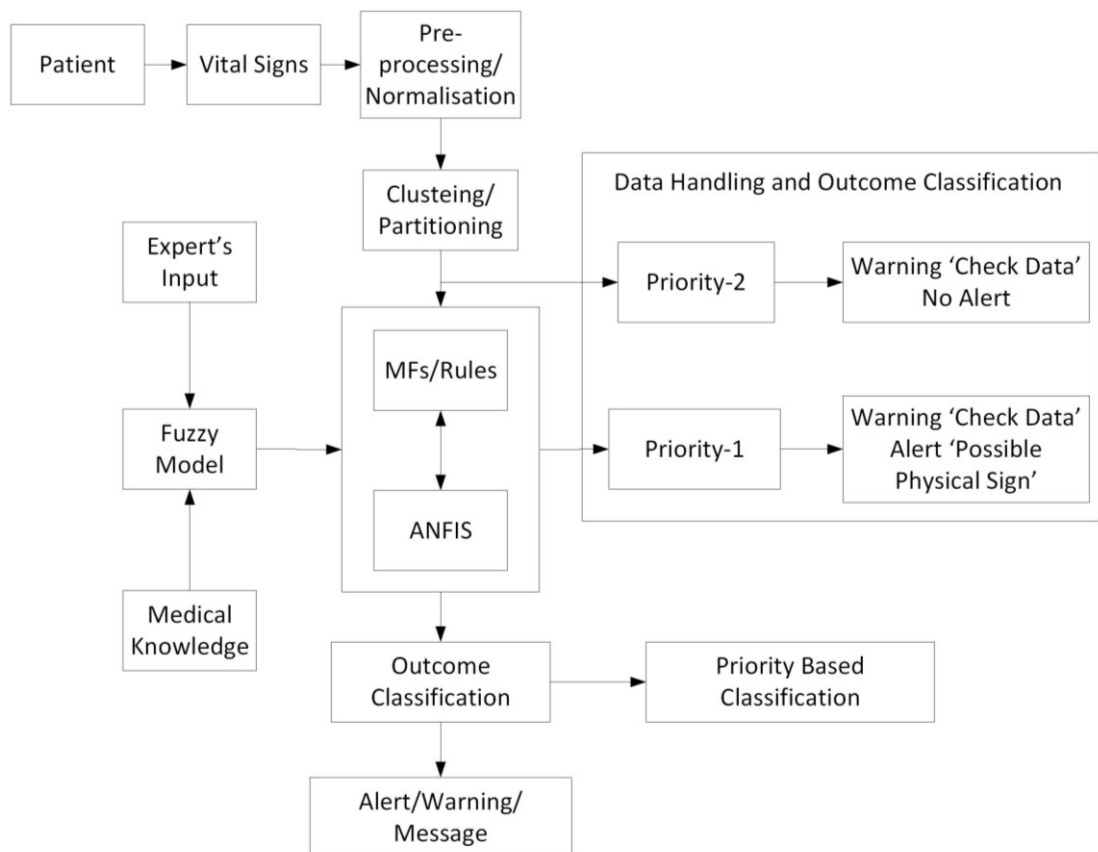
Figure 5.11 System model flow chart with data handling and outcome classification.

5.5 System Modelling and Framework

To remove the noise and artefacts: low pass filtering, removing missing values (zeroes or negative), sampling the data, checking and removing outliers from the data set have been performed. The calculation of statistical/descriptive values such as: maximum, minimum, mean, median, mode, standard deviation and range were also performed, in order to have a normalised data set throughout the 'diagnosis'. Detailed pre-processing and data analysis have been carried out in order to achieve the unique data set throughout 'diagnosis' phase [276-279, 303]. Systolic blood pressure sample of pre-processing is shown in APPENDIX D. Figure 5.12 shows the main blocks of the fuzzy model which is explained in detail in this section.
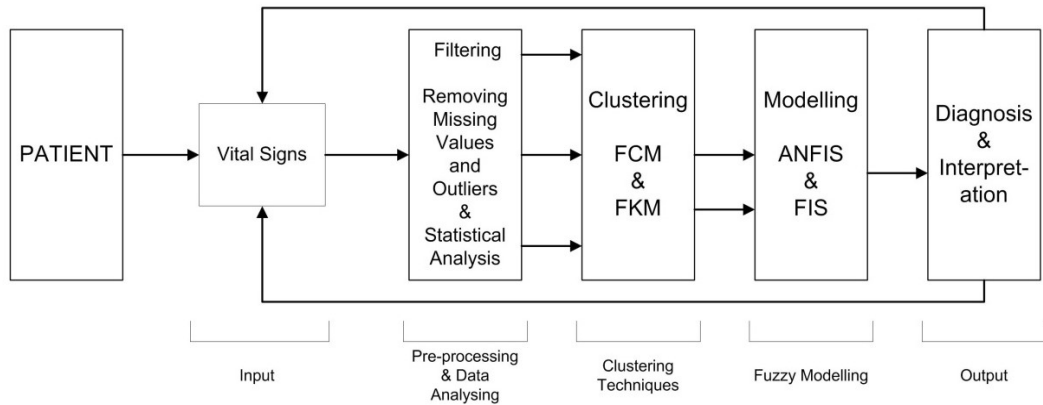
Figure 5.12 Fuzzy model overview and description.

A robust six layer adaptive neuro fuzzy inference system (ANFIS) has been employed to set the parameters and limits automatically according to the input data and to analyse the membership functions and rules. Figure 5.15 shows this six layer network architecture with a discussion of each layer in detail as follows.

5.5.1 Layer 1: Input layer (V_1, V_2…V_n)

The vital data input obtained after performing the pre-processing and normalisation, is now fed to the fuzzy neural network system. This layer is called input node and corresponds to one input variable.

5.5.2 Layer 2: Clustering (c_1, c_2…c_n)

Clustering of numerical data forms the basis of many classification and system modelling algorithms. The purpose of clustering is to identify the natural grouping of

data from a large data set to produce a concise representation of a system's behaviour. Clustering is used to achieve a highly accurate and reliable medical data classification for the proposed expert system (event diagnosis, decision support or patient monitoring). It is simply known as the unsupervised classification of patterns, observations or data items into groups (clusters) [304]. Cluster analysis has been extensively used in several applications, including segmentation of medical images, pattern recognition, and image processing. This thesis discusses two widely-used fuzzy clustering techniques in respect of the highly important medical/clinical data (patient's physiological data); 'fuzzy c-means' clustering (FCM) and 'fuzzy k-means' clustering (FKM). Many authors have proposed different standards based on fuzzy set theory as the appropriate approach towards the clustering techniques [305]. Fuzzy clustering techniques, such as FCM and FKM have been successfully applied to conduct image segmentation, pattern detection, and physiological data analysis [306].

A hybrid fuzzy ARTMAP (FAM)-FCM neural network has been proposed to detect pattern classification tasks with missing features. This technique does not reject the incomplete data set rather it estimates and replaces missing features using a number of FCM-based strategies [307]. The F2CM algorithm has been developed to allow direct clustering of asynchronously sampled data [308]. In a similar approach, a fuzzy item response model (FIRM), combined item response theory and fuzzy set theory using a partial credit model (PCM) for outpatient diagnosis of depression [309]. A Possibilitic Latent Variables (PLV) clustering algorithm has been developed for pattern recognition of medical data for complex diagnosis [310]. After studying several clustering techniques and methods the two most common clustering techniques (FCM and FKM) were adopted and tested in our medical scenario. The step-by-step performance of both the techniques follows.

5.5.2.1 *Fuzzy c-means clustering (FCM)*

Fuzzy c-means clustering (FCM) is a data clustering technique in which a set of data is grouped into *n* clusters to a certain degree. For example, a cluster will have a high degree of membership if it lies close to the centre of a data set and vice versa. FCM gives the best result for the overlapped data set whereas what this technique lacks in Euclidean distance measures can unequally weight underlying factors. FCM works according to the following steps:

1. Starts with an initial estimation for the cluster centers.
2. Each cluster will be assigned a membership grade for every data point.
3. Iteratively updates the cluster centers and the membership grades for each data point.
4. Cluster centers will be located to the right location within a data set.
5. Finally a large set of data is grouped into clusters of smaller sets of similar data.

The above five steps are based on minimization of the following objective function [311, 312]:

$$J_m = \sum_{i=1}^{N} \sum_{j=1}^{C} u_{ij}^m \|x_i - c_j\|^2, \qquad 1 \leq m < \infty \qquad (5.13)$$

where N is the total number of data, C is the total number of clusters, u_{ij} is the degree of membership of x_i in the cluster j, x_i is the ith of d-dimensional measured data, c_j is the d-dimension centre of the cluster, and $\|*\|$ is any norm expressing the similarity between any measured data and the centre. The fuzzy c-means algorithm consists of the following three steps:

Step 1 – Parameter initialization

The initial values of the membership function are randomly selected according to the given dataset.

Step 2 – Cluster centre calculation

Obtaining the cluster centroids (the centroid of a cluster is the mean of all points, weighted by their degree of belonging to the cluster group) from step 1, new values are calculated and updated. With the change in the cluster centroids the membership values will also change.

Step 3 – Dissimilarity Computation

The difference between the cluster centroids and the patterns are calculated.

5.5.2.2 Fuzzy k-means clustering (FKM)

Fuzzy k-means clustering (FKM) is one of the simplest unsupervised learning algorithms linked each other with well-distributed outlines. FKM is also adoptable in the situation where one data group belongs to one or more than one cluster group, such as in our case, multiple physiological signs are assigned to similar patterns or groups or

symptoms that they belong to. Several studies also reported that the FKM algorithm cannot be applied to the real-life clustering problems when the data contains missing values [313]. FKM works according the following steps:

1. Initializes the centroids by randomly selecting points among all the data points.
2. Calculates the distance between each data point and cluster centres.
3. Determines the membership function of each data point and associates it to the nearest cluster centre.
4. After assigning the objects, it recalculates the positions of the K centroids.
5. Repeats steps 2, 3 and 4 till the centroids are stable. This results in separation of the objects into groups.

FKM aims at minimizing an objective function known as squared error function given by:

$$J(V) = \sum_{i=1}^{C} \sum_{j=1}^{C_i} (\|x_i - v_j\|)^2 \tag{5.14}$$

Where, '$\|xi - vj\|$' is the Euclidean distance between x_i and v_j, 'c_i' is the number of data points in i^{th} cluster and 'c' is the number of cluster centres. FKM consists of three main steps:

Step 1 – Initialization

FKM is functional to the set of applicable patterns which relates to the initial cluster number.

Step 2 – Detecting and Removing Outlier

Data points which appear to dramatically differ from the rest of data or any missing values or any unexpected error value are outliers.

Step 3 – Assessment

If the available patterns fail to improve the current cluster arrangement, the algorithm will increase the number of clusters and resume execution from the previous step (step 2).

From Figure 5.13 and Figure 5.14, it is evident that both techniques performed well when detecting normal and abnormal data from the given data sets. The clustering and partitioning of raw data into normal and abnormal data is the key module for the proposed system.
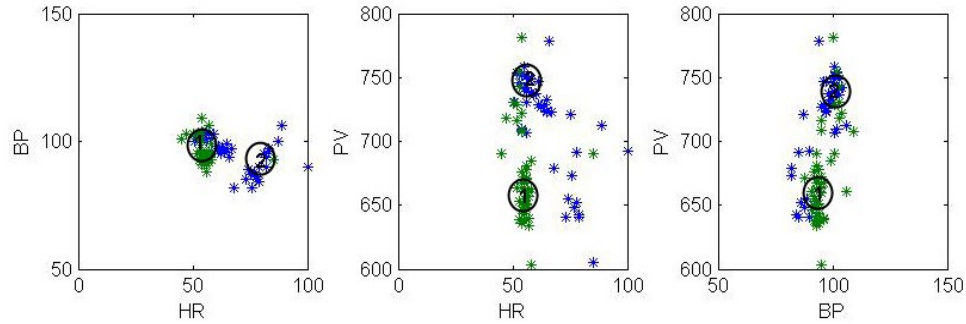
Figure 5.13 FCM performed on the HR, BP and PV dataset, where 1 represents the centre of the normal data and 2 is the centre of the abnormal cluster group represented as HR-BP, HR-PV and BP-PV respectively.
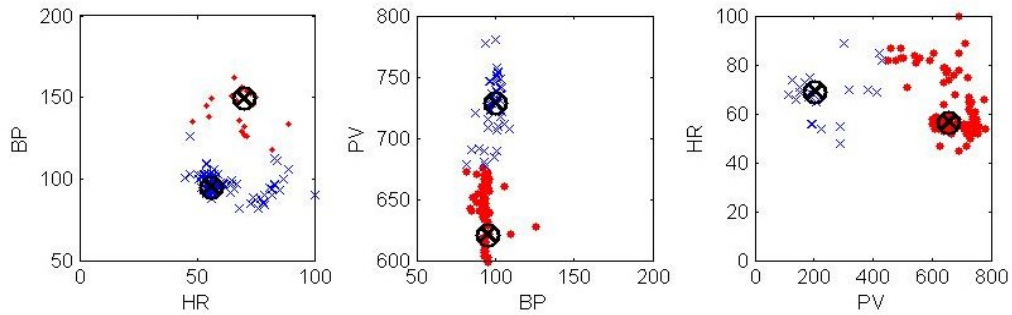
Figure 5.14 FKM performed on HR, BP and PV dataset, 'blue cross' is normal data and 'red dots' are abnormal data with its centroid as 'cross-in-a-circle' and it is represented as HR-BP, BP-PV and PV-HR respectively.

5.5.3   Layer 3: Grouping (g_1, g_2….g_n)

Groups in this layer are called input group terms, each of which corresponds to one linguistic label (high, normal, low) of an input variable; each group in this layer calculates the membership function value specifying the degree to which an input value belongs to a fuzzy set. A local membership function is used in this layer.

5.5.4   Layer 4: Rules (r_1, r_2…r_n)

This layer is called a fuzzy rule. 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 layer 2 and the other from the medical experts' knowledge (external layer).

1. *If (HR is L) and (BP is L/H) then (Diagnosis is P2-Bradycardia) (1)*
2. *If (HR is VL) and (BP is VL/VH) then (Diagnosis is P1- Bradycardia) (1)*
3. *If (HR is H) and (BP is L/H) and (SpO2 is L) then (Diagnosis is P2-Tachycardia) (1)*
4. *If (HR is VH) and (BP is VL/VH)) and (SpO2 is VL) then (Diagnosis is P1-Tachycardia) (1)*
5. *If (HR is L) and (BP is L) then (Diagnosis is P2-Hypotension) (1)*
6. *If (HR is VL) and (BP is VL) then (Diagnosis is P1-Hypotension) (1)*
7. *If (HR is H) and (BP is H) then (Diagnosis is P2-Hypertension) (1)*
8. *If (HR is VH) and (BP is VH) then (Diagnosis is P1-Hypertension) (1)*
9. *If (HR is L/H) and (BP is L/H) and (SpO2 is L) then (Diagnosis is P2-Hypoaxemia) (1)*
10. *If (HR is VL/VH) and (BP is VL/VH) and (SpO2 is VL) then (Diagnosis is P1-Hypoaxemia) (1)*
11. *If (HR is H) and (BP is L/H) and (SpO2 is L/H) and (T is H) then (Diagnosis is P2-Fever) (1)*
12. *If (HR is VH) and (BP is VL/VH) and (SpO2 is VL/VH) and (T is VH) then (Diagnosis is P1-Fever) (1)*
13. *If (HR is L) and (BP is L) and (SpO2 is L/H) and (T is L) then (Diagnosis is P2-Hypothermia) (1)*
14. *If (HR is VL) and (BP is VL) and (SpO2 is VL/VH) and (T is VL) then (Diagnosis is P1-Hypothermia) (1)*

5.5.5 Layer 5: Output Sets (E₁, E₂…Eₙ)

In this layer the output sets will be clubbed together according to their membership functions and event rules execution. This layer is also called the consequent layer and the sets in this layer are called output term sets. Each output term set represents a multi-dimensional fuzzy set obtained during the clustering operation in structured learning phase (layer 2).

5.5.6 Layer 6: Diagnosis and Interpretation (D)

Each output set in this layer is called linguistic output and corresponds to one output linguistic variable. This layer performs the defuzzification operation. The output sets in this layer together with the membership values and the relationship between the input-output rules will present the event diagnosis as a message, warning or alert one at a time as output (D), such as Bradycardia, Tachycardia, Hypotension, Hypertension, Hypoxaemia, Fever or Hypothermia detected in a patient using the given vital physiological parameters.
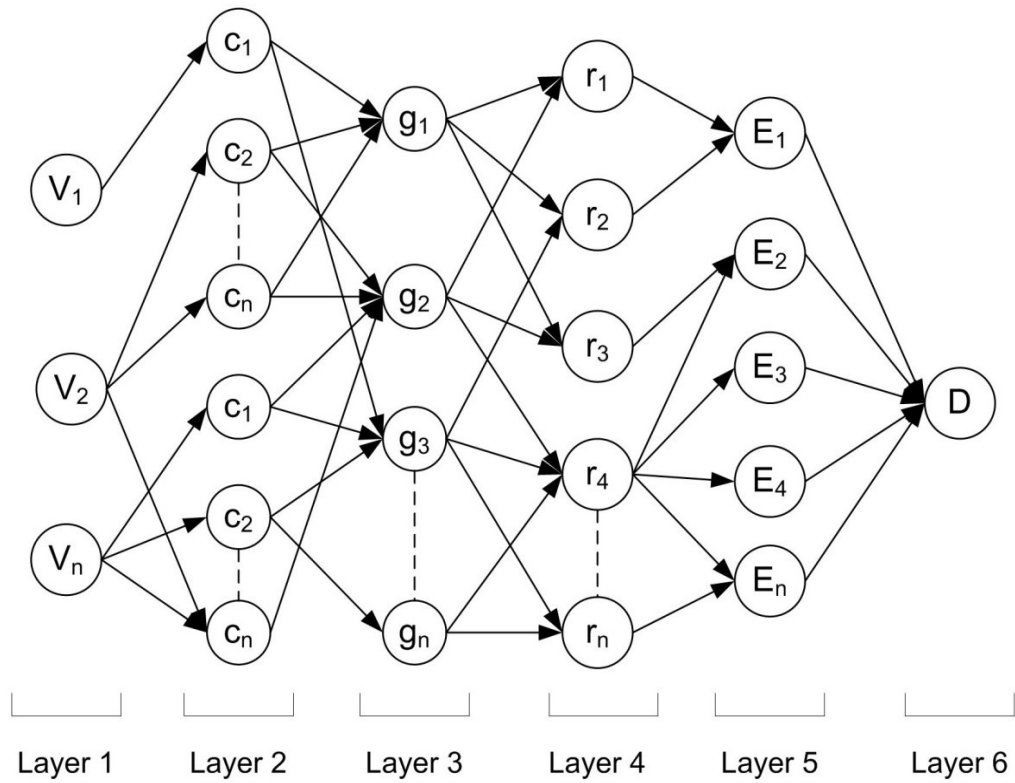
Figure 5.15 Six layer adaptive neuro fuzzy network designed for the proposed diagnostic module.

5.5.7   Physical Signs Extraction and Classification

Vital signs have been categorised into two outcome priorities (Table 5.2) in order to have a reliable, robust interpretive system with high clinical accuracy. Each vital sign has been given several levels of importance in relation to the health event. For example: blood pressure has more weight/importance when considering Hypotension and Hypertension. The mapping and linking of multiple vital signs for detecting a single event using the fuzzy model provide a higher accuracy with a reliable indication of health events. For example, Hypotension is defined as 'low blood pressure', irrespective of the other parameters. Whether the Hypotension is of any clinical relevance will depend on (to some degree) the other parameters measured. When the proposed fuzzy model classifies a health event as Hypotension, it is due to giving a higher weight to the blood pressure, instead of considering blood pressure as only one of the possibilities of Hypotension. Moreover, 'High heart rate' should be considered as other possible clinical relevance of Hypotension from the clinician's point of view. This criterion is applied to all other possible physical signs which can provide a robust indication of possible or clinically relevant Hypotension.

Instead of setting crisp numeric limits, linguistic variables have been employed, such as fuzzy sets, membership functions (MFs) and rules [314], to describe the degree of occurrence of a certain medical event. Fuzzy sets are defined as:

- Low BP (Lbp) and High HR (Hhr) for priority-2 Hypotension,

- Very Low BP (VLbp) and Very High HR (VHhr) for priority-1 Hypotension.

5.6 Physical Signs Detection and Working Details

Patient physical signs are assigned as E1-E7 with priorities (P1-P2) for each of the physical signs. This section shows the detection and identification of physical signs with respect to one input, two inputs and all inputs when interpreting the physical signs.

E1: Bradycardia.
E2: Tachycardia.
E3: Hypotension.
E4: Hypertension.
E5: Hypoaxemia.
E6: Fever.
E7: Hypothermia.

5.6.1 Physical Sign Detection using One Input

Bradycardia: Let us consider the physical sign E1 to demonstrate the working of the proposed model using one input. Figure 5.16 shows the initial patient status as normal (N in green); when there is a low heart rate (denoted as 'Lhr') the status changes to E1P2, i.e. possible 'bradycardia' with priority-2 warning. Further, if the heart rate goes 'very low' (denoted as 'VLhr') then the current status changes to possible 'bradycardia' with priority-1 alert and returns to the normal state when the heart rate is back to the normal range for that particular data pattern (patient). This case has a single input (HR) on which the interpretation is predicted.
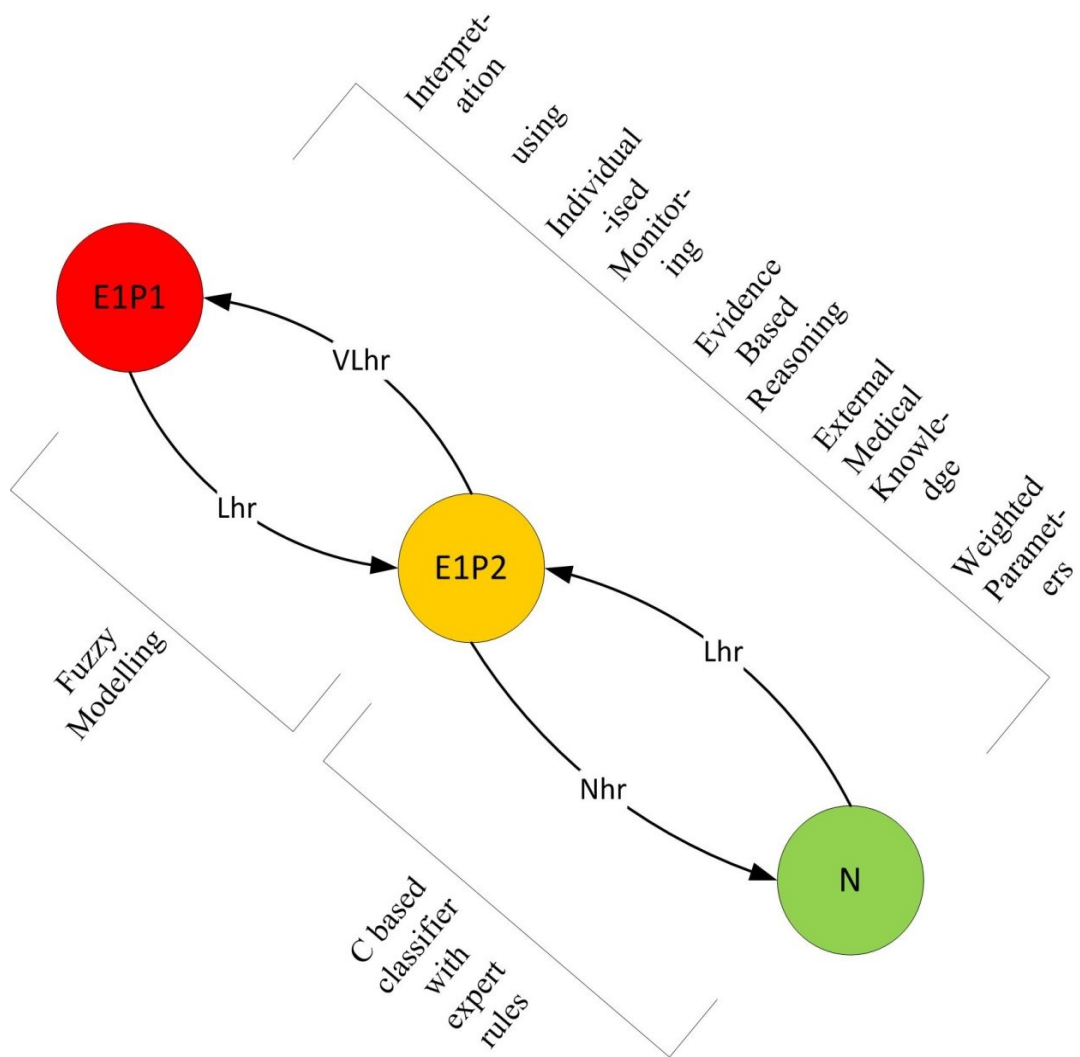
Figure 5.16 Possible Bradycardia using two categories of heart rate: low and very low with two levels of priority.

5.6.2 Physical Sign(s) Detection using Two Inputs

Hypertension: Let us consider the physical sign E4 to demonstrate the working of the proposed model using two inputs. Figure 5.17 shows the initial patient status as normal (N in green), when there is a high blood pressure (denoted as 'Hbp') and high heart rate (denoted as 'Hhr') then the status changes to E4P2, i.e. possible 'hypertension' with priority-2 warning. Furthermore, when 'very high' blood pressure (denoted as 'VHbp') and 'very high' heart rate (denoted as 'VHhr') are detected then the current status changes to possible 'hypertension' with priority-1 alert and returns to the normal state when the heart rate is back to the normal range for that particular data pattern (patient). This case has two inputs (BP and HR) on which the interpretation is predicted.

Fever: Let us consider the physical sign E6 to demonstrate the working of the proposed model using two inputs. Figure 5.17 shows the initial patient status as normal (N in green). When there is a high heart rate (denoted as 'Hhr') and high temperature (denoted as 'Ht') then the status changes to E6P2, i.e. possible 'fever' with priority-2 warning. Further, when a very high heart rate (denoted as 'VHhr') and a very high temperature (denoted as 'VHt') are detected, then the current status changes to possible 'fever' with priority-1 alert and returns to the normal state when the heart rate is back to normal range for that particular data pattern (patient). This case has two inputs (HR and T) on which the interpretation is predicted.
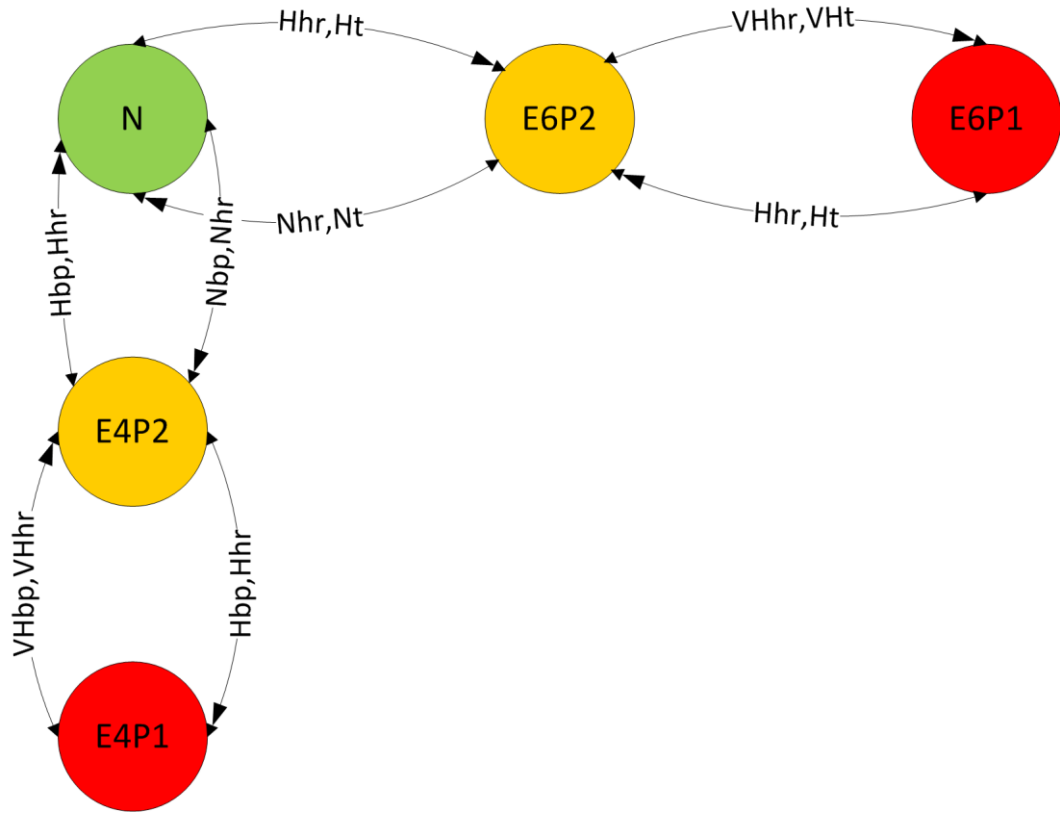
Figure 5.17 Possible hypertension (E4) and fever (E6) using two inputs with two priorities.

5.6.3   Physical Signs Detection using All Vital Signs

Now, let us consider E1-E7 physical signs, depicted in Figure 5.18, using the combination of four vital signs: HR, BP, SpO2 and T with two levels of priority (P1 and P2). In this case, let us consider all possible scenarios where the physical signs extracted from any physiological measurement include additional and finer fuzzy sets, with the inclusion of *Very Low (VL), Low (L), High (H) and Very High (VH)*. For example,

priority-1 Hypotension (E3P1) is possible when the combination of vital signs indicates Very Low BP (VLbp) and Very High HR (VHhr), as shown in Figure 5.18. In some other cases such as Hypoxaemia, it is necessary to consider Low SpO2, but also, HR and BP which can be high or normal or low. In this case, the proposed model gives more weight to SpO2 for 'Low' and assigns normal weight to HR and BP. Centre N (green) is the initial status and E1-E7-with P2 (orange) are the priority 2 classified physical signs and P1 (red) is the priority-1 health outcomes as an alert. Prioritisation of outcomes gives clinicians a high degree of control over the system's outcome because of two levels of priorities. This structure potentially gives high reliability and stability with only priority 1 generating alarms.
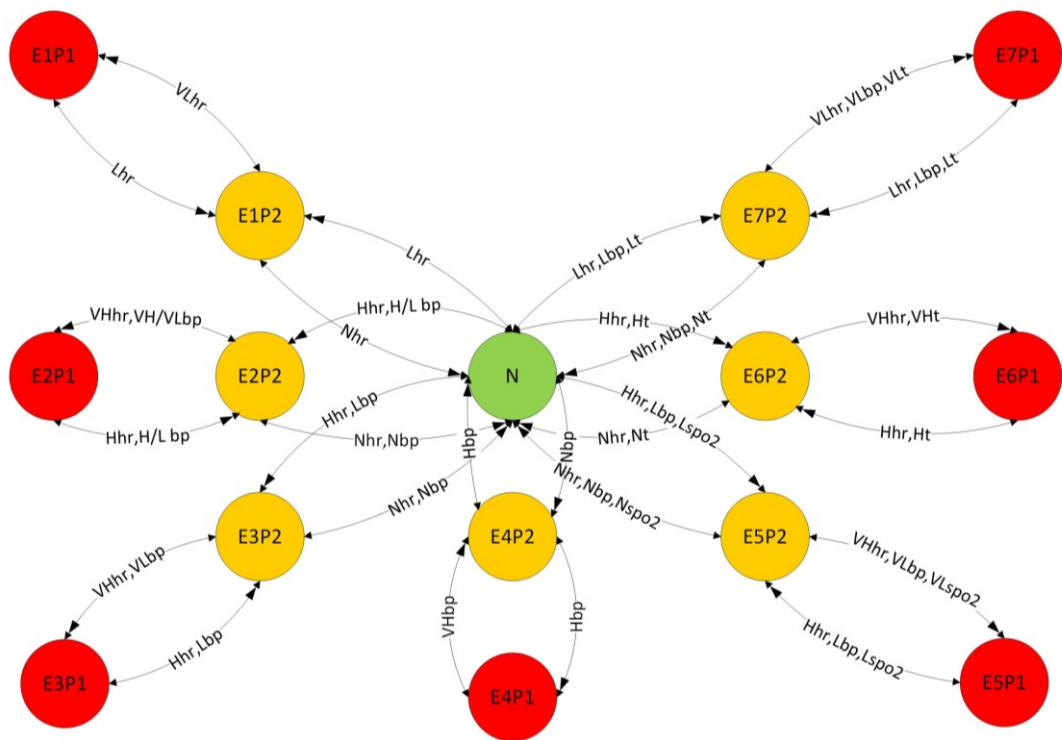
Figure 5.18 System working model with all possible seven physical signs using four vital signs and two levels of priority and a centre green normal state as the initial patient's condition.

The terms 'very high', 'high', 'very low' and 'low' are automatically/continuously optimised using the individualised monitoring module, where each vital sign is divided into four abnormal categories with respect to that particular patient. In the case of E6 (fever) the system uses two input HR and T as shown in the Figure 5.18. In direct association with fever is the body temperature; hence in this case the T has more weight when predicting 'fever'. For example if T is missing then there will be no prediction for

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'fever' whereas 'fever' will be predicted if HR is missing but not T, due to the indirect association with 'fever'. A similar mechanism has been adopted for all vital signs for the interpretation of multiple physical signs.

5.7 Summary

Fuzzy Logic provides a completely different, unorthodox way to solve problems related to this patient monitoring system. Tuning of the monitoring system is done by changing the rule antecedents, changing the centres of the input and/or output membership functions, adding additional degrees to the input and/or output functions such as 'very high', 'high', 'very low' and 'low' levels and several physical signs as output responses of the system. These new levels generate additional rules and membership functions which overlap with adjacent functions, forming longer 'mountain ranges' of functions and responses. Implementing different techniques to make these changes systematically is one of the turning points for the work of this project.

The logical product of each rule is inferred, so as to arrive at a combined magnitude for each output membership function. Once inferred, the magnitudes are mapped into their respective output membership functions, delineating all, or part, of them. The 'fuzzy centroid' of the composite area of the member functions is computed and the final result taken as the crisp output. Tuning the system involves 'tweaking' the rules and membership function definition parameters to achieve an acceptable system responses.

A fuzzy logic monitoring system has been developed and tested successfully. Before the final development phase each MF, the rules and structure, were checked several times with necessary changes according to its performance.

Figure 5.19 shows a block diagram overview of the interpretation engine and the proposed multi-layered outcome for early detection of several physical signs. 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 which complement each other when the information is complete and each component 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 detect of physical sign(s) as the priority-2 warning and at the time of the actual health event the priority-1 alarm will be activated. This mechanism is best utilised in this context by feeding a multiple input-output combinational relationships in real time. Detailed results and validation of testing and enhancements are described in Chapter 7.
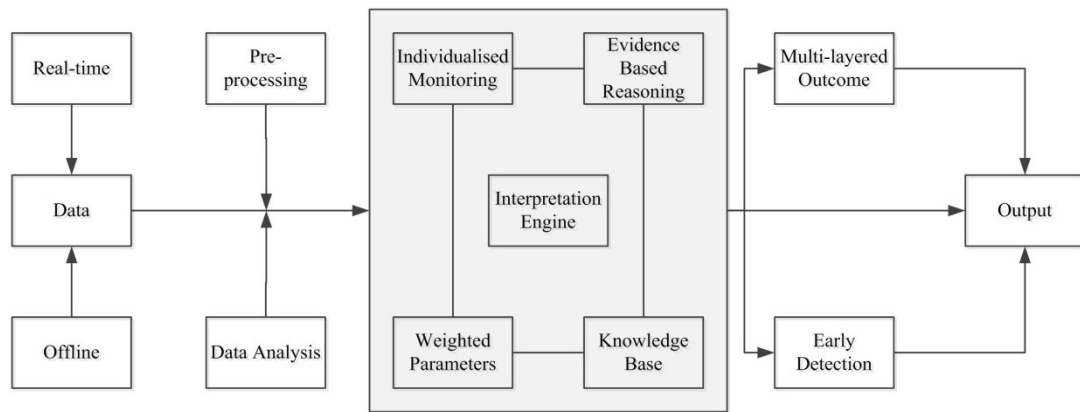
Figure 5.19 Block diagram overview of interpretation engine.

CHAPTER 6   Falls Prevention and Detection

6.1 Introduction

Falls and fall-induced injuries in older adults are common worldwide and ageing populations will further contribute to the increasing number; therefore fall-induced injuries represent one of the most common causes of long-lasting pain, functional impairment, disability and death in the older adult populations [315].

Falls are prominent among the external causes of unintentional injury. They are coded as E880-E888 in the International Classification of Disease-9 (ICD-9), and as W00-W19 in ICD-10, which includes a wide range of falls specifying those on the same level, upper level, and other unspecified falls.

According to the WHO, Falls are commonly defined as "inadvertently coming to rest on the ground, floor or other lower level, excluding intentional change in position to rest in furniture, wall or other objects" [316].

In this context, the operational definition of a fall is critical in order to predict a fall in an older adult [218, 315]. Therefore, the operational definition of a fall with explicit inclusion and exclusion criteria is highly important, and this can create an ultimate boundary between direct factors and indirect factors. The rate of hospital admission due to falls for people aged 60 and older in Australia, Canada and the United Kingdom ranges from 1.6 to 3.0 per 10000 population [316]. Fall injury rates resulting in emergency department visits of the same age group in Western Australia and in the United Kingdom are higher: 5.5-8.9 per 10,000 population. Therefore, there are areas in hospital practice that would benefit from interventions to reduce the number of falls and consequent injury (see chapter 1) [316].

One of ten falls in older adults results in injuries such as hip fractures, subdural hematoma, serious soft tissue injuries and head injuries [317]. In addition to physical injury, falls can also have psychological and social consequences. Fear of falling and post-fall anxiety syndrome are well-recognised negative consequences of falls. The loss of self-confidence that leads to an inability to ambulate safely can result in self-imposed functional limitations [216].

6.2 Falls Risk Assessment and its Effectiveness

Multi-disciplinary risk assessment and management strategies are the most effective preventative tools. In most inpatient settings, a member of the nursing staff is generally the first provider to assess the patient for falls risk. Nurses typically perform an initial falls risk screening within the first few hours after an older patient is admitted to care [318].

There is no single assessment tool for all facilities or patients; however, comprehensive standardised tests and measures with reliability and validity, especially predictive validity, are recommended for use in every setting [216]. In other words, to accurately assign a risk value based on the outcome of a standardised risk screen or assessment, the implement should be employed in populations and settings equivalent to those in which it has been investigated. In the acute care setting, popular tools include the Morse Fall Scale (MFS) [145], the STRATIFY risk assessment tool [319], and the Hendrich Falls Risk Model II (HFRM-II) [320].

The Morse Fall Scale (MFS) [145] scores six areas in the ranges of no risk, low risk, and high risk. The areas include:

- History of falling; immediate or within 3 months
- Secondary diagnosis
- Ambulatory aid
    - Bed rest/nurse assistance
    - Crutches/cane/walker
    - IV/Heparin Lock
- Gait/transferring
    - Normal/bed rest/immobile
    - Weak
    - Impaired
- Mental Status
    - Orientated to own ability
    - Forgets limitations

The Hendrich II Falls Risk Model [320] has been validated in acute care, skilled nursing and rehabilitation settings. Similar in many ways to the Morse Scale, the Hendrich II Falls Risk Model assesses:

- Medications
- Confusion
- Vertigo
- Elimination
- Depression
- Gender
- Mobility (Get Up and Go test)

A score of five or greater on the Hendrich II Falls Risk Model [320] indicates a high risk for falls. The Mini-Mental State Exam [321] and the Geriatric Depression Scale [322] have also been analysed to extract the most common features used by such tools. Overall, standardised tools have shown varying effectiveness in falls prediction.

Prediction tools mainly aim to predict risk in categorical terms ('high' 'medium' or 'low' risk of falling or 'at risk of falling – yes/no'). The main idea behind the predictive tools is that once the patient is identified as 'likely' to fall, then the clinician and/or multidisciplinary team can intervene to prevent falls. Examples of numerical risk prediction tools used in falls prevention include STRATIFY, The Hendrich II Falls Risk Model and Morse Falls Scale [323]. Oliver and Healey [318] specified four key elements required for a falls prediction tool (1) High sensitivity – 'true positive' rate; (2) High specificity – 'true negative' rate; (3) High positive predictive value and (4) High negative predictive value.

Regardless of the tool used, the initial screening is only the first step in falls risk identification. The nature of an inpatient's status is often evolving; therefore, ongoing assessment and the clinical judgment of the care providers at each encounter are key factors in preventing falls. All healthcare providers working with patients at risk of falling in inpatient settings should recognise that patients have the potential throughout their hospital stay to change the status regarding falls risk. Those who were at a high risk for falls on the initial assessment may reduce their risk, while a patient with a low falls risk upon admission may require increased falls prevention strategies with a

change in condition. Regardless of when the risk for falls is identified, practitioners should further evaluate patients or residents considered as at-risk; they should develop individualised approaches and continue prevention strategies throughout the patients' stay.

6.3   Falls Prevention Strategies and Common Risk Factors

Several studies have shown that the risk of falling increases considerably as the number of risk factors increases. Stevens [317] categorised falls risks factors as personal or environmental. Personal factors include characteristics of the individual (such as age, functional abilities and chronic conditions) while environmental risk factors usually refer to fall hazards in and around the home (such as tripping hazards, lack of stair railings or grab bars, unstable furniture and poor lighting). The risk of falling increases with the number of risk factors present and the prevalence of many risk factors increases with age [317].

Fall risk can be reduced by modifying risk factors such as lower-body weakness, problems with gait and balance, use of psychoactive medications and visual impairment. Identifying and treating symptoms of certain chronic diseases such as Parkinson's Disease, a history of stroke and arthritis may also reduce the risk of falling as indicated by Stevens [317] as well as Oliver and Healey [318].

The Rand Report [324], a systematic review of fall interventions, concluded that fall prevention programs as a group reduced the risk of falling by 11% and the monthly rate of falling by 23%. Interventions that focused on high-risk individuals (e.g., those who had fallen and were at increased risk of falling again) were more likely to be effective than were those that targeted an unselected group of seniors. Based on a meta-analysis of randomized controlled trials, the Rand Report [324] concluded that the most effective intervention strategies used clinical assessment combined with individualized fall risk reduction and patient follow-up. Such an assessment includes testing gait, balance and neurological function, reviewing all medications, developing a tailored medical management approach and making appropriate referrals. When analysed as a group, interventions that used clinical assessment and risk reduction lowered the risk of falling by 18% and reduced the average number of falls by 43% [324].

Prevention of falls and injuries is not easy, however, because they are complex events caused by a combination of intrinsic impairments and disabilities (i.e. increased liability to fall) with or without accompanying environmental hazards (i.e. increased opportunity to fall) [297]. A fall is classified as a 'complex event' involving more than 'hundreds' of contributing factors. There is some success in falls and/or injury prevention reported in the literature when the some (usually more than one) or all of the following components are included: strength, balance and gait training, improving transferring and ambulation, footwear improvements, investigation and management of untreated medical problems, medication review and adjustment (especially psychotropic drugs), vision tests, hip protectors, patient and staff education about fall prevention, fall risk alert cards, post-fall assessments, and environmental and home risk assessment and management [297, 315, 318].

6.3.1 Fall Risk Factors

Recognised falls risk factors can number up to a hundred and vary from one individual to another. Some commonly reported risk factors are [325, 326]:

- Advanced age
- Pyrexia (high temperature)
- Previous history of falls
- Medications (especially psychotropic drugs)
- Alcohol abuse
- Diabetes mellitus
- Disturbed vision
- Gait disorders
- Confusion (especially delirium [acute confusion] but also dementia)

In addition, falls produce psychological damage and a continued fear of falling, with consequent self-imposed mobility restriction and a further increase in risk of falls [327]. A common scenario for falls in older adults occurs when rising from a chair or bed to get moving, which requires rapid autonomic reflexes to maintain (or increase) blood pressure on standing, balance, muscular power and whole-body and joint position sense. Lack of activity and intrinsic ageing can adversely affect all of the above risk factors.

In the context of this work, which is based on real-time vital signs recording, monitoring and interpretation, the proposed model is more of a prediction tool than a prevention program/intervention. Falls prevention (as an outcome) can be claimed by predicting the falls, and followed by appropriate medical assessment/treatment. From the above-mentioned studies, trials and successful interventions, the most common and critical risk factors identified and considered for the proposed (thesis) model are:

- Vital signs (Hypotension or Pyrexia)
- Falls History (Multiple falls, recent falls or injurious fall)
- Medication (for example Antiarrhythmics, antidepressants, antihypertensives, diuretics, hypoglycemics, neuroleptics, psychotrophics, sedatives and vasodilators)

Apart from the above risk factors the proposed model intelligently incorporates motion data as a unique feature in order to predict falls continuously throughout the patient's stay in hospital. Real-time vital signs and motion data (walking pattern) were added into proposed predictive model. Real-time information of a patient's vital signs and motion data combined with the above mentioned risk factors is hypothesised as helping in predicting the falls risk in a hospitalised older adult patient.

6.4 Overview of the Proposed Falls Prevention Model

The patient's stationary (fixed) information such as: falls history, age, gender and types and number of medications, combined with real-time and continuously changing information such as vital signs and motion data provide the proposed model with uniqueness in falls risk prediction. Figure 6.1 shows the overview of the falls prediction model and its key components. Motion data is incorporated into the falls prediction model in by using a tri-axial accelerometer which gives walking and daily life activity (ADL) data. Moreover, real time vital signs are also integrated from the medical devices as well as from the outcome of the physical sign interpretation model. Falls history and types of medication features are fed to the parameter weighted module for the confidence scoring and falls risk assessment (high, medium or low). The next section describes each module in detail with their working and data models.
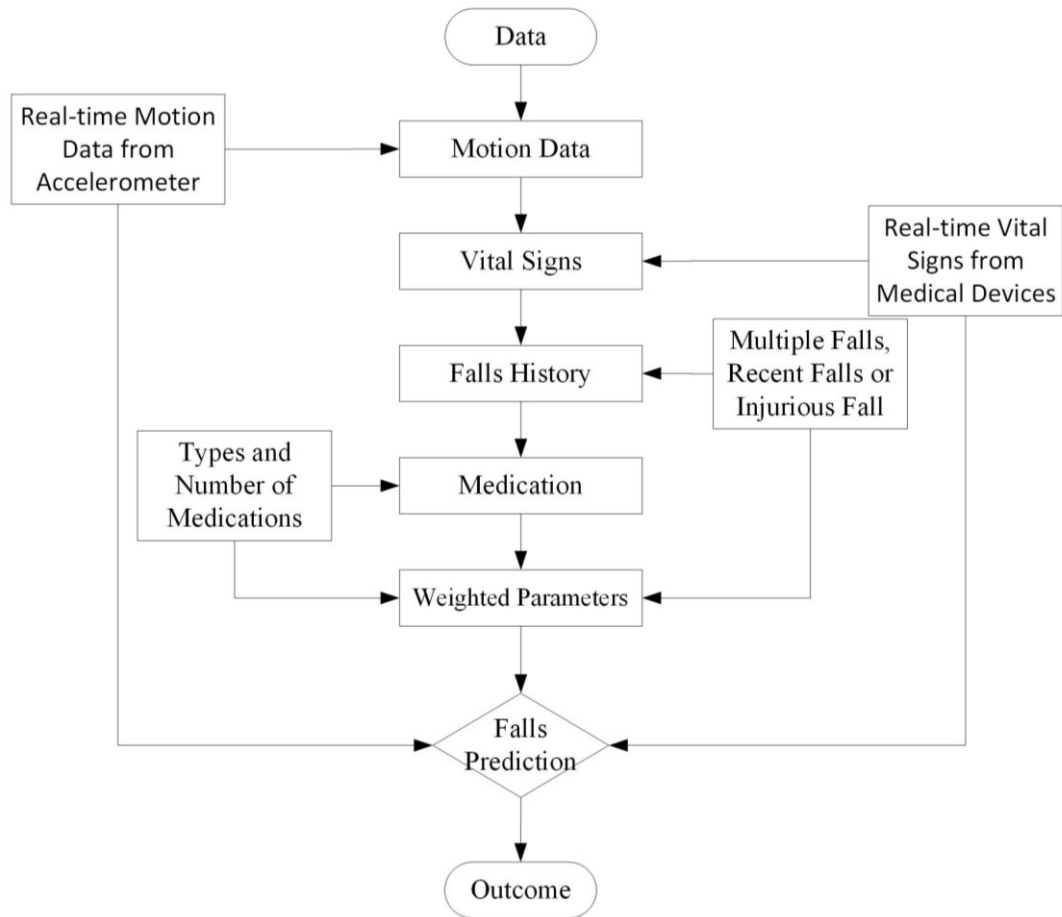
Figure 6.1 Overview of falls prediction model.

6.4.1 Motion Data Analysis

The device used to collect motion data is the 8XM-3 mini, tri-axial 14-bit ±8g accelerometer from Gulf Coast Data Concepts [284] shown in Figure 4.2 device #8. This device is attached to the patient's chest/arm/waist for 24 hours and data is stored in the device with a real-time-stamp. The device is compact in size with the sampling rate of 6 to 200 Hz and can work up to four days continuously. The captured data is stored in the internal 2GB flash memory. To best extract the motion features from the tri-axial accelerometer, a number of methods have been proposed in the literature [328] and their effectiveness varies in terms of successful prediction, but there are numerous algorithms which proved successful in detecting a fall using a similar accelerometer. However, the area of focus in this thesis is to predict falls in order to prevent them rather than detect the falls 'after the damage (fall) has been done'.

Initially normal motion data patterns from older adults (Table 7.10) (who don't have any fall history or walking issues) were collected including walking, sitting, stumbling, falling (right, left, backward and forward) with daily life activity (ADL). This database serves as the core framework for the proposed model. A unique two-way classification model was adopted based on the collected information. Firstly, threshold based detection is adopted, where threshold limits are set by analysing the collected data patterns comprising: gait speed, step length, sway and asymmetry of gait; data points exceeding those set threshold limits for each activity were considered 'not normal' motion data patterns and can be further elaborated into low, medium or high risk depending upon the mean or SD values of exceeded limits.

Secondly, motion data from the accelerometer was compared against the already collected database in a moving window analysis (5sec, 10sec or 15sec window) in each particular activity (sitting, walking, standing, etc.). The falls prediction model uses both methods; in the case of incomplete information the earlier method (standalone) works well and if the information is complete (at the end of each time window), then both methods will contribute towards the falls prediction.

6.4.1.1 Features Identification and Working Model

To detect the negative changes from categorised (activity based) continuous sampled accelerometer data and comparing that data against the collected data for any changes requires trend based prediction exponents analysis. One of the most successful and best suited methods is Lyapunov's direct method (also called the second method of Lyapunov) best described in [329]. Lyapunov exponents measure "exponential rates of average divergence or convergence of nearby trajectories as a system evolves in time" [330]. The proposition for this work is that these Lyapunov coefficients will track the instability of a user and allow the system to extrapolate a user's propensity for a fall based on current and past data. This behaviour can be modelled by the expression,

$$V(t) = Xe^{\gamma t} \tag{6.1}$$

where, $V(t)$ represents the average divergence at time t, X is the initial separate normalisation constant, and γ is the spectrum of Lyapunov exponents. The spectrum of exponents can be calculated by realising that "Two randomly selected initial trajectories

should diverge, on average, at the rate determined by the largest Lyapunov exponent," or LLE. Calculating the LLE can accurately evaluate the stability of a system – in this case, the identification of falls risk features from the motion data.

The basic proposition of Lyapunov methods is best described by assuming V (x, t) to be a non-negative function with derivative V along the trajectories of the system.

- If V (x, t) is locally positive definite and ˙V (x, t) ≤ 0 locally in x and for all t, then the origin of the system is locally stable (in the sense of Lyapunov).
- If V (x, t) is locally positive definite and decrescent, and ˙V (x, t) ≤ 0 locally in x and for all t, then the origin of the system is uniformly locally stable (in the sense of Lyapunov).
- If V (x, t) is locally positive definite and decrescent, and −˙V (x, t) is locally positive definite, then the origin of the system is uniformly locally asymptotically stable.
- If V (x, t) is positive definite and decrescent, and −˙V (x, t) is positive definite, then the origin of the system is globally uniformly asymptotically stable.

A focus on this exponent implies that if the patient's trajectory deviates from the expected (ideal) trajectory, the system may be unstable, indicating that the patient's motion data has falls risk features, and it may predict that this patient may fall in the near future or has a high risk of falling. In other words, the value of an exponent indicates how quickly the trajectory departs from the nominal trajectory. Therefore, if the model yields a higher, positive value of the LLE, the trajectory will be assumed to exponentially deviate even more quickly, indicating a more unstable system. If the LLE is equal to (or very close to) zero, the system is stable, and if it is negative, the system is stationary.

When the average expansion rate of the trajectory demonstrates a strong linear increase in the given time series, the slope will be used to calculate the LLE. Factors such as noise, undersized time series, and small embedding dimensions can result in an absent linear region, resulting in a miscalculation of an LLE. Many Lyapunov methods can be utilized to analyse the stability of patient dynamics, but Rosenstein's method to calculate LLEs is most appropriate for this situation. This is because Rosenstein's

approach is more reliable with small data sets, less computationally expensive, and less sensitive to noise compared to other similar models [331].

The accuracy of Rosenstein's method [331] to calculate LLEs depends on several factors, such as the size of the embedding dimension, the embedding lag and the length of the time series. Each of these factors can be calculated or estimated, depending on the sample data. Since the LLE could potentially be calculated up to several hundred times per second for this application, the length of the time series data set inserted into the algorithm is important. A greater number of time series samples used for each LLE calculation yields greater accuracy. However, while a smaller time series leads to faster computations, the resulting LLEs may be inaccurate.

6.4.1.2 Detection of Unstable Pattern

Accurate identification of normal and abnormal or unstable patterns are critical in this system an over-prediction can lead to a 'normal' patient being exposed to high falls risk management (with potential adverse consequences). Under-prediction can lead to grave consequences, where a high falls risk patient can be classed as a low or no falls risk. Data captured from the accelerometer in readable file format is shown in the APPENDIX E and visual representation of various data patterns are displayed here.

Figure 6.2 displays the short time series for all three axes of accelerometer data for a patient walking consistently and stably, while Figure 6.3 displays similar data for a patient walking unstably.
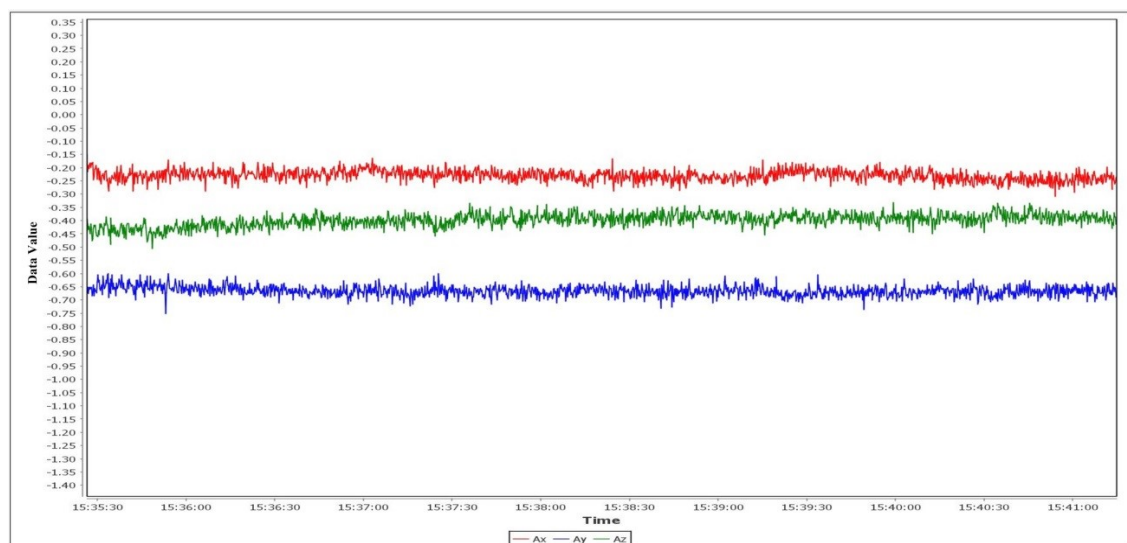
Figure 6.2 Patient's normal walking pattern.

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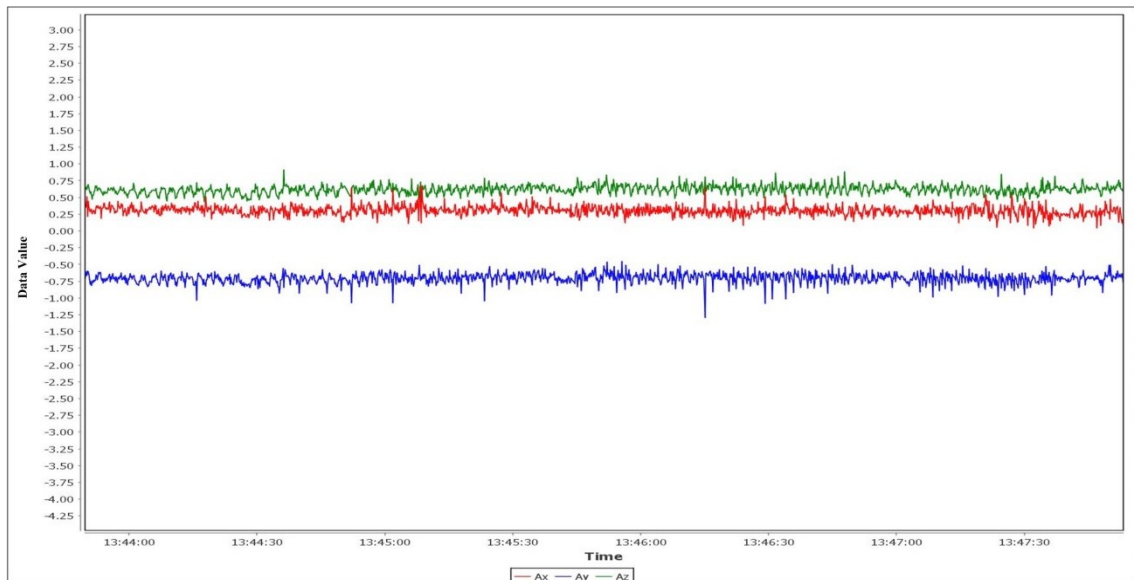
Figure 6.3 Patient's abnormal walking pattern.

It is important to note that the visually similar pattern emerges from the sensor data in both cases. Therefore, when applying Rosenstein's method for the Lyapunov algorithm, the calculated LLEs tend to be very small because very little deviation and few inconsistencies exist in the time series data. However, inconsistent data, as shown in Figure 6.3, yield higher LLEs because of deviations from the nominal trajectory (see section 7.5). This phenomenon is further explored through different activities under both stable and unstable conditions.

6.4.1.3 *Detection of Sitting vs. Stumbling vs. Fall Patterns*

Classifying each event accurately is critical for this model to predict the deterioration in the patient's motion data when compared to the normal data trajectories. The model accurately classifies various events with unique activity-based classifiers for each activity/event. Figure 6.4 shows the accurate classification of sitting on a chair, stumbling to the left and an intended forward fall in a 'normal' patient data pattern. Each classified event is validated and confirmed with the manually maintained observational notes throughout the walking activity. Figure 6.5 shows the detection of stumbling to the left and a fall on the bed (which may indeed be a risk factor for falls but is not within the accepted definition of a fall), it is important to annotate that the classifier accurately detected the fall on the ground as well as the fall on the bed; a detailed explanation is in Section 6.5.

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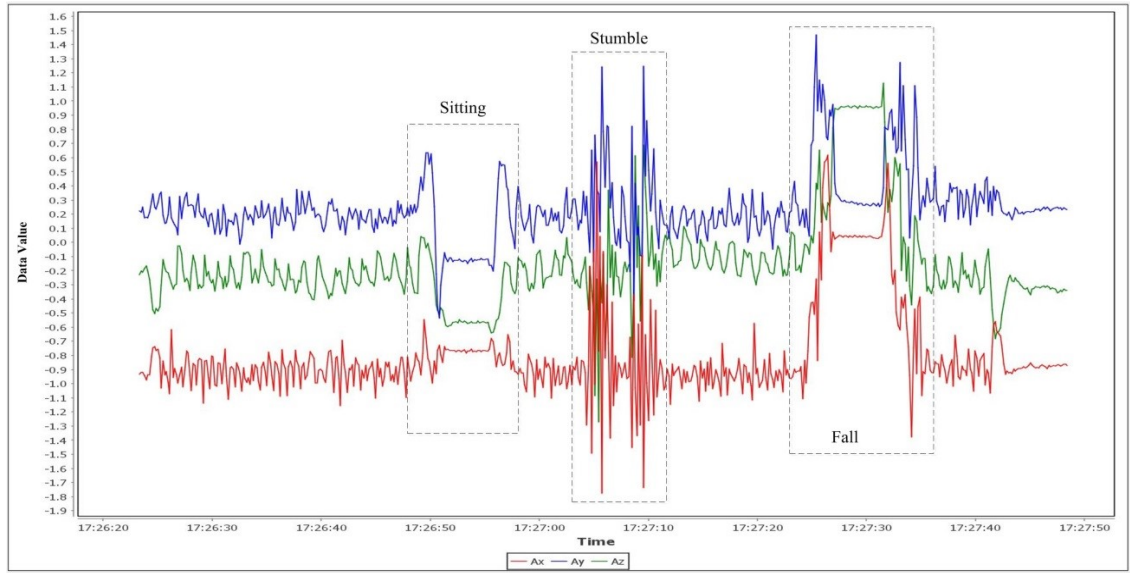
Figure 6.4 Identification and classification of sitting, stumbling and falls patterns in a healthy person.
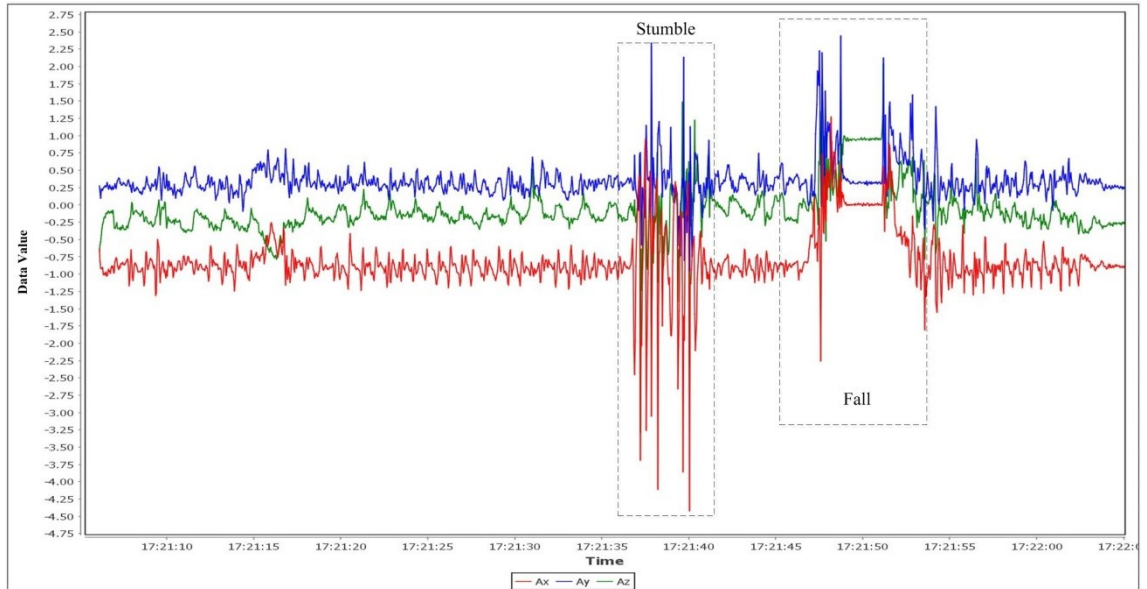
Figure 6.5 Identification and classification of stumble and fall in a hospitalised patient.

6.4.1.4 Detection of Stumbling vs. Backward Fall

Figure 6.6 shows the corresponding accelerometer data for stumbling to the right and a backward fall on the chair. The classifier calculated the time of change in trajectory in both cases, because the falls have faster changes than sitting on the chair. Therefore the speed, change and diversion from normal trajectory are the unique features incorporated into the classifiers when detecting various activity-based events. The classifiers also accurately identified the direction of falls or stumbles (forward, backward, left or right) from the X, Y and Z axis.

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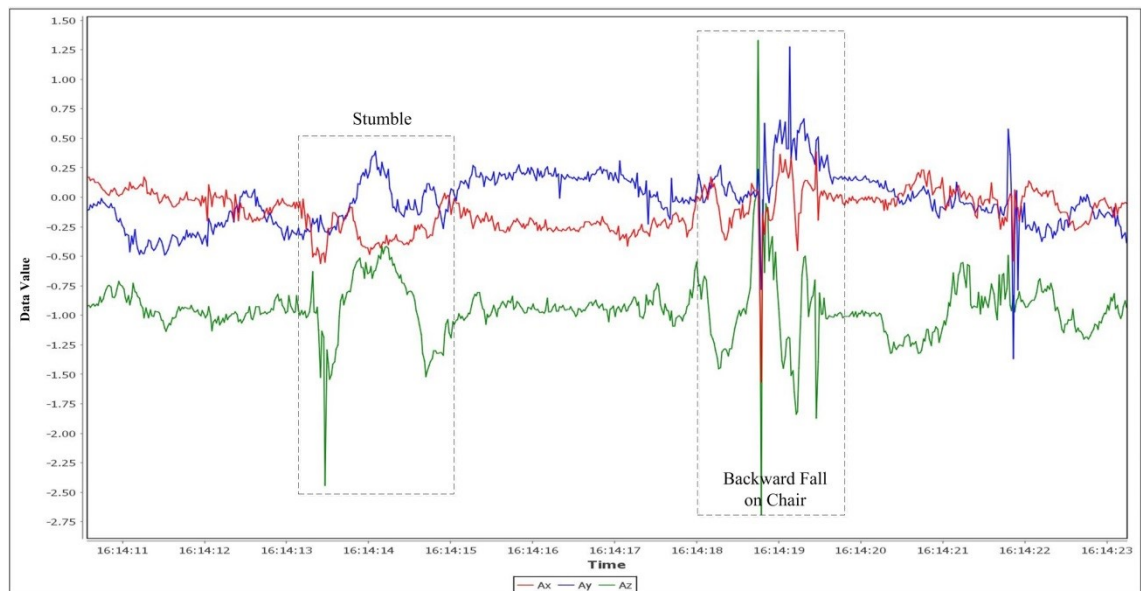
Figure 6.6 Detection of stumble and backward fall on a chair in a healthy person.

6.4.1.5 *Walking Pattern of a Patient with Gutter Frame and Weak Lower Body*

Figure 6.7 shows the data pattern of a patient walking with a gutter frame (a tall walking frame with high arm rests shaped like gutters) with the assistance of a helper. From the clinical notes, this patient had a lower body weakness as well as a history of falls. The classifier was unable to detect any events, though the visual data pattern resembles the stumble or fall, due to the absence of the speed and changes in the trajectory. The core boundary framework integrated the already-known fact and identified features such as speed, change in trajectories, free falls and instant peaks followed by a stable median. It was found that considerable changes in the trajectories are the important phases which can be compared with the existing database of falls. This classifier will contribute towards the confidence scoring for a weighted parameter module when predicting the falls risk.

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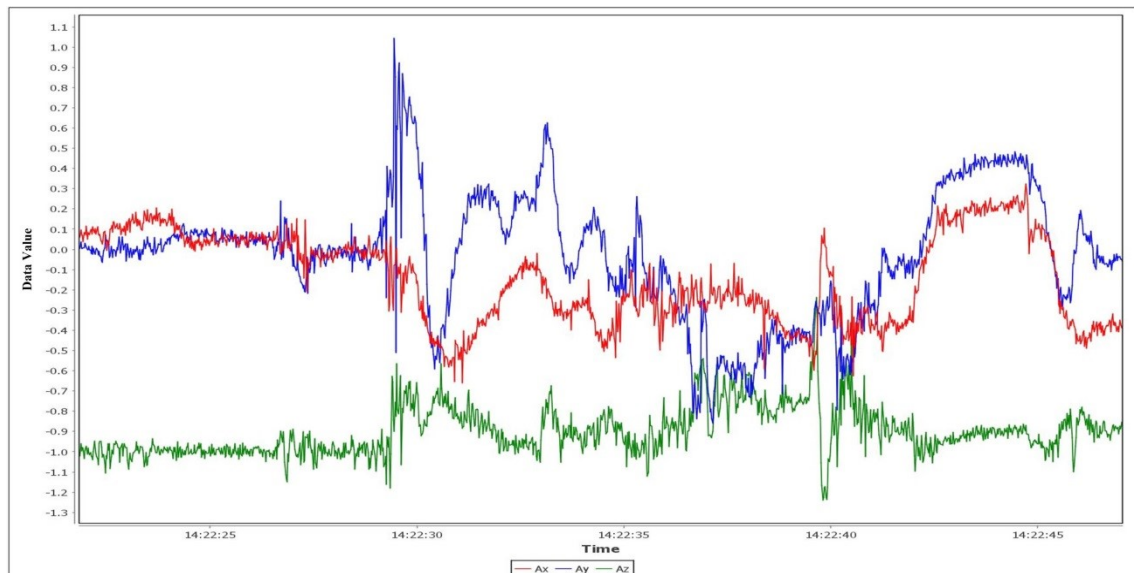
Figure 6.7 Sample of walking pattern of a hospitalised patient with weak legs using gutter frame.

6.4.2 Real-time Vital Signs

Integration of vital signs into the falls prediction system gives an enormous advantage to the proposed prediction model in identification, detection and classification of falls risk. Integration of vital signs has not been given much attention and has been poorly addressed in the literature [318, 332]. However, there is a good report for concrete association between the vital sign(s) and falls [333]. One of the expert rules/conditions adopted here is the case of postural hypotension where:

'A fall of more than 20 mmHg in systolic blood pressure and/or more than 10 mmHg in diastolic blood pressure when standing (compared to the sitting blood pressure) indicates risk of fall' [333].

Figure 6.8 is the extended version of the Figure 5.19 which shows the model design overview. A direct link between the vital signs and the falls prediction model was implemented as well as a link between identified physical signs and overall weighted parameters which also contribute to the falls risk prediction. Direct and indirect links between the input and the output have been maintained throughout the design and development due to the fact that the clinical situation, particularly of hospitalised patients, is often variable (unstable) over days or even hours. As this work revolves around the real-time wireless vital signs recording, monitoring, diagnosis and interpretation, the integration of outcomes from the interpretation model and/or direct

incorporation of real-time vital signs towards the falls prediction has given the proposed model a unique tool in predicting falls risk.
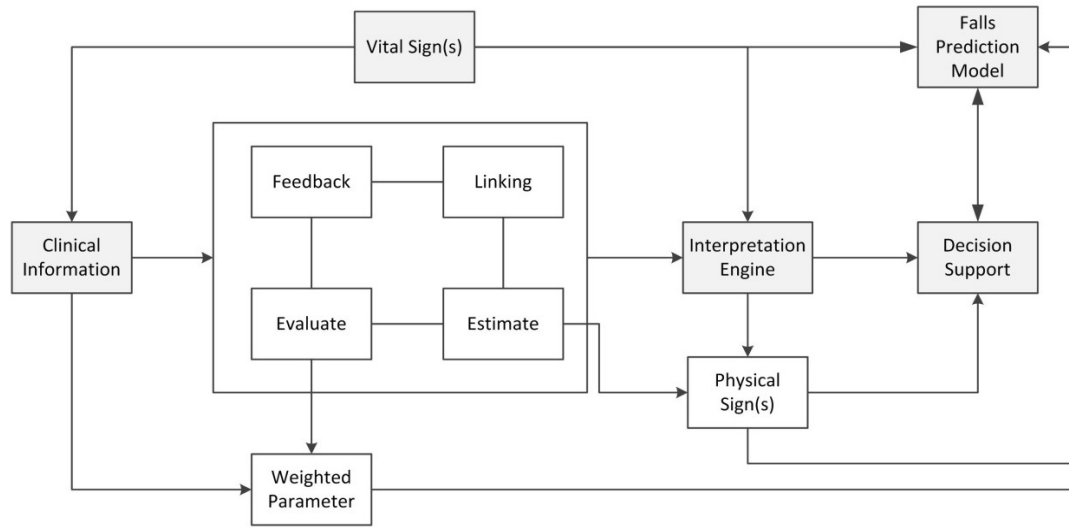
Figure 6.8 Block diagram of vital signs linkage with falls prediction model.

6.4.3 Falls Detection using Motion Data and Vital Signs

Apart from falls *prediction*, the proposed model also detects the falls using the unique combination of the accelerometer based motion data and real-time vital signs. Figure 6.9 shows the falls detection model using tri-axial accelerometer data with real-time vital signs. The proposed falls detection model has two mechanisms; falls detection based only on motion data and falls detection based on combined motion data and vital signs.

The motion data based model has three important conditions to satisfy before the generation of an alert; the classifier identifies the event as a fall (excluding stumbling and sitting on a chair), then the model waits for any changes in the next five seconds to check any movement in the subject after a fall. If there is a detected change, then the system waits for a change in position which indicates that the person is conscious and can respond to the fall (irrespective of the movement, the warning will be generated as soon as the fall is detected, to avoid underestimation of a genuine fall). If there is no change after the fall, it indicates that the person is possibly unconscious (or more seriously ill) and a fall detection alarm will be generated.

When considering motion data as well as vital signs, the system simultaneously processes both data; in the case of motion data, the model detects a fall. Then, changes

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in the vital signs model will be checked for any considerable changes in the vital signs from the point of fall so that the person's status can be recognised before generating the alert. Vital signs are considered to be an indirect link in this model, so processing the fall is not only based on the vital signs.
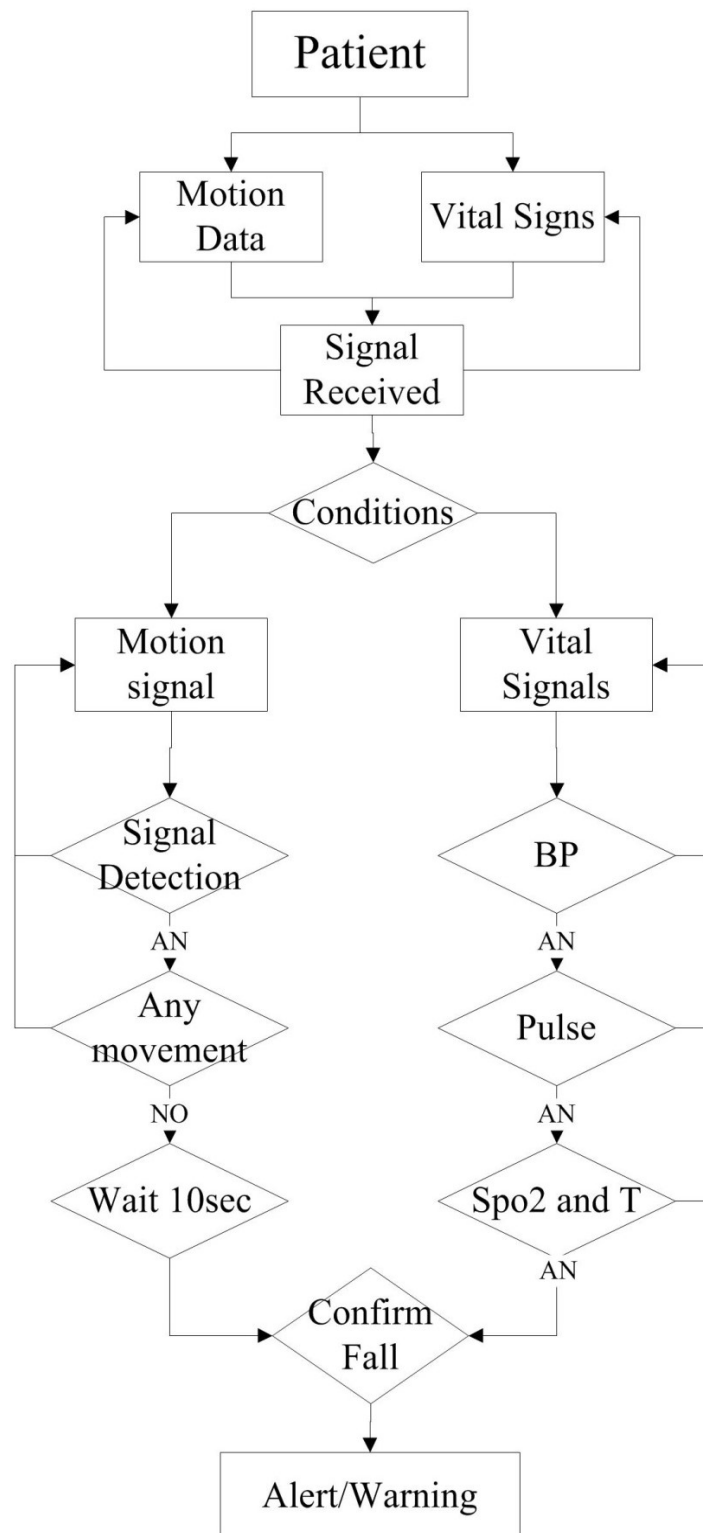
6.4.4 History of Falls

Information about the previous falls is advantageous for the future prediction of falls [214, 315, 318, 332]. In the proposed model, three main phases are considered for falls risk assessment; past history, current status and any ongoing falls-related illness as shown in the Figure 6.10.

Firstly, the 'recent falls' tab checks falls less than three months or six months from hospital admission, then the model also makes notes of the walking aid (if any) the patient is currently using. Secondly, the number of previous falls is considered (excluding the 'recent falls') in order to categorise the risk of future falls. Finally, the injurious falls tab identifies the type (if any) of injury or injuries due to the previous fall(s). This can indicate any short, medium or long term disability in relation to the recent or the previous falls.
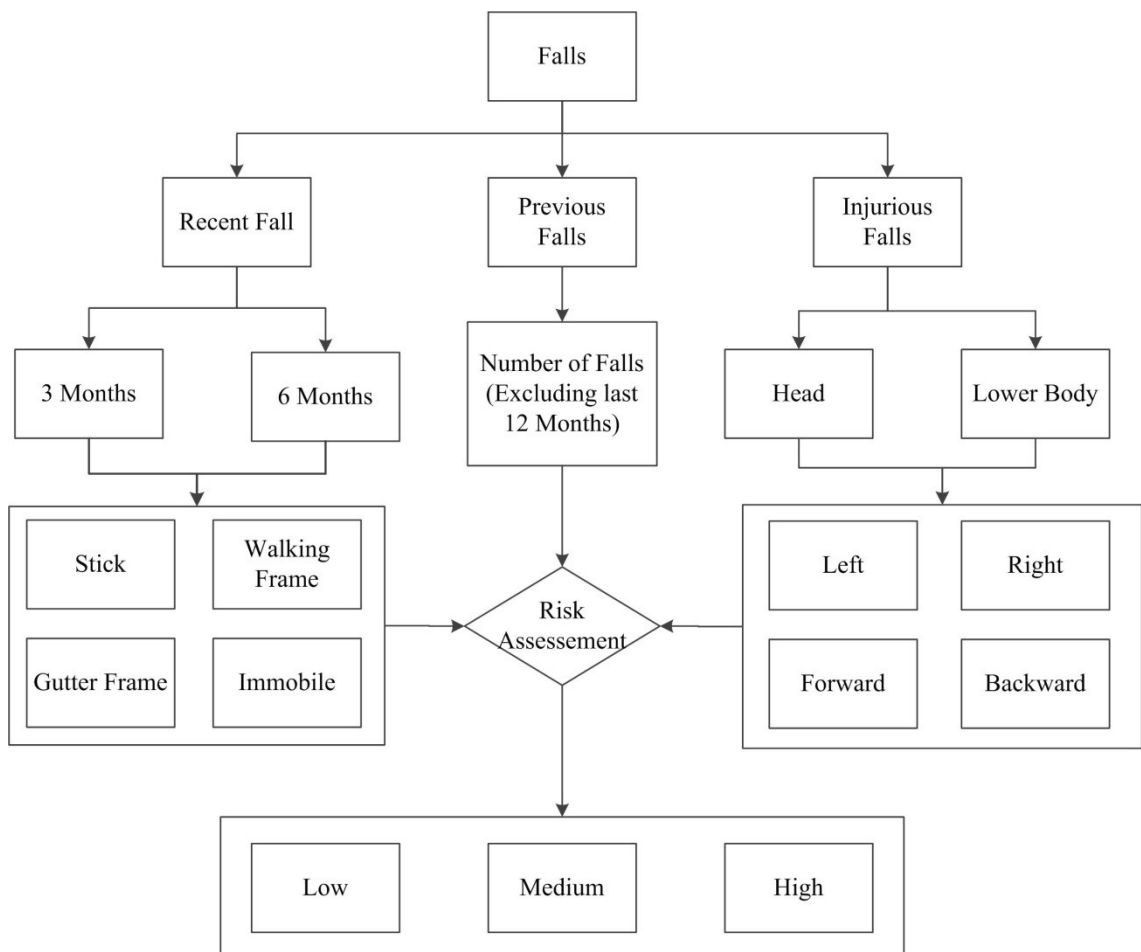
Figure 6.10 Flow diagram of patient's fall history.

6.4.5 Medications

Another critical factor that has been widely adopted in the majority of falls risk assessment tools is the relationship between falls risk and the use of different types of medications. It is reported in the literature that there is an association between falls and medication, which indicates that falls risk increases with the increase in the number and types of medication. Some studies have classified the drugs into low, medium and high risk for falls as described below [334];

Table 6.1 Classification of drugs into low, medium and high falls risk.

Falls Risk	Medication
High	Antidepressants
	Antipsychotics including atypicals
	Anti-muscarinic drugs
	Benzodiazepines & Hypnotics
	Dopaminergic drugs used in Parkinson's disease
Medium	ACE inhibitors / Angiotensin
	II antagonists
	Alpha – blockers
	Anti-arrhythmics
	Anti-epileptics
	Anti-histamines
	Beta-blockers
	Diuretics
	Opiate analgesics
Low	Calcium
	Channel Blockers
	Nitrates
	Oral anti-diabetic drugs
	Proton Pump Inhibitors (PPIs) & H2 Antagonists

Figure 6.11 shows the basic classification adopted by the proposed model in falls risk prediction. The inclusion of all drugs is beyond the scope of this research and requires the inclusion of a complete list of drugs legally allowed in New Zealand hospitals by the

Ministry of Health and running of that list into the structured query language (SQL) database (server), which is a big task by itself. Instead the proposed model classifies the risk factors as low for 0 to 4 for different types of medications and medium for 4 to 6 and 6+ are categorised as high risk [317]. The number of different types and number of medications will be entered by the clinician into the system.
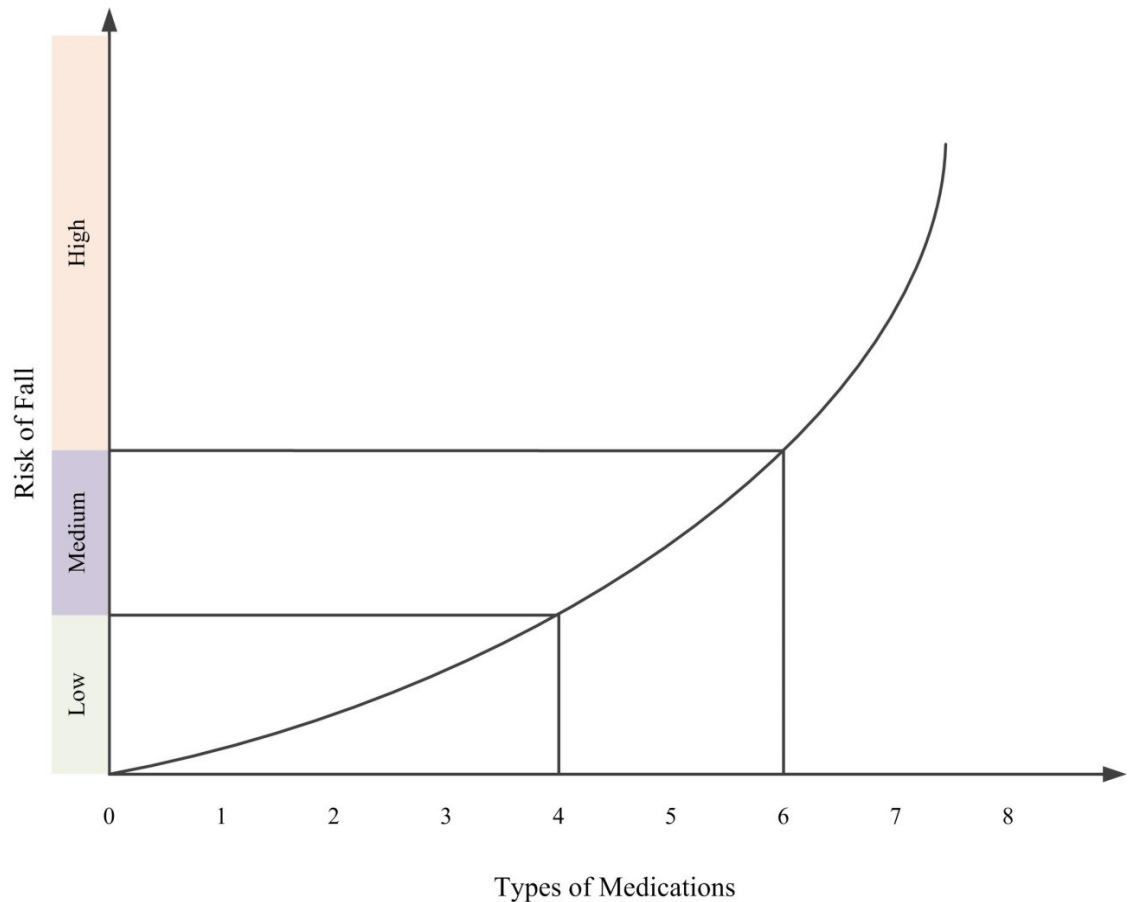
Figure 6.11 Graphical illustration showing increase of falls risk with increase in number of different types of medications [317].

6.4.6 Weighted Parameters

Outcome information is gathered from all of the modules described above to calculate the confidence score. This module works on the similar principle which is explained in detail in Section 5.4.4. Specifically, for falls prediction scoring, the calculation carried out by the weighted parameters module is by assigning direct and indirect links. For instance, high weightage is given to 'Low BP' because of the direct relation to falls, whereas less weight is given to T or SpO2 because of their indirect (not absent e.g. pneumonia) relationship to falls. All the scores from other modules are summed up and confidence ratings are given to each factor in predicting low, medium or high falls risk.

From all gathered information, for each module the system sets points that will be forwarded to the weighting parameter module for possible risk assessment scoring. Figure 6.13 shows the overall data flow model showing weighted parameter module linkage with other key modules in order to predict falls risk.

6.5 Falls Detection and Classification Mechanism

When falling, the person frequently hits the ground or an obstacle. The 'sudden rise' results in an intense inversion of the polarity of the acceleration vector in the direction of the trajectory, which can be detected with an accelerometer or wave peak detector, with a previously determined fixed threshold limit/range. Even if most of the falls occur in the "frontal" plane (forwards or backwards), the direction of the fall trajectory is obviously variable from one fall to another. Also the location of the sensor on the body related to the point of impact modifies the "signature" of the signal recorded at the time of the falls. Lack of movement is also used to detect the fall as, after a "serious" fall, where the person may be seriously injured, they frequently remain immobilized in a posture and/or a place. A movement classifier is used to detect that 'silent phase'.

It is observed that during a fall there is a temporary period of "free fall", during which the vertical speed increases linearly with time due to gravitational acceleration. The vertical speed of controlled movements of the person (to rise, bend down, sit down) is measured to discriminate these speeds from those occurring during a fall, which exceed an appropriate fixed threshold as well as considerable changes being observed from the normal data pattern. The range gap is very narrow and the difficulty lies in the choice of this threshold, if it is too low the device also detects negative events ("false positive"); when the threshold is too high it does not detect positive events ("false negative"). This threshold is also dependent on the subject-to-subject variability (see section 5.4.1 for individualised monitoring).

Fall detection is either positive if the detector properly recognises a fall, or negative if it does not. As the output is a binary one, the quality of the detector cannot be evaluated simply from a single test; instead it is necessary to carry out a statistical analysis on a series of tests. There are four possible cases:

- True positive (TP): a fall occurs, the device detects it
- False positive (FP): the device announces a fall, but it did not occur

- True negative (TN): a normal (no fall) movement is performed, the device does not declare a fall

- False negative (FN): a fall occurs but the device does not detect it

To overcome this critical issue, a learning period of either "supervised" or "unsupervised" learning is adopted using the database which has various activities and patterns for model learning. During data collection of normal walking patterns, the statistical information such as: normal speed of sitting on a chair, lying on a bed and standing are recorded. Then in real-time data analysis, each recorded measurement is checked and synched to carry out a statistical analysis on measured speeds of each patient individually.

Figure 6.12 shows a block diagram overview of falls risk assessment with a multilayer outcome (low, medium and high) for falls risk prediction. The proposed model consists of four key components: motion data, vital signs, falls history and types of medication (Figure 6.12), which complement each other when the information is complete, limited and/or imperfect. A multilayer concept has been introduced to enhance the overall outcome reliability and accuracy of the proposed system. The multilayer outcome has the potential to indicate early the level of falls risk. This mechanism is best utilised in this context by feeding multiple input-output combinations using two stationary modules: falls history and types of medications as well as real-time and changing data for motion and vital signs for falls risk prediction. Multiple outcome categorisations (low, medium and high) gave the proposed model a potential advantage of achieving high accuracy and reliability.
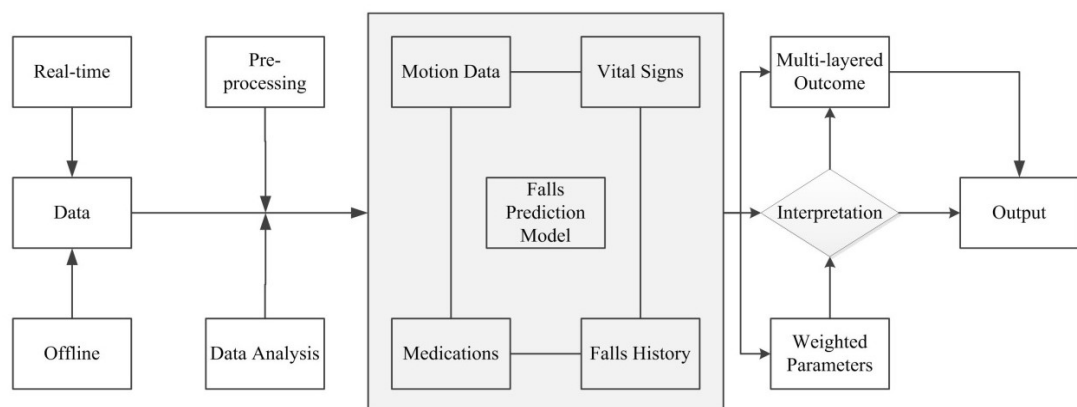
Figure 6.12 Block diagram overview of falls risk prediction model.

6.6 Summary

Falls and fall-related injuries represent an enormous burden to individuals, society and health care providers. Because the population is ageing, this problem will increase unless vigorous preventive action is taken. There is a need to refine, promote and implement effective interventions. In addition, more information is needed in order to tailor interventions for populations with differing characteristics and risk factors.

The pattern recognition classifier accurately detects and classifies the difference between a fall on the ground and a fall on the bed, a stumble to the right and left, sitting on the chair and a fall onto a chair. A falls detection model using motion data alone as well as a combination of motion data and vital signs was also explored. More focus has been given to the falls risk prediction and classification model when compared with the detection of falls. Figure 6.13 shows the overall architectural data model of the proposed system representing key modules and their linkage. Each module represented is explained in its respective sections.
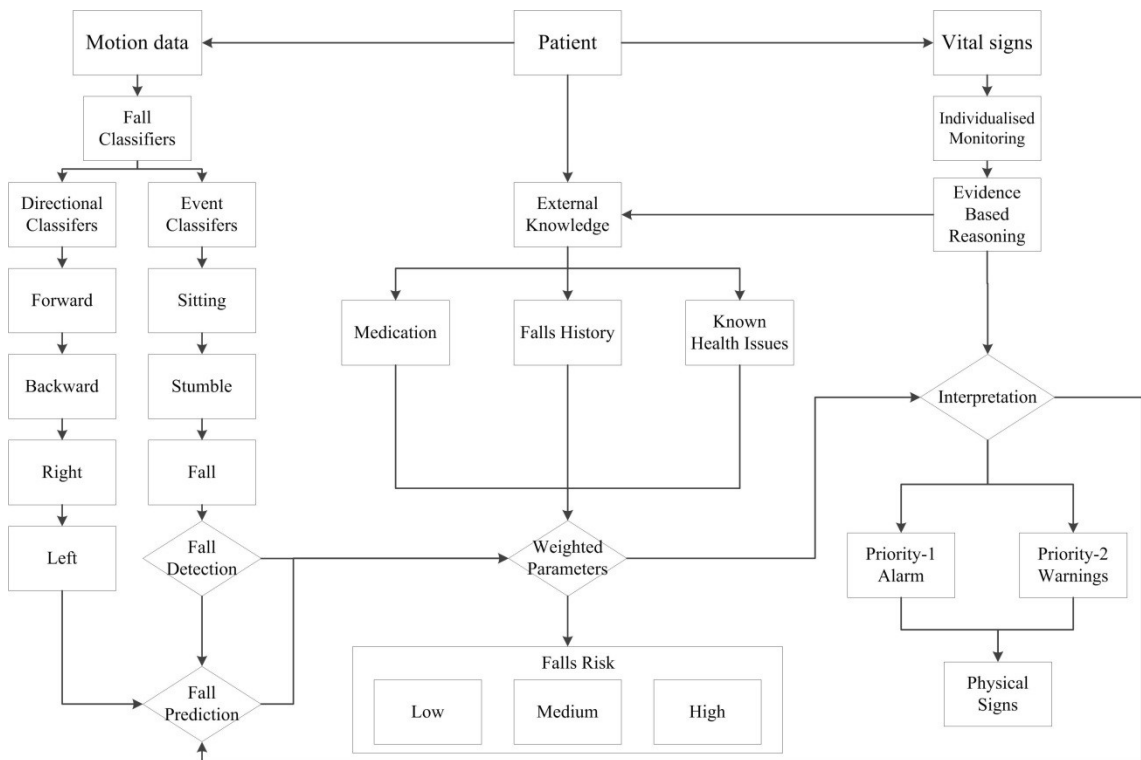
Figure 6.13 Architectural data model of the proposed system representing key modules and their linkage.

The proposed model has been tested with healthy older people, hospitalised patients, intentional falls and other daily life activities. Extensive data analysis and pre-

processing is carried out on the tri-axial accelerometer data so that the input data carries maximum features for the classifiers to detect. Detailed results, validation, testing and system enhancements are described in the next chapter.

CHAPTER 7   Results and Validation

7.1 Introduction

The objective of the proposed project was to develop automated (computer) software that would help in assisting hospital based clinicians to reduce their work load as well as enhancing ward-based patient monitoring. The proposed system is designed as an assistant device to the clinicians in that it aims to record, monitor, detect, interpret and 'diagnose' problems that can occur during a patient's hospital stay by analysing vital signs and motion signals. In addition, as an expert system it can incorporate the knowledge of many consultant clinicians. It is also capable of suggesting reasons for its conclusions. The final management decisions, however, are left to the clinicians. Specifically, the proposed system is distinguished from other medical monitoring systems by the following characteristics:

- Designed for use in hospital ward for a wide variety of daily-routine procedures
- Use of fuzzy logic for representing domain knowledge
- Capable of predicting a multilayer outcome for physical signs as well as falls risk

The above three points relate to the real-time physiological information environment, medical knowledge representation, and knowledge processing/interpretation methods; overall 'knowledge' can be considered as belonging to one of those three classes. The proposed system makes use of all three types of knowledge. The core mechanism adopted throughout the processing and development is that every module should work independently as well as being integrated; this step is taken due to the constant variability of vital sign data in the medical information and processing of partial information in an integrated system which would severely jeopardise the prediction accuracy and overall reliability of the system (refer to section 5.4).

7.2 Proposed System Implementation

Currently the proposed system is not integrated into any other medical system because the geriatrics ward on which it was initially tested has a manual patient monitoring policy using a national early warning score, periodically maintained by on-duty ward

staff. The proposed system uses external medical knowledge as text input and adopts a scoring mechanism based only on the information inserted by the clinician.

Design, development, testing, validation and enhancement of the system were carried out in three phases. Phase-1 of the proposed system was tested using a clinical database (physionet) with limited input/output to check accuracy, complexity and stability. Phase-2 comprised the pre-hospital enhancements and modification of phase-1 in which data from ten real patients was used as off-line testing. In phase-3, real-time data collection and testing were carried out with 20 patients. Evaluation of the devices was also carried out (with 30 older individuals) in terms of mobility, usability, comfort and acceptability; this is explained in the next section in detail.

7.3   Performance Validation and Evaluation

7.3.1   Technical Verification of Medical Devices

Medical devices shown in Figure 4.2 were tested individually with the manual meters before the start of the experimental data collection. The automatic blood pressure meter was evaluated with the (standard) manual mercury column meter, and it was found that the wireless BP meter is more accurate on the left hand and in a relaxed (2 minutes) sitting position. The pulse oximeter was verified using a manual one minute test which showed an accurate result but in some cases the wireless meter takes longer than 10 seconds to give stable measurements due to the finger position. The ear thermometer was verified with the mercury thermometer and was found to be accurate when used in both ears. All the devices were tested and verified in order to conduct the experimental data collection using 30 individuals. The wireless data transmission test showed no errors in real-time patient physiological data transmission from patient to set-top-box to PC based software. Few connection losses occurred due to signal interference and/or bad location.

7.3.2   Evaluation of Medical Devices

It is important to take note that here the researcher is not trying to verify the clinical usability, accuracy and product validation of these devices, because it is not the scope of this research. In fact all devices have been certified (accurate and safe for use) and tested before being available on the market. Instead, evaluation is carried out on these

devices in terms of user (patient) acceptability of the device, usability and comfort with their feedback on each device and its usage.

30 individuals (P1 – P30) were asked to participate in the evaluation of the proposed system. These 30 individuals (18 males and 12 females), with an average age of 60 years were given a 10 point scale (10 is completely satisfied, 5 is neutral and 0 is completely unsatisfied) to rate the medical devices for mobility (size and weight), usability (how easy the device can be operated), comfort (how comfortable they feel when using the device) and overall acceptability. The 10 point evaluation scale and sample assessment questionnaire is shown in APPENDIX F. Each participant was given the basic instructions on how to operate the device before every measurement. However, average age of inpatients on our chosen ward is 82 years 1 month, which is much more than that of above population; further (self-evidently) inpatients, in contrast to P1-P30, are unwell: hence the evaluation results may not be fully representative of older inpatients.

A score above seven seems acceptable (after analysing maximum, minimum and mean); however, there are several aspects where the outcome has been recorded as six or less. Comfort in using a blood glucose monitor is recorded as an average score of six, due to the (unavoidable and common to all testing systems) use of the needle into the finger tip. Usability and comfort of a spirometer is recorded as five for the reason that the majority of participants have difficulty in using the device and blowing air without any error; almost everyone took more than one attempt to get the reproducible reading (again an almost universal [patient-related rather than device-related] feature of spirometry itself rather than of individual spirometers). The usability of the accelerometer has rated six, because of the difficulty in operating the device, which requires a magnet to be held near the device for two seconds and when both the lights (blue and red) stop flashing, then the magnet should be immediately removed, or else it will switch off the device again.

Table 7.3-1 shows the medical device evaluation in terms of mobility, usability, comfort and overall acceptability. The most widely used vital sign monitoring devices (blood pressure and pulse oximeter) have been compared with other similar systems (wireless devices, end-user acceptance and device usability/operation) reported in the literature for in-depth evaluation.

Table 7.1 Evaluation of elected medical devices for mobility (M), usability (U), comfort (C) and acceptability (A) with 30 participants (P1-P30).

User/Devices	Blood Pressure [55]				Pulse Oximeter [65]				Blood Glucose [282]				Ear Temp. [68]				Spirometer [283]				Accelerometer [284]			
Categories	M	U	C	A	M	U	C	A	M	U	C	A	M	U	C	A	M	U	C	A	M	U	C	A
P1	5	9	8	7	9	9	10	10	8	6	6	9	8	8	9	5	7	5	4	8	9	3	9	9
P2	8	9	7	9	9	9	9	8	9	8	5	8	5	9	8	7	8	4	6	8	8	8	9	8
P3	5	9	8	8	8	9	9	9	8	7	8	5	8	5	7	8	9	5	5	7	9	7	6	9
P4	5	8	9	7	7	8	8	8	9	8	6	9	6	9	8	9	5	7	4	4	8	8	8	8
P5	8	10	10	8	10	7	7	8	8	6	5	8	6	6	9	8	6	4	8	5	7	6	9	9
P6	8	9	9	9	9	5	9	8	7	8	4	7	9	8	8	7	8	5	7	8	8	8	7	8
P7	7	9	9	5	8	6	8	8	9	9	5	8	8	9	7	8	4	6	5	7	9	5	8	9
P8	6	7	8	7	10	10	9	9	8	8	5	5	8	8	8	8	7	5	4	5	8	7	9	8
P9	6	8	9	6	9	8	9	9	7	7	6	8	5	7	9	7	8	8	7	6	8	5	5	9
P10	5	10	9	7	8	9	10	9	8	8	8	9	8	8	8	4	5	7	8	8	8	5	6	9
P11	6	6	7	5	9	9	10	9	9	9	7	8	7	5	7	5	6	4	5	5	9	7	9	8
P12	6	9	9	6	8	9	10	7	5	6	5	8	8	6	5	8	8	5	6	4	9	5	8	9
P13	8	8	8	8	9	8	8	7	7	5	5	9	5	7	6	7	7	8	6	7	9	8	7	9
P14	9	9	9	9	10	7	9	5	8	6	8	6	9	8	8	9	4	6	6	8	8	6	8	9
P15	8	7	7	7	8	10	9	5	9	8	7	6	6	5	6	6	5	6	4	5	8	8	9	8
P16	7	9	8	7	10	9	10	10	6	8	5	9	5	5	4	8	8	6	5	6	8	6	6	9
P17	5	8	6	5	9	8	10	10	8	9	6	8	9	8	8	5	9	5	4	9	7	7	9	8
P18	6	8	8	5	8	10	10	9	9	8	5	7	7	7	4	7	6	4	7	8	8	5	8	8
P19	8	8	9	5	10	8	10	8	7	7	7	8	8	5	7	4	9	4	4	5	9	7	9	9
P20	8	9	7	6	7	9	9	9	9	5	8	9	5	8	5	8	9	5	4	8	6	6	6	8
P21	9	7	9	7	9	8	8	8	8	8	5	8	6	9	8	6	8	4	4	7	9	5	9	7
P22	5	9	6	8	9	9	9	9	7	8	4	7	5	5	6	5	8	7	5	4	6	7	8	9
P23	7	7	8	9	9	7	9	7	8	5	5	8	8	5	9	8	7	5	5	5	9	5	7	8
P24	4	8	7	5	8	5	8	8	9	8	5	9	8	7	8	7	8	4	5	7	8	5	8	9
P25	7	6	8	7	7	9	9	9	6	5	5	8	5	8	7	8	8	2	4	8	9	5	9	8
P26	7	8	9	8	9	10	7	7	8	5	4	7	8	5	8	6	9	5	7	5	8	7	6	8
P27	6	7	7	9	8	9	9	9	9	4	5	8	5	8	5	8	7	4	5	5	9	5	9	7
P28	7	4	8	4	10	8	9	8	7	5	5	7	8	7	4	7	8	5	4	5	8	4	8	8
P29	6	5	6	5	9	9	9	7	9	8	5	8	8	5	8	9	9	7	5	6	8	6	7	6
P30	5	4	8	8	9	9	9	8	6	5	2	7	5	8	9	8	8	5	5	8	9	5	9	8
Average Score	7	8	8	7	9	8	9	8	8	7	6	8	7	7	7	7	7	5	5	6	8	6	8	8

7.3.2.1 Blood Pressure Device

The Boso-medicus prestige blood pressure monitor [55] has achieved mean mobility score of 70%, usability of 80%, and comfort of 80% and acceptability of 70%. The mobility score is given as seven, because the participants felt constrained when carrying the devices' base unit and cuff attached to their arm. Table 7.2 compares similar blood pressure monitoring devices.

Table 7.2 Comparison of similar Blood Pressure monitoring devices in a clinical context.

Name/ Device	Model	Purpose	Evaluation type	Particip- ants	Result	Limitations
Takayuki et al. [335]	Jentow, Japan	Arterial Tonometry	Accuracy	30	Acceptance 50%	Movement artefacts
Shennan et al. [336]	Space Labs 90207	Use in Pregnancy	Accuracy	122	Reasonably accurate	Arm cuff too tight
Nakano et al. [337]	Microlife WatchBP O3	Self-usage	Accept- ability	37	86% feels very easy	Un- comfortable
Used here	Boso- medicus BP monitor [55]	Vital sign Monitoring	Accept- ability	30	Acceptance 70%	Low mobility

7.3.2.2 Pulse Oximeter

Nonin's Onyx II finger clip pulse oximeter [65] has achieved a mobility score of 90%, usability of 80%, and comfort of 90% and acceptability of 80%. Table 7.3 compares similar pulse oximeter devices.

Table 7.3 Comparison of similar Pulse Oximeter devices in a clinical context.

Name/ Device	Model	Purpose	Evaluation type	Number of Participants	Result	Limitations
Fisher et al. [338]	Pulse Oximeter Tester (POT)	Arterial Tonometry	Simulation	-	2 SD difference	Faulty sensor
Ibáñez et al. [339]	biox 3700 pulse oximeter	vasoactive therapy	Accuracy	24	4% difference	Not reliable
Kathryn Aughey et al. [340]	Baxter ASAT pulse oximeter	Pre-hospital Care	Accuracy	30	100%	Lack of depth
Used here	Nonin's Onyx II Pulse Oximeter [65]	Vital sign Monitoring	Acceptability	30	Acceptance 80%	-

7.3.2.3 *Blood Glucose Meter, Ear Thermometer and Spirometer*

The Accu-Chek Compact plus blood glucose meter [282] has achieved a mobility score of 80%, usability of 70%, comfort of 60% and acceptability of 80%. Participants felt it was difficult not only to take the measurement, but also to transfer the readings remotely. The comfort rate is low because of the use of a needle. Omron's instant ear thermometer [68] has achieved a 70% score for mobility, usability, comfort and acceptability. It is reported that initially it was difficult to understand how to use the device, especially knowing on which beep the device should be removed from the ear while pressing the top button.

nSpire's Piko-6 meter [283] has achieved a mobility score of 70%, usability of 50%, and comfort of 50% and acceptability of 60%. In order to achieve high measurement accuracy, the user has to be in a standing position, has to take a deep breath in and then has to blow out fast into the mouth piece of the device and initially participants found it difficult to achieve reproducible results (this is the case for all spirometers).

The Gulf Coasts Data Concept's accelerometer/Magnetometer Data Logger X8M-3mini [284] has achieved a mobility score of 80%, usability of 60%, and comfort of 80% and acceptability of 80%. In some body positions participants felt uncomfortable while mobile but suggested changing the body position for better mobility. Finally, the chest or upper back side was comfortable for the users. Operating the device was found to be difficult, especially switching on and off using the external magnet and its exact timings.

Evaluation of medical devices and systems is important to achieve a high level of acceptability. Tamura et al. [341] conducted a home healthcare system trial to monitor blood pressure at two different locations for about one year; 42% and 55% of participants at each location continuously monitored their blood pressure. BP was measured with a commercially available BP monitor (CH-462E, Citizen Japan), and a modified semiautomatic oscillometric device was used for data communication; all data were automatically transmitted to the healthcare centre via a home gateway. It was reported that many participants could not understand the user manual, and found the system cumbersome and troublesome, which discouraged them from participating. Freund et al. [342] conducted a research study in hospital to investigate the failure of pulse oximetry at four different hospitals. Bitterman [343] surveyed the monitoring devices from a home perspective, where special focus was given to the patients' need for a patient acceptable monitoring system in their home. Bergmann and McGregor [40] reported that the successful design of a healthcare system is only possible when medical professionals as well as patients are consulted at every stage of the system design and development. Sixsmith [344] evaluated an intelligent home monitoring system in terms of user acceptability and usability and reported that the system achieved 50% acceptance from the users.

7.3.3 Evaluation of Data Transmission Precision, Delay and Data Loss

As discussed earlier, a three-way cross validation data collection approach is adopted here to achieve high data accuracy i.e. initially vital signs were collected using wireless medical devices, secondly a (double-blinded) manual record of each and every measurement was made immediately. Thirdly, vital signs were recorded (double-blinded) using hospital devices for the same parameters within 10sec, and those readings were also recorded manually. Table 7.4 shows the mean value of the data

collected and the comparison of wireless transmitted data vs. manual recorded data as well as wireless transmitted data vs. hospital collected data (using different devices) with an overall transmission delay. 2160 measurements were collected from 30 hospitalised patients for this thesis (see section 7.5.2).

Table 7.4 Accuracy evaluation with transmission delay and data loss.

Parameters	Mean Value (WTD)	WTD vs HRD (diff.)	Delay (Sec)	Data Loss (%)
BP (Systolic/ Diastolic)	125/71	±7/5	1.82	0.80
Heart Rate	77 BPM	±5 BPM	1.82	0.80
Oxygen Saturation	96%	±1.5%	0.51	0.44
Blood Glucose	134.7mg/dl	±3 mg/dl	-	0.20
Tympanic (ear) Temperature	36.5 ºC	±0.2 ºC	-	-

WTD is wireless transmitted data; HRD is hospital recorded data; WTD vs. HRD difference was calculated to identify the measurement difference between the devices for the same patient and parameter; transmission delay was calculated after allowing device stabilising time for each device of approximately 7 seconds and all the values were calculated from the total of approximately 2500 wireless data transmissions.

The difference between the wireless blood pressure monitor and the hospital's blood pressure device was found to be ±7 mmHg for systolic and ±5mmHg for the diastolic. However, it was found that there was a difference of ±10/8 mmHg for three patients who had a sore arm or tremor. It was found that the data transmission delay was due to poor signals, signal drops, connection loss (at the time of transmission) and/or poor location.

7.4 Result Validation Criteria

Kappa analysis [345] was used to measure the level of agreement/disagreement between the proposed system and a medical expert (Professor of Geriatric Medicine) i.e. as the measure of how accurately the system can mimic human performance. Accuracy is generally used to assess the performance of classifiers. However, on its own it is not a realistic metric that should be used to assess classifiers' performance for the used data set, as the influence of negative samples on overall accuracy is much higher than that of

positive samples. Precision, as it pertains to agreement between observers (inter-observer agreement), is often reported as a Kappa analysis [345].

Kappa is intended to give the reader a quantitative measure of the magnitude of agreement between two or more observers, in this case the system and the medical expert. The positive agreement (P_{pos}) and negative agreement (P_{neg}) indices were calculated as follows.

$$P_{pos} = \frac{TP + TP}{(TP + FP) + (TP + FN)} \tag{7.1}$$

$$P_{neg} = \frac{TN + TN}{(FP + TN) + (FN + TN)} \tag{7.2}$$

The third index of agreement gives the overall agreement (P_o) level between the expert and the system and (P_e) is the agreement by chance.

$$P_o = \frac{TP + TN}{\Sigma(TP + TN + FP + FN)} \tag{7.3}$$

$$P_e = \left(\frac{((TP + FP) \text{ X } (TP + FN)) + ((FN + TN) \text{ X } (FP + TN))}{\Sigma(TP + TN + FP + FN)} \right) \tag{7.4}$$

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.

$$K = \frac{P_o - P_e}{(1 - P_e)} \tag{7.5}$$

The standard error (SE) of k is,

$$SE = \sqrt{\frac{P_o(1 - P_o)}{n(1 - P_e)^2}} \tag{7.6}$$

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

$$CI_{95\%} = K \pm 1.96 \times SE \qquad \text{(7.7)}$$

Table 7.5 Kappa value against the strength of agreement classification.

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

The quantitative categories like accuracy sensitivity, specificity and predictability can be calculated by the following standard equations:

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

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

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

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

7.5   System Results

The evaluation of the proposed system has been directed towards three primary aspects. These are:

- Utility as a remote and wireless vital signs recording and monitoring – is reflected in the sensitivity and specificity of the proposed system – that is, whether it generates an alarm or prompt in response to an adverse condition in the patient, and the rate of false alarms. Moreover, identified problems should be correctly classified. Results pertaining to this aspect are presented in this section.

- Usefulness for physical signs interpretation – the usefulness of the system as an aid to interpreting multiple physical signs is explained in Chapter 5 in detail and results are discussed in this section.

- Precise enough to predict falls risk – precision of the falls risk assessment is somewhat difficult to determine due to the fact that the patients who were identified as having a low, medium or high risk of falls cannot be tested in a real-time hospital environment due to the project time constraints. Such a project would require at least several months (possible longer depend on the falls incident rate) of patient monitoring with respect to falls.

The results shown in this section are collated from more than 200 hours of data collected by a ward-based trained registered nurse and the student researcher over approximately 24 months. The nurse and researcher were mutually blinded to each other's activities/observations and the nurse was blinded to the automatic recordings and alarms generated. Data collection was performed at North Shore Hospital and Waitakere Hospital, which come under the Waitemata District Health Board (WDHB). The data collected thus represents a sampling of daily routine activities performed on older adult patients during their hospital stay. During the collection of the data, the attending nurse could make annotations regarding any potentially clinically significant observations and by verbal discussion of factors such as visible wounds, weakness, pain, dizziness, intake of food or medicine, exercise/physiotherapy, etc. These annotations were then included in the external medical module of the proposed system for weighted parameter scoring. The data was also examined for any events not

annotated at the time by the staff. These sets of events provided justification for any alarms or warning/prompts generated by the system. Furthermore, the justified events were also categorised according to their diagnoses. This information was used to test the accuracy of the system in correctly identifying problems. No events of types outside the system's diagnostic/interpretive capabilities were encountered.

7.5.1 Pre-testing of Physical Sign Detection

Figure 7.1 shows the block diagram (initial) of the proposed remote patient monitoring system and the flow chart of the diagnostic module using fuzzy logic for the detection of two physical signs. The aim of this project was to develop a 'universal' diagnostic module based on vital signs. The diagnostic module should be compatible with existing monitoring systems and/or medical devices. Two physiological parameters, blood pressure and heart rate, contributed to the early diagnosis of hypertension and hypotension. The diagnostic module as shown in Figure 7.1 is described below.

Data conversion, file read and pre-processing modules convert the incoming data from an external monitor to a readable format. The diagnostic module was tested by integrating several alarm monitors such as: GE Healthcare's Datex-Ohmeda S/5 monitor (currently in use at Auckland City Hospital) and Boso-medicus BP monitor, which send data in a digital format. After converting the raw data to a readable format the next step is to read the file for pre-processing, this includes: filtering, averaging, normalization, calculating statistical values (mean, median, mode, and range) and standard deviation (SD) to identify changes in the physiological parameters.

Batch processing: This part creates batches of one to five minute time frame windows to batch process the incoming data. This method provides a more accurate diagnostic output because it incorporates the changes in the parameters, by calculating the SD, instead of crisp numerical limits. By this method, the number of false alarms is reduced (physiological data has high variability among individuals).

As discussed earlier in detail, fuzzy logic is found to be one of the most valuable techniques when numerical values, such as vital signs, are associated with concepts, such as 'Hypertensive' and 'Hypotensive' instead of a set range/limit. Using fuzzy logic, the continuous coinciding shift from 'Hypertension' to 'normal blood pressure' feeds the module to sense that 150 mmHg (mean arterial pressure) is 70%

'Hypertension' and 30% 'normal', expressed as 'somewhat hypertensive'. But other methods are usually forced to express the above scenario as 100% 'hypertension' and 0% 'normal'. Fuzzy sets, membership functions and rules are derived using normal and abnormal vital data range from a physician as well as from the literature [346].
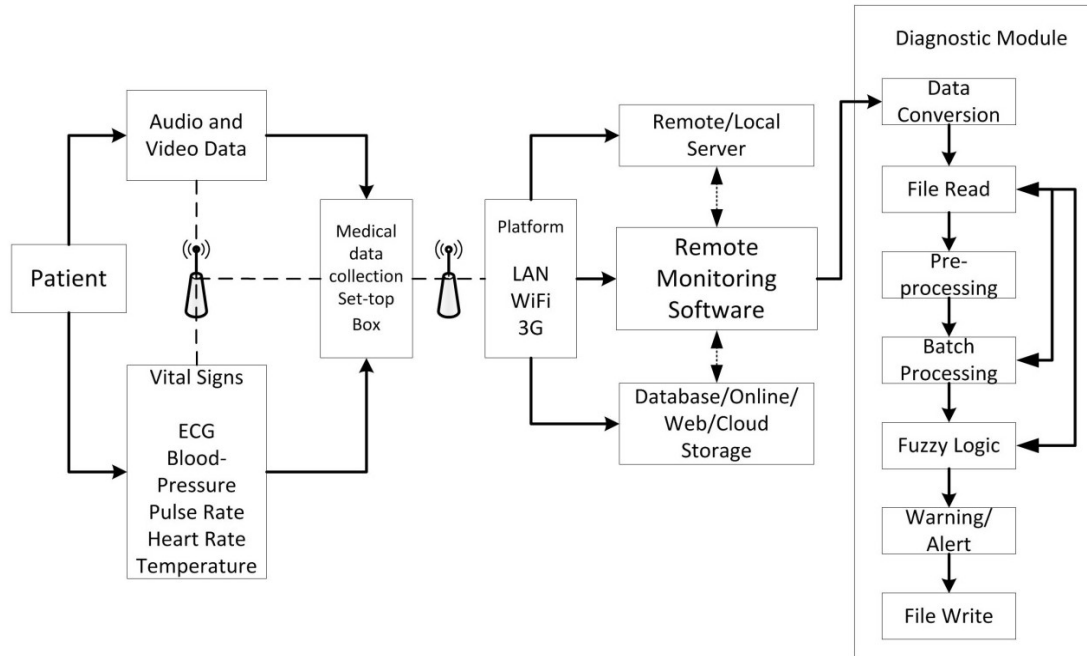
Figure 7.1 The block diagram of the proposed remote patient monitoring system and fuzzy diagnostic module.

Alert/warning display and file write: The system displays an alert based on the changes in parameter (SD) as well as user-defined limits. However, there will be no alarm generated solely based on the user-defined limits. The module will compose and save (write) all key information such as: date, time, data value, SD change, generated alarm and display message (hypertension or hypotension) in a readable formatted file for future analysis and patient's record. Sample processing is shown in Figure 7.2 where logic is running on the left side and the output window can be seen on the top right with possible hypertension detected in batch 24 of the patient data (database). The bottom right window shows the output file read with date (column A), time (column B), mean BP value detected (column C), pulse value (column D), possible outcome (column E), SD of BP (column F) and SD of Pulse (column G).

Results of the proposed system (using database) for detecting hypotension and hypertension are shown in Table 7.6. The results are compared with other similar

monitoring systems for evaluation of the alarm accuracy, sensitivity, specificity and predictability.
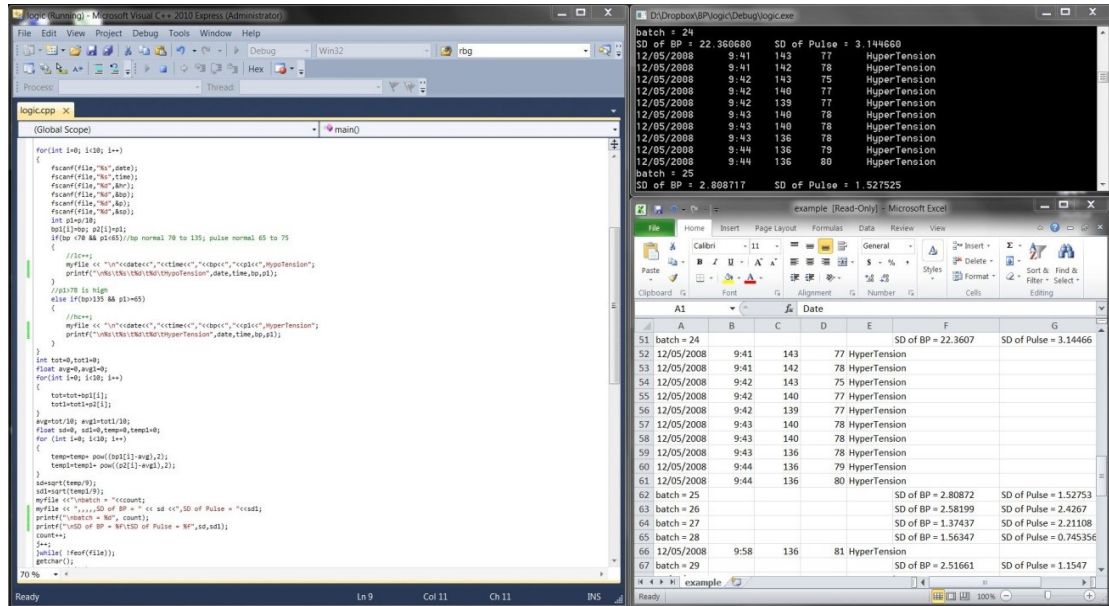
Figure 7.2 Processing and detection of hypotension and hypertension with file read/write.

Table 7.6 Results of the proposed system and comparing with other systems

Alarms	Proposed System		Oberli et al [286]	
	Diagnostic Module	Datex-Ohmeda S/5 Monitor	Expert System	Space Labs ™ Monitor
TP	117	104	169	149
TN	296	327	112	181
FP	26	82	8	737
FN	7	35	24	88
Total Alarms	446	548	289	1067
Accuracy (%)	92.60	78.64	89.77	28.57
Sensitivity (%)	94.35	74.82	87.56*	62.86*
Specificity (%)	91.92	79.95	93.33	19.71
Predictability (%)	81.81	55.91	95.48*	16.81*

Where TP is true positive, TN is true negative, FP is false positive and FN is false negative. * The authors used TP and TN to calculate the sensitivity and predictability.

7.5.2 Real-time Testing of Physical Signs Detection Model

On an average each patient was visited three times during the trial. During each visit, four sets of vital signs were collected. Each set contained seven measurements: two blood pressure measurements – one standing and one sitting with the time difference of one minute on an average, heart rate, oxygen saturation, ear temperature and blood glucose readings. Overall, for data collection each patient was visited three times, four sets of measurements were collected and each set had six recordings. Therefore, a total of $1_{patient}$ X 3_{visits} X $4_{data\ sets}$ X $6_{recordings}$ = 72 recordings for one patient were collected. Finally, for 30 patients, a total of ($72_{recordings}$ X $30_{patients}$) which is equal to 2160 recordings was collected.

Figure 7.3 shows the overall performance of the proposed system as a physical signs detection system. The proposed system raised a total of 356 alarms and of these, 127 alarms were promoted to P1 (priority-1) alarms and the rest were P2 warnings (229). It is important to mention that only P1 alarms are considered for Kappa analysis compared with a medical expert's diagnosis, due to the fact that P1 were designed as an alarm and P2 were designed as prompts or message, for more flexibility to the clinicians. From another viewpoint, P2 (229) represents 64% of total alarms (356) when compared to 36% P1 (127), which suggests that for 1 P1 there was 1.8 P2, indicating that the proposed system successfully detects the P1 early by means of P2, as explained in detail in section 5.4.5. This evidence demonstrates the early detection of multiple physical signs as well as high predictability of the proposed system.
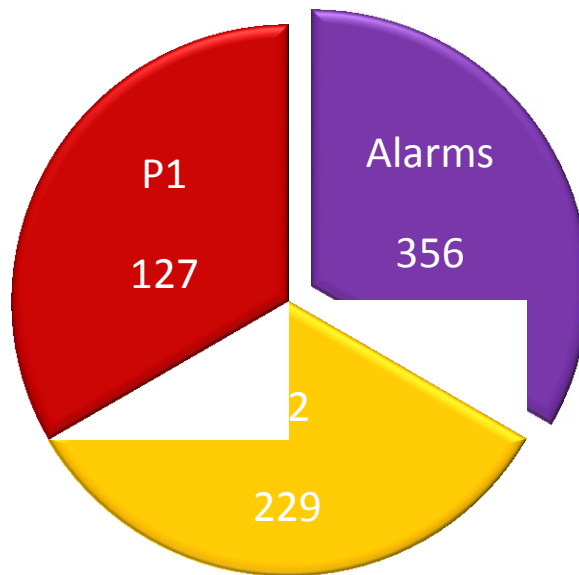
Figure 7.3 Total number of alarms generated by the proposed system with P1 and P2 classification.

Table 7.7 below details the P1 alarms categorised according to the physical signs and compares it with the medical expert's diagnosis for the same data.

Table 7.7 P1 alarms generated by the proposed system compared with the medical expert's diagnosis.

Physical Signs	Proposed System	Medical Expert
Hypotension	8	8
Hypertension	11	9
Tachycardia	12	12
Hypoxaemia	15	15
Hypothermia	6	3
Total	52	47

The results are summarised that in 47 out of 52 instances, the system and the expert were positive (true positive) and for the remaining five instances the system was positive but the expert was negative (false positive). There were no instances recorded where the system was negative and the expert was positive (0 – false negative) and the rest of the alarms were characterised as true negative (75) where the system and expert were both negative; this classification is defined in Table 7.8.

Table 7.8 TP, TN, FP and FN values extracted from 20 patients' data for Kappa analysis.

System/Expert	Expert (+ve)	Expert(-ve)	Total
System (+ve)	47 (TP)	5 (FP)	52
system (-ve)	0 (FN)	75 (TN)	75
Total	47	80	127

Based on values from Table 7.8, Kappa analysis was carried out using the standard calculations as explained in detail in section 7.4 of this chapter. Agreements between the two diagnoses may be affected by chance. Kappa (k) is a measurement of agreement between the expert and the system which has been corrected for error by chance. Kappa (k) was 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. The Kappa analysis results for the proposed system's performance are described in Table 7.9; P_o, P_{pos}, and P_{neg} are overall, positive, and negative agreements, respectively. SE represents the standard error and $CI_{95\%}$ is 95% confidence intervals for Kappa.

Table 7.9 Results from Kappa analysis and agreement evaluation.

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	$CI_{95\%}$
0.96	0.94	0.96	0.52	0.03	0.98 and 0.83

The overall Kappa value is calculated as K = 0.91 and according to Table 7.5 the strength of agreement beyond chance lies in the range of 0.81 to 1 described as 'almost perfect'. The Kappa based statistical analysis showed a substantial level of agreement (k = 0.91 or 91%) between the expert's and the system's diagnoses. Table 7.9 shows that the proposed system achieved an overall agreement of 96% with Kappa K with a value

of 91%. Now, the quantitative categories were calculated such as accuracy, sensitivity, specificity and predictability using the standard equations (refer Table 7.8 for TP, TN, FP and FN values). The proposed system achieved an accuracy of 96%, sensitivity of 100%, specificity of 93.75% and predictability of 90.38% compared with the diagnosis of an expert for the same physical signs.

7.5.2.1 *Alarms Justification*

The proposed system achieved an overall positive agreement (P_o) and accuracy 95% and Kappa value 91%. There are five disagreements (FP) with the medical expert (post data collection evaluation by Professor Martin J. Connolly, Freemasons' Professor of Geriatric Medicine, University of Auckland and North Shore Hospital) (Table 7.8) which are briefly discussed here. On three occasions 'possible hypothermia' was detected because the detected ear temperature value was below normal for that particular patient. The system generated a possible alert but the medical expert disagreed and reported that it was a borderline value and would have a delay to see the next few temperature readings before actually considering this as a possible alert. On two occasions the system detected 'possible tachycardia and hypertension' for each of two particular patients based on their individual values. The blood pressure was slightly on the high side and the heart rate was very high, which indicated possible considerable changes in the patient's vital sign values when compared with previous values and the overall normalised data trend. The medical expert agreed with the alert for 'tachycardia' but disagreed with the 'hypertension' conclusion explaining that the blood pressure values were borderline, it was not justifiable to say 'possible hypertension' at that stage, but instead they would go for possible tachycardia. It is expected that the proposed optimally designed alarm system generates warnings within a short interval in order to provide the opportunity for clinicians to take appropriate action before a critical pathological event occurs. On the other hand, the system should limit its false alarms (false positives), as discussed in detail in the next chapter.

7.5.3 Accuracy Evaluation of Falls Classifiers

In order to evaluate the falls detection classifiers of the proposed model, four healthy male individuals (aged 62Y7M, 69Y9M, 72Y3M and 75Y9M respectively) performed intentional falls and normal activities of daily life (ADLs). For testing and evaluating the system individuals with impaired vision, imbalance, walking with any support or

cognitive impairment were excluded. Activities performed included forward, backward, right-side and left-side falls as suggested by Noury et al. [347]. A total of 80 intentional falls and 40 ADLs were simulated as shown in Table 7.10.

Table 7.10 Accuracy results of the proposed system when detecting backward, forward, right side and left side falls.

Category	TP	TN	FP	FN	Accuracy %
Forward Fall	20	20	0	0	100
Backward Fall	18	18	0	4	90
Left-side Fall	17	17	0	6	85
Right-side Fall	19	19	0	2	95
Total	74	74	0	12	

7.5.4   Testing of Falls Risk Prediction Model

As mentioned earlier, a similar data processing process was followed here with 10 patients' data used for initial testing and training of the falls prediction model. The remaining 20 patients' data was used for real-time testing. Figure 7.4 shows the falls risk prediction results by the proposed system and categorises them into high, medium and low falls risks. The numbers in the bracket are the falls risk results obtained from the Morse falls scale (MFS), performed by (blinded) medical staff on the same 20 patients.
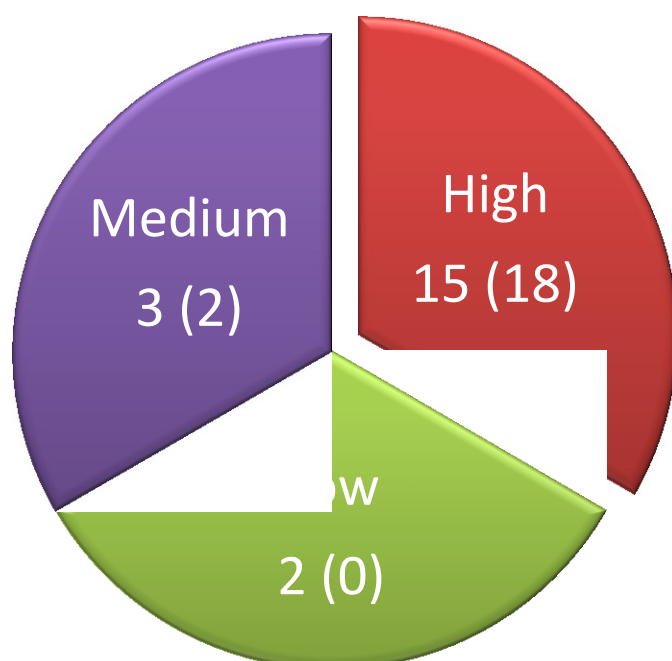
Figure 7.4 Total number of falls risk prediction by the proposed system with high, medium and low classification. Numbers in the bracket are blinded Morse Falls Risk results for the same patients.

Table 7.11 shows the both proposed system and MFS agreed and were positive 15 times for high risk and twice for medium falls risk (TP = 15) while the system was positive and MFS showed negative assessment three times (one for medium risk and two for low risk) (FP = 3). There were two incidents recorded where the system was negative and MFS was positive (FN = 2), and there were no incidents recorded where the system and MFS were both negative (TN = 0).

Table 7.11 TP, TN, FP and FN values extracted from 20 patients' data for qualitative analysis.

System/MFS	MFS (+ve)	MFS* (-ve)	Total
System (+ve)	15 (TP)	3 (FP)	18
System (-ve)	2 (FN)	0 (TN)	2
Total	17	3	20

*MFS is Morse Falls Scale

From the above obtained values the proposed system achieved an accuracy of 75%, sensitivity of 88% and predictability of 83%. The best available option for the evaluation of the proposed system results is comparing them with MFS risk assessment scores. The MFS categorised the falls risk scoring as: everyone (0-24), medium (25-44) and high (45+). It should be mentioned that from the whole 30 patient data, the MFS indicated only two patients as medium risk and the remaining patients (28) as high risk, giving the high risk indication of 93%. As mentioned earlier, further prospective validation of the system (i.e. its ability [vs the MFS] to predict actual falls) was not possible for the proposed system in real time as this would have required requires a larger study over a longer time period (the duration of inpatient stay for many more than 30 patients).

MFS is a manual falls scoring scale which uses falls history, secondary diagnosis, aid, IV infusion, gait and mental status to predict the risk of falls, whereas the proposed monitoring system uses real-time vital signs, real-time motion data (walking pattern), falls history and types of medication and integrates the gathered information into the weighted parameter module for the falls risk prediction. The above-mentioned results can be considered as the comparison between two (technically) different methods/models and it is not possible (in the absence of the prospective study discussed above) to conclude which one is more accurate. However the system described in this thesis has reasonable agreement with the MFS, a previously validated and widely adopted scoring tool in hospitals. The proposed model has the advantage of using real-time component and it is a real-time computerised monitoring system. This is discussed in detail in the next chapter.

7.6 Summary

In this chapter, results from vital signs interpretation and the falls detection and prediction system were reported with the evaluation of medical devices in terms of mobility, usability, comfort and acceptability. One of the main reasons for the evaluation of wireless medical devices was to address the lack of medical professionals' or patients' (user) involvement throughout the design and development phase, thus, with the consequent risks of low user acceptability and minimum clinical efficiency (from the clinician's point of view) [40, 104]. It has also been reported that patients cannot use the devices/system independently because they are too complex to use and difficult to

operate [341]. Therefore, such devices or systems are of little use outside a hospital (inpatient) setting even though the system's overall performance is acceptable. Thus, the clinicians' as well as the users' involvement and feedback are critical at every stage of design and development.

The proposed falls detection model was developed to establish a robust method in which effective fall prediction can be used to minimise the personal and financial cost of associated injuries in older adults. The aim was also to minimise false predictions which are a nuisance for patients as well as for caregivers and can greatly compromise effectiveness of care [140]. The users' needs and clinicians' preferences were taken into account and non-invasive, wireless and body-worn sensors were employed in the design of the proposed system [40]. There is now strong evidence that a clinically important proportion of falls experienced by older adults are preventable. However, further research needs to be done to determine the actual predictive value of the new system in a prospective trial, what type of falls can be prevented and if/how older adults can benefit from interventions by computerised systems. Those who could benefit may be identified by individual assessment and by studying the characteristics of falls. Current monitoring devices are not designed to replace healthcare professionals but rather to support them in making decisions in complex situations through more rapid processing of patient information and thus speedier delivery of treatment. A more effective means of delivering proven interventions and treatments to reduce the risk of falls is required.

CHAPTER 8 Discussion and Conclusions

8.1 Overview

The use of computerised monitoring systems to automate medical diagnoses may improve quality of care as well as reduce staff work load. With the advancement of wireless sensor technologies, the acquisition of characteristics of people's behaviour (physical as well as physiological) becomes much easier than before. The proposed monitoring system could be customised to suit the most common diseases and symptoms encountered in New Zealand hospitals. This research work will yield a highly specialised system that has the potential to lower the mortality rates of the nation's population due to medical errors and the heavy work load of medical professionals. This research is aimed to evaluate and develop an intelligent monitoring system combined with physiological data for patient monitoring and motion data for falls prevention. It also aims to improve the performance of current patient monitoring systems by identifying the shortfalls of existing technology and developing a system for providing alerts to the healthcare professionals as well as to the user in the event of detecting a serious illness or symptoms. Three main concepts have been addressed in this thesis: wireless/remote monitoring, detection of multiple physical signs and falls risk prediction – that could be used in a geriatrics ward in hospital (currently being tested) to monitor older adults. This section serves to present the major conclusions of this thesis. It summarises important concepts and justifies the adopted methods.

8.1.1 Wireless/Remote Monitoring

The proposed system was evaluated with 30 individuals for mobility, usability, comfort and users' acceptability. The crucial aspect is the configuration of different medical devices in one system (set-top-box), to collect and transmit the patients' physiological data in real-time. In addition, the collected data is diagnosed and an alert/warning for any potential physical signs are sent to medical professionals in real time. This thesis focuses on addressing the current limitations of this technology, such as interoperability, complexity, high cost and user acceptability using the proposed solution [242].

It is expected by the healthcare technologist [5] that such a solution will play an important role in the ever-growing automated medical diagnostic area by providing a

cutting-edge and state-of-the-art solution. Moreover, the thesis addresses the current challenges and limitations reported in the literature and reports on an advanced telehealth care system to benefit the overall healthcare sector. Special emphasis has been given to the evaluation of medical devices and their use in clinical settings. Medical device interoperability has been addressed to a great extent with advanced features for both medical professionals as well as for patients (users).

Currently, the majority of systems focus on capturing information related to a specific health condition and/or a single parameter monitoring of users' health and physical activities [115, 348]. Lin's survey [7] on wireless/remote/mobile monitoring gives an insight into the various mobile platforms and technologies. With the ever-growing research in wireless/remote healthcare applications, end-user consideration is often ignored or neglected in the design of such applications. There is still an open research question to be worked on to address user acceptability issues. Moreover, there is room for research on the quality of such healthcare applications related to patient's (end-users) well-being.

To answer these important aspects, many researchers have included patients' as well as medical professionals' feedback at every stage of the design and development [84, 147, 233]. It is believed that acceptance of any system in the healthcare industry depends on the perception of the user. User-centred design is essential in order to transfer the concept into the product, especially at the earlier stages of a project [85]. As suggested by Steele et al. [86], the theoretical framework should be built based on user preferences. It is evident that even with advanced healthcare systems, if the user does not fulfil the requirements such as wearing the sensor for the allocated periods of time, then the application becomes irrelevant [19, 87]. Nonetheless, the most successful techniques and guidelines proposed in the literature reviews [24, 349], surveys [7, 113, 176, 177], frameworks [77, 85, 115, 123, 348] and end-user acceptability [39] have been carefully considered in the design and development of the proposed monitoring system in the current thesis

8.1.2   Vital Signs Interpretation

The developed vital signs interpretation system has shown that evidence-based expert diagnostic systems can accurately diagnose multiple physical signs in hospitalised older adults and could be useful in providing decision support to clinicians. The complete

validation of the system, as a clinically useful diagnostic alarm system, has been carried out with real-time hospital testing.

There is also a major concern regarding the false alarms generated by the clinical decision support system (CDSS). Several authors in the literature have reported a continuous increase in the generation of false alarms from the CDSS and expert system. Imhoff and Kuhls reported a false alarm rate of up to 90 percent [34]. Chambrin et al. [350] and Tsien and Fackler [351] reported the highest alarm rates in noisier environments, including simple threshold based systems [34, 350].

The proposed decision support system will be an advantage to clinicians in the hospitals in early detection of seven key physical signs and their related critical events. The system was developed in consultation with medical experts throughout the system design and development, which gave full insight into the medical professional's needs and key clinical requirements. The other main focus was to minimise the false alarms, because, from the literature it is clear that the medical professionals' biggest perceived problem in using the CDSS/expert system is the generation of false alarms. The use of the fuzzy logic model is to enhance the accuracy and prediction of the system. It is a well-known fact that physiological parameters vary considerably from one person to another. For example, the key physiological parameters vary with age, gender and disease; hence the normal value of one person will not be accurately normal for others, so using the crisp limits in this scenario will definitely generate high false alarms. The proposed model will behave according to the individual's vital data (physiological parameters) and this will give an advanced 'diagnosis' of the different physical signs.

The proposed system was tested with two clusters of normal and abnormal data. Authentic diagnosis datasets have been clustered using the MIMIC II waveform database from physionet. The number of training epochs chosen for the proposed system in each scenario is determined based on the desired accuracy. In simple terms, the training of the proposed system is stopped once it has achieved high learning efficiency. The proposed system is constructed by expanding the powerful ability of a neural fuzzy network to deal with pattern recognition, data classifications and temporal problems. The system itself realizes the dynamic fuzzy reasoning by creating recursive fuzzy rules, which are generated automatically and optimally during the process (training) via pattern recognition and parameter learning. The fuzzy structure

identification process proposed can effectively reduce the number of rules, membership functions and network size. Moreover, the proposed system was also tested in a real-time hospital setting and results were compared with the medical expert's diagnosis.

8.1.3   Falls Detection and Risk Prediction

The proposed falls detection model was developed to establish a robust method in which effective fall prediction can be used to minimise the personal and financial cost of associated injuries in hospitalised older adults. It also aimed to minimise false alarms which are a nuisance for patients and caregivers and can compromise effectiveness of care [140]. Users' needs and clinicians' preferences were taken into account and non-invasive, wireless and body-worn sensors were employed in the design of the proposed system [40].

In many fall detection research studies, the starting point of algorithm design has been to set the threshold(s) to the same level as the slowest fall event. By doing this, a sensitivity of 100% is obtained by allowing some false alarms to arise. The proposed system introduced a novel method by including real-time vital signs and motion data with falls history and types of medication to reduce the false alarms, which can be a serious problem for nurses looking after several patients. This can be done by categorising falls by means of directional/postures sub-categories combined with incoming real-time vital signs. Reducing false alarms makes the fall detection system comfortable to use for the clinicians. Another addition to the existing falls prevention model could be the inclusion of more structured input information from clinicians as well as patients, such as: body mass index, height, weight, urinary frequency, confusion, footwear and clothing and other known health issues, specially arthritis, osteoporosis, diabetes and high blood pressure.

8.1.4   Data Processing Issues

More improvements to the overall quality of healthcare delivery raise difficulties in processing both the dense and heterogeneous biomedical data. For example, the high-resolution and dynamic data of medicinal images result in the data transfer and image analysis being extremely time-consuming. Several works leverage the cloud approach to tackle the difficulties.

As to the clinical informatics, a major challenge is to integrate a wide range of heterogeneous data into a single and space-saving database for further queries and analyses. Electronic health record (HER) could be an ideal solution because it is the patient-centred record that integrates and manages personal medical information from various sources. EHRs are built to share information with other healthcare providers and organizations, while the cloud technologies can facilitate EHR integration and sharing. Developing EHR services on the cloud can not only reduce the building and operation costs, but can also support interoperability and flexibility. There are a great number of systems contributing to different cloud-supported frameworks to improve EHR services. For instance, an e-health cloud system is defined capable of adapting itself to different diseases and growing numbers of patients, i.e. improving the scalability [9]. Rothman et al. [9] proposed an intelligent cloud-based EHR system, and claimed that it has the potential to reduce medical errors and improve patients' quality of life. A recent work introduces the state of cloud computing in healthcare [352]. However, there are a number of security issues/concerns associated with cloud computing, which is one of the major obstacles for commercial considerations. As the emerging cloud technology is used in the healthcare system, more recent studies have investigated the security and privacy issues [352].

8.2 System Implications

The healthcare of the community in general and of older people in particular is now one of the major concerns globally. In New Zealand the ageing population has grown fast with more cases of chronic illnesses which involving higher healthcare costs. The proposed system can complement the role of nurses in monitoring patients' vital signs. Nurses will be able to focus on the holistic needs of patients thereby providing better personal care. Advanced and complex medical algorithms are developed in order to detect several physical signs.

Following further validation as discussed above the research presented here may benefit the New Zealand healthcare system in terms of: (1) Early diagnosis and early warnings or alarms to assist clinicians to avoid any critical situations in the care of their patients. (2) Patient's information such as falls history, medical information, history, allergies and other known information can be loaded in to this system to minimise medical related errors. (3) Older people can be monitored continuously or periodically from a

remote place (home, rest home, or hospital) and (4) Early detection of physical signs and falls, by giving a warning or alarm, so that critical situations can be minimised or avoided.

Moreover, this research will be able to contribute to the development of intelligent patient monitoring at hospitals and older adults community centres. Collecting, monitoring and analysing medical data to generate alerts/warnings to medical staff is a considerable change in the current healthcare system and this will be a new and advanced technology that this research can deliver.

8.3 Conclusion

Wearable monitoring systems for older adults are getting good clinical acceptance due to versatile nature of the connectivity with the patient. It gives the patient freedom and flexibility while they are monitored. Very few studies have reported a high percentage of acceptance for wearable monitoring systems mainly due to its low-invasive nature and non-interference in their normal daily activities [353]. Bergmann and McGregor [40] reported that the overall quality of individual studies was relatively low, a small number of participants were included, there was limited methodology and the reporting of research processes was restricted. Likewise, the author agrees with the three main challenges proposed by Chan et al. [4].

- Proposed solutions must match or exceed the patient's quality of live.
- Patient and clinician usage and intentions should be studied in detail and considered.
- Further research is required into legal and ethical issues, user and provider acceptance, requirements and satisfaction.

Lin [7] recommends that mobile telemedicine engineers should consider the performance of wireless multimedia networks according to the health level-7 (HL7) (HL7 and its members provide a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information) standard based design model. He also advocates the involvement of medical experts throughout the developmental stage in order to facilitate usage by clinicians and thereby, increase the quality of medical services delivered. A wireless sensor network survey conducted by

Alemdar and Ersoy [113], identified the hardware challenges as well as those related to security, privacy, mobility and user-friendliness.

Although, vital signs based hospital monitoring systems are still in the developmental stage and the realization process has only just begun [178], the future work will help to fine tune the concept and bring forth the realisation of a reliable healthcare environment. The majority of the literature reported that there are several factors discouraging the adaptation of these systems by medical professionals. Some of these factors include: difficulty in operation, poor usability (size and excess weight), difficulty in medical implementation and lack of clinical significance. Due to the wireless nature of remote and mobile monitoring systems, there is room for further research to incorporate user preferences.

8.4 Suggestions for Further Research

A number of studies support the effectiveness of patient monitoring systems both in a hospital setting as well as in the home environment. The standardisation of and demand for such systems and their applications are a fast growing area for research. For instance, a vital signs transmission system, based on VITAL and DICOM standards for telemedicine applications has already been developed [356]. It was identified that online monitoring and real-time transmission of bio-signals, and related systems require high quality signals without artefacts to be capable of operating without delay. To address such challenges, online monitoring systems needs to be developed. The development of a trend detection algorithm for EEG monitoring is one example. Such online or web based monitoring systems are playing a major role in remote patient monitoring, producing high quality data and accuracy [16, 93, 117].

Panescu [354] identifies several commercial wireless remote monitoring systems and stipulates the requisite design factors. These include power consumption, communication range, size, cost and security. Moreover, such systems are dependent on the internet (connectivity and speed) or mobile communications (transfer rate and signal strength) using GPRS or 3G and further, development of new generation 4G [176] and 5G infrastructure for a mobile devices is also proposed . William and Michael [355] explored methodological guidelines and the importance of data accuracy in computer-based patient records, essential for any healthcare system. Like any other technological advance, smart health monitoring systems have both benefits and limitations and

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currently, there is on-going research to improve these systems [178]. Another challenging aspect in the field of patient monitoring system is to design further clinical trials to ascertain the value, practicality and efficacy of monitoring different patient groups according to age, ethnicity, gender, specific disease, and situation (hospital, aged care facility, persons' own home, emergency situations [e.g. road traffic accident etc). Similarly predictive algorithms (e.g. for falls prediction as in the current thesis) need evaluation in prospective studies (as discussed in detail above).

The application of wireless patient monitoring is likely to be expanded in future due to the following reasons. Firstly, the advancement of embedded sensors (e.g., the accelerometer used to change the display orientation) is changing the scope of possible applications. The technology will soon be programmed to support new disruptive sensing applications wirelessly such as sharing the user's real-time activity with friends on social networks such as Facebook, keeping track of a person's carbon footprint, or monitoring a user's well-being. Secondly, there is increasing awareness of chronic diseases, the growing market for smart devices, advanced mobile connectivity and the expansion of 3G and 4G networks, augurs a promise of cost-effective healthcare. Thirdly, the programmability feature of such technologies will lead to developing a variety of healthcare applications with high acceptance among diverse users. This provides healthcare researchers with additional resources for computing collections of large-scale sensor data with supporting advanced features such as persuasive user feedback based on the analysis of big sensor data. The combination of these advances opens the door for innovative research and will lead to the development of wireless patient monitoring systems that are likely to revolutionise current healthcare delivery as well as our everyday lives.

As stated in the introduction to 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 the theoretical to the practical. However, the research presented in this thesis would be an investigation of other suitable approaches applied to hospitalised older adults' monitoring, but using a deep knowledge representation.

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APPENDIX A1 – Australia New Zealand Clinical Trials Registry (Web Captured Copy)

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Descriptions of intervention(s) / exposure	In this system vital signs (with informed consent) will be gathered from patients and sent to a control unit for centralized monitoring. The system can complement the role of nurses in monitoring patients' vital signs. They will be able to focus on holistic needs of patients thereby providing better personal care. Advance and complex medical algorithms will be developed in order to detect several events by using vital signs.
	Wireless network technologies will be utilized for transmission of vital signs in the proposed system, as they provide flexibility and mobility to patients. The proposed system will be tested in real-time in public hospital wards after obtaining ethical approval. The capability, suitability and limitation of the chosen technology and the results will be evaluated and validated with two different methods, i.e. comparing with other systems and by agreement with expert using Kappa analysis.
	Total 30 participants will be considered. Each participant will be monitored for 5 hours.
Intervention Code:	Not applicable - Observational study
Comparator / control treatment	No treatment
Control group	Uncontrolled

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Primary Outcome:	Older patient monitoring: Older people can be monitored continuously or periodically from a remote place (home), older people home, rest home, handicap home, or hospital. This will help reducing work load of medical staff and access to the patient's vital data. This outcome will be validated with two different methods, i.e. comparing with similar remote monitoring systems and by agreement using Kappa analysis.
Timepoint:	at sixth month after the sample data collected
Primary Outcome:	Early and multiple disease detection: The early detection of the events, by giving a warning or alarm, so that any critical situation can be avoided and depending upon the input parameters, different events can be detected. This outcome will also be validated with two different methods, i.e. comparing with similar monitoring systems and by agreement using Kappa analysis.
Timepoint:	at sixth month after the sample data collection
Secondary Outcome:	Better health monitoring: Proposed system will monitor patient's vital signs continuously, identify events and alerts medical staff in case of an emergency. This system can be implemented in hospital or home. In case of hospital it will reduce work load of medical staff and in case of home, it will reduce patient's travelling time, money, doctor's time, hospital cost and patient will have its environment freedom. This outcome will be validated by agreement with the expert using Kappa analysis.
Timepoint:	at one year after the data collection

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APPENDIX A2 – Northern X Regional Ethics Committee

Approval Letter

Health and Disability Ethics Committees

Northern X Regional Ethics Committee
Private Bag 92522
Wellesley Street
Auckland 1141
Phone: (09) 580 9105
Fax (09) 580 9001
Email: northernx_ethicscommittee@moh.govt.nz

29 March 2012

Dr Hamid Gholam Hosseini c/- Mr Mirza Baig
School of Engineering
Auckland University of Technology
PB 92006
Auckland 1142

Dear Hamid

Re: Ethics ref: **NTX/12/EXP/073**   (please quote in all correspondence)
     Study title: Smart patient monitoring system for advanced remote health care for older adults. PIS/Cons v#2, 07/03/12
     Investigators: Dr Hamid Gholam Hosseini (Principal), Mirza Mansoor, Dr Martin Connolly
     Locality: Waitemata DHB

Thank you for your full application received 26 March 2012 which was considered jointly by the Chairperson and Deputy Chairperson of the Northern X Regional Ethics Committee under delegated authority.

This study has been given ethical approval under the "Ethical Guidelines for Observational Studies (December 2006)" through expedited review process.

Approved Documents
— Protocol number [version 1, dated 27/02/2012]
— Information sheet/Consent form version [2, dated 07/03/2012]
    o Consent form - please amend version number and date to version 2, and the date in paragraph one to 7 March 2012 as in the information sheet.

The following document has been reviewed:
— Letter of Maori support from Waitemata DHB MRRC dated 14 March 2012

This approval is valid until 30 March 2014, provided that Annual Progress Reports are submitted (see below).

Amendments and Protocol Deviations
All significant amendments to this proposal must receive prior approval from the Committee. Significant amendments include (but are not limited to) changes to:
— the researcher responsible for the conduct of the study at a study site
— the addition of an extra study site
— the design or duration of the study
— the method of recruitment

— information sheets and informed consent procedures.

Significant deviations from the approved protocol must be reported to the Committee as soon as possible.

<u>Annual Progress Reports and Final Reports</u>
The first Annual Progress Report for this study is due to the Committee by **29 March 2013**. The Annual Report Form that should be used is available at www.ethicscommittees.health.govt.nz. Please note that if you do not provide a progress report by this date, ethical approval may be withdrawn.

A Final Report is also required at the conclusion of the study. The Final Report Form is also available at www.ethicscommittees.health.govt.nz.

<u>Statement of compliance</u>
The committee is constituted in accordance with its Terms of Reference. It complies with the *Operational Standard for Ethics Committees* and the principles of international good clinical practice.

The committee is approved by the Health Research Council's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990.

We wish you all the best with your study.

Yours sincerely

Cheh Chua-Ethics Committees
Administrator
Northern X Regional Ethics Committee

cc: Lorraine Neave, Waitemata DHB

APPENDIX A3 – Waitemata District Health Board –

Maori Research Review Committee Approval Letter

Waitemata
District Health Board

Te Wai Awhina

Nga Kai Tataki
Maori Research Review Committee

Private Bag 93503
Takapuna Auckland 9
Telephone: 09 4861491 ext:2553
Facsimile:094498171

Wednesday 14 March 2012

Dr Hamid Gholamhosseini
Senior Lecturer
AUT University
31-33 Symonds Street
Level 2, WL Building, School of Engineering
Private Bag 92006
Auckland 1142

Tena koe Dr Hamid Gholamhosseini

Re: Research Application entitled "Smart patient monitoring system for advanced remote health care for older adults"

As you know, your research application was reviewed at the Nga Kai Tataki Maori Research Review Committee, held 2 March 2012.

The committee noted that this was, in our opinion, an excellently prepared application. Section F3 specifically identified how this research will contribute to improving Maori health outcomes and reducing health inequalities for Maori.

We are pleased to inform you that your research application was approved at the Nga Kai Tataki Maori Research Review Committee, held 2 March 2012.

Nga manaakitanga

Tanekaha Rosieur
Chairperson
Nga Kai Tataki MRRC

Te Aniwa Tutara
(Acting) Maori Research Advisor
***Awhina* Health Campus**

APPENDIX A4 – Auckland University of Technology

Ethics Committee Approval Letter

M E M O R A N D U M
Auckland University of Technology Ethics Committee (AUTEC)

To: Hamid GholamHosseini
From: **Dr Rosemary Godbold** Executive Secretary, AUTEC
Date: 7 May 2012
Subject: Ethics Application Number 12/117 **Smart patient monitoring system for advanced remote health care for older adults.**

Dear Hamid

I am pleased to advise that on 7 May 2012, the Chair of the Auckland University of Technology Ethics Committee (AUTEC) and I approved your ethics application. This delegated approval is made in accordance with section 5.3.3.2 of AUTEC's *Applying for Ethics Approval: Guidelines and Procedures* and is subject to endorsement at AUTEC's meeting on 28 May 2012.

Your ethics application is approved for a period of three years until 7 May 2015.

I advise that 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/research/research-ethics/ethics. When necessary this form may also be used to request an extension of the approval at least one month prior to its expiry on 7 May 2015;

- A brief report on the status of the project using form EA3, which is available online through http://www.aut.ac.nz/research/research-ethics/ethics. This report is to be submitted either when the approval expires on 7 May 2015 or on completion of the project, whichever comes sooner;

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 reminded that, as applicant, you are responsible for ensuring that research undertaken under this approval occurs within the parameters outlined in the approved application.

Please note that AUTEC grants ethical approval only. If you require management approval from an institution or organisation for your research, then you will need to make the arrangements necessary to obtain this.

To enable us to provide you with efficient service, we ask that you use the application number and study title in all written and verbal correspondence with us. Should you have any further enquiries regarding this matter, you are welcome to contact me by email at ethics@aut.ac.nz or by telephone on 921 9999 at extension 6902. Alternatively you may contact your AUTEC Faculty Representative (a list with contact details may be found in the Ethics Knowledge Base at http://www.aut.ac.nz/research/research-ethics/ethics).

On behalf of AUTEC and myself, I wish you success with your research and look forward to reading about it in your reports.

Yours sincerely

Dr Rosemary Godbold
Executive Secretary
Auckland University of Technology Ethics Committee

Cc: Mirza Mansoor Baig mirza.baig@aut.ac.nz

From the desk of ...   Private Bag 92006, Auckland 1142   Tel: 64 9 921 9999
Dr Rosemary Godbold   New Zealand   ext 8860
Executive Secretary   E-mail: ethics@aut.ac.nz   Fax: 64 9 921 9902
AUTEC   page 1 of 1

APPENDIX B1 – Patient Information Sheet

Waitemata
District Health Board
Te Wai Awhina

Participant Information Sheet

AUT
UNIVERSITY
TE WĀNANGA ARONUI O TAMAKI MAKAU RAU

Project Title

Smart Patient Monitoring System for advance remote health care for older adults

Principal Investigator

Dr. Hamid GholamHosseini, AUT University, 9219999 ext 8755

Co-Investigators

Professor Martin J. Connolly, University of Auckland and Mr. Mirza Mansoor Baig, Auckland University of Technology

Introduction:

You are invited to take part in a study that is part of the development of a sophisticated computer monitoring and alarm system for use by hospital staff. The information that is gathered (blood pressure, heart rate, pulse volume and temperature) known as "vital signs", is used to make assessment of your state of well being. It is like an early warning system.

The information that we collect will be in addition to usual measurements of pulse, blood pressure etc, that are routinely collected in the ward. Your doctors or nurses will not be dependent of the information collected in this research study. However we will tell the doctors and nurses if the changes we observe are significant. We will also be asking the doctor at regular intervals what he/she thinks of your state of well being and their views on the usefulness of the information provided by our monitoring system.

This study forms part of the requirements for a Doctoral degree at Auckland University of Technology.

About the study:

Your treatment will not be changed in any way. Your treatment will be as usual and under direct control of your doctor. We collect the information, process it and then tell the doctor if there are changes of significance.

Benefits risks and safety:

There is no direct benefit to you from participating in this study; however the information we collect has the potential to change future clinical treatment for others.

The hospital will be informed that the alarm system is still in the process of being developed and that the hospital staff must rely on their own clinical judgment for making decisions.

1

Version 2; Date: 07/03/2012

Participation:

Your participation is entirely voluntary (your choice) and whether or not you agree to take part will in no way affect the level of care that you receive. 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 continuing health care.

Frequently asked questions:

What will happen at the end of the study?'

The results will be collected, analysed and published in a scientific journal.

Where can I get more information about the study?

Feel free to contact any of the researchers for further information about the study.

If I need an interpreter, can one be provided?

As informed consent is a requirement an interpreter will be provided as necessary.

You may have a friend, family or whānau support to help you understand the risks and/or benefits of this study and any other explanation you may require.

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate:
Free phone: 0800 555 050
Free fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

To ensure ongoing cultural safety Nga Kai Tataki - Maori Research Review Committee Waitemata DHB encourage those who identify themselves as Maori and who are participating in health research or clinical trials to seek cultural support and advice from either Mo Wai Te Ora – Maori Health Services or their own Kaumatua or Whaea.

For assistance please contact the Services Clinical Leader for Mo Wai Te Ora – Maori Health on 09 486 1491 ext: 2324 or the Maori Research Advisor on 09 486 1491 ext: 2553

Confidentiality:

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.

2

Version 2; Date: 07/03/2012

Results:

The results from this research will be published in a scientific journal. No individual will be identified. There will be no reference to you or your name in any publications. The delay between starting the study and publishing results may be over two years.

Compensation:

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation, and Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

This study has received ethical approval from Northern X Regional Ethics Committee.

Please feel free to contact the researcher if you have any questions on 9219999 ext: 8755

Version 2; Date: 07/03/2012

APPENDIX B2 – Patient Consent Form

Waitemata District Health Board *Te Wai Awhina*

Consent Form

AUT UNIVERSITY
TE WĀNANGA ARONUI O TAMAKI MAKAU RAU

Project title: **Smart Patient Monitoring System for advance remote health care for older adults**

English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a NZ sign language interpreter	Yes	No
Māori	E hiahia ana ahau ki tetahi kaiwhaka Māori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Māori	Ka inangaro au i tetai tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai
Sāmoan	Ou te mana'o ia i ai se fa'amatala upu	Ioe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	Io	Ikai

○ I have read and understood the information provided about this research project in the Information Sheet dated 07 March 2012.

○ 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 myself or any information that I have provided for this project at any time prior to completion of data collection, without being disadvantaged in any way.

○ I agree to be monitored by the device proposed by the researchers and my physiological data be collected for the purpose of this project.

○ I agree to take part in this research.

○ I wish to receive a summary of the report from the research (please tick one): Yes○ No○

Participant's signature: ....………………………………….

Participant's name: ....……………………………….

Date:

Consent obtained by...

Signature: .... Date: ....

Note: The Participant should retain a copy of this form.

Version 2; Date: 7/03/2012

	Date	Time	Blood Pressure			Position / Resp.	Pulse Oximeter		Temp.	Patient No	Additonal Comments	Age
			SYS	DIA	HR		SpO2	Pulse				
3	31/05/2013	15:25	122	74	90	Sitting	98	94	37	P19		85Y 9M
4	31/05/2013	15:30	110	73	92	Standing	97	93		P19	Male	
5	1/06/2013	14:20	102	61	85	Sitting	97	86	35.7	P19	Left hand/leg bandage	
6	1/06/2013	14:25	105	61	90	Standing	97	81		P19		
7	3/06/2013	15:00	102	57	92	Sitting	97	88	36.2	P19	Gutter Frame	
8	3/06/2013	15:05	90	58	94	Standing	98	93		P19	No Dissy	
9	6/06/2013	11:50	100	58	89	Sitting	98	89	36.8	P19	High Fall Risk	
10	6/06/2013	12:00	98	63	95	Standing	99	88		P19	Legs Swollen	
11	7/06/2013	11:45	107	66	91	Sitting	99	94		P19	Spots on body	
12	7/06/2013	11:50	122	86	100	Standing	97	91		P19	Depression: GDS score of 11	
13						Resp.				P19	Hypertension	
14	3/05/2013	12:30	101	59		18	90		35.6	P19	Left hip fracture-2006	
15	3/05/2013	15:45	102	59	94	18	98	94	35.5	P19	2 falls in last 6 months	
16	4/05/2013	7:30	90	50	78	18	95	78	36.5	P19	several falls in last 10 years	
17	4/05/2013	13:00	90	50	80	18	95	80	36	P19	Alergic	
18	4/05/2013	15:30	100	55	82	18	98	82	37	P19	13 Medications	
19	5/05/2013	20:30	99	50	91	18	97	91	36.5	P19	Feel off balance during balance test	
20	6/05/2013	8:00	91	50		17	96		37	P19		
21	6/05/2013	15:30	95	61	81	17		81	37	P19		
22	7/05/2013	7:30	120	50	93	18	97	93	37	P19		
23	7/05/2013	9:30	93	55	85	18	96	85	36	P19		
24	7/05/2013	15:40	85	52	82	18	97	82	36.5	P19		
25	8/05/2013	7:30	92	50	85	18	98	85		P19		
26	8/05/2013	15:00	86	50	85	17	95	85	36	P19		
27	9/05/2013	7:30	103	55	88	16	99	88	36	P19		
28	9/05/2013	15:00	101	50	85	16	99	85	36	P19		
29	10/05/2013	7:15	112	55	88	19	96	88	36.5	P19		
30	10/05/2013	13:15	100	60	88	18	96	88	36.5	P19		
31	11/05/2013	7:10	101	58	94	19	97	94	35.5	P19		
32	11/05/2013	15:00	103	59	65	18	97	65	37	P19		
33	12/05/2013	7:00	102	59	92	18	95	92		P19		
34	12/05/2013	15:00	101	60	82	19	96	82	36	P19		
35	13/05/2013			60	88	19	96	88	36.8	P19		
36	13/05/2013	15:00	103	59	88	18	98	88	36.5	P19		
37	14/05/2013	7:30	100	60		18	98		36.5	P19		
38	15/05/2013	6:00	99	60		17			36.4	P19		
39	15/05/2013	8:00	99		82	19	96	82	36.3	P19		
40	15/05/2013	13:45	100	60	82	18	97	82	36.5	P19		
41	16/05/2013	15:45	101	60	85	18	97	85	36.6	P19		
42	16/05/2013	18:00	120	61	85	19	95	85	36.7	P19		
43	17/05/2013	7:30	100	59	85	19	96	85		P19		
44	17/05/2013	15:05	101	59	88	18	97	88		P19		
45	18/05/2013	7:30	101	60	85	18	96	85	36.5	P19		

APPENDIX D – Sample Pre-processing of Systolic Blood Pressure (Raw Data)

Date	Time	BP(SYS)	BP(SYS)-10th AVG	BP(SYS)-AVG	BP(SYS)-SD
12/12/2012	10:45	116		2	2.83
12/12/2012	11:00	120		-2	1.41
12/12/2012	11:15	118		0	0.71
12/12/2012	12:00	117		1	2.12
12/12/2012	12:15	120		-2	3.54
12/12/2012	12:30	125		-7	5.66
13/12/2012	17:42	117		1	6.36
13/12/2012	17:45	126		-8	4.24
13/12/2012	17:50	120		-2	4.95
13/12/2012	17:52	127	118	-9	6.36
13/12/2012	17:55	118		-5.5	4.24
15/12/2012	11:50	124		-11.5	0.71
15/12/2012	11:55	123		-10.5	1.41
15/12/2012	12:00	125		-12.5	16.26
15/12/2012	14:50	102		10.5	8.49
15/12/2012	14:55	114		-1.5	5.66
15/12/2012	15:00	106		6.5	5.66
12/12/2012	12:00	98		14.5	19.80
12/12/2012	12:15	126	112.5	-13.5	12.02
12/12/2012	12:30	109		15	6.36
12/12/2012	12:30	118		6	4.95
13/12/2012	17:32	111		13	2.12
13/12/2012	17:32	114		10	2.83
13/12/2012	17:45	118		6	6.36

13/12/2012	18:30	127		-3	4.95
13/12/2012	18:33	120		4	1.41
13/12/2012	18:40	122		2	14.14
15/12/2012	10:35	102	124	22	7.07
15/12/2012	10:40	112		-5	2.12
15/12/2012	10:45	115		-8	13.44
15/12/2012	12:00	96		11	8.49
15/12/2012	12:15	108		-1	7.07
15/12/2012	12:30	118		-11	4.95
15/12/2012	12:45	111		-4	7.07
15/12/2012	12:50	121		-14	6.36
16/12/2012	9:35	112		-5	4.24
16/12/2012	9:40	118	107	-11	17.68
12/04/2013	11:30	93		14	10.61
12/04/2013	11:45	78		29	31.82
12/04/2013	17:30	123		-16	12.02
12/04/2013	17:35	106		1	0.71
12/04/2013	15:15	105		2	7.78
12/04/2013	15:30	94		13	14.14
12/04/2013	17:20	114		-7	17.68
12/04/2013	17:30	89		18	46.67
12/04/2013	14:40	155		-48	24.04
12/04/2013	14:45	121		-14	0.71
12/04/2013	17:40	122	107	-15	

APPENDIX E – Sample Accelerometer Data in Readable

File Format

Time	Ax	Ay	Az	Mx	My	Mz
1.282	0	-164	-1016			
1.3	16	-200	-1012			
1.32	-16	-164	-976			
1.338	8	-192	-1004			
1.358	-4	-180	-976	-140	-12	-146
1.377	-8	-188	-936			
1.396	-20	-164	-1028			
1.415	-12	-160	-1020			
1.434	0	-196	-1032			
1.453	-16	-176	-1008			
1.473	-12	-164	-984			
1.491	-52	-180	-996			
1.511	-56	-160	-1052			
1.529	20	-180	-972			
1.549	-32	-180	-1048	-140	-12	-146
1.569	-12	-184	-1016			
1.587	-20	-160	-972			
1.607	-16	-184	-1032			
1.626	-28	-156	-1004			
1.648	-20	-172	-992			
1.668	-16	-180	-980			
1.686	0	-164	-1036			
1.706	4	-172	-1004			
1.724	-4	-172	-1020			
1.744	0	-152	-992	-139	-12	-145
1.763	-28	-164	-1032			
1.782	-4	-204	-1032			
1.801	36	-160	-1008			
1.821	12	-176	-988			
1.839	0	-164	-1004			
1.859	-32	-164	-1016			
1.878	0	-168	-996			
1.897	0	-180	-988			
1.917	-12	-152	-1004			
1.935	4	-180	-1028	-139	-9	-146
1.955	4	-148	-1000			
1.973	4	-188	-1016			
1.993	12	-140	-1008			

2.012	-16	-156	-1000			
2.031	-36	-172	-1004			
2.05	-12	-176	-1008			
2.069	-20	-180	-992			
2.088	-40	-192	-972			
2.108	-20	-176	-996			
2.126	-40	-200	-1000	-138	-7	-146
2.146	-36	-188	-1032			
2.165	-64	-180	-1016			
2.184	-60	-180	-1040			
2.203	-40	-160	-1004			
2.222	-32	-172	-1000			
2.242	-76	-164	-1012			
2.261	-84	-160	-1000			
2.28	-68	-160	-992			
2.299	-72	-160	-1004			
2.318	-48	-164	-1060	-138	-11	-147
2.337	-44	-136	-996			
2.357	-68	-144	-1052			
2.375	-48	-156	-1016			
2.395	-48	-164	-1004			
2.414	-8	-188	-1012			
2.433	-48	-176	-984			
2.452	-48	-148	-988			
2.471	-20	-160	-1032			
2.49	-20	-164	-976			
2.51	-24	-128	-1004	-135	-32	-149
2.528	-20	-136	-1052			
2.548	-28	-136	-1032			
2.567	28	-140	-1008			
2.586	-24	-140	-1012			
2.606	16	-128	-1012			
2.624	20	-140	-1044			
2.647	8	-136	-996			
2.666	-16	-128	-1028			
2.685	0	-148	-1004			
2.705	-4	-116	-1020	-125	-63	-149
2.723	12	-148	-1036			
2.743	8	-156	-1004			
2.761	0	-128	-984			
2.781	0	-136	-1012			
2.8	-8	-144	-1028			

APPENDIX F – 10 Point Scale Used for Medical Device Evaluation

Medical Device Evaluation 10 point scale Chart

Participant Number: **Age:**   **Sex:**

Please use below 10 point scale to rate your evaluation where **10 is acceptable, 5 is neutral and 1 is unacceptable**

Mobility – How you feel about the mobility of this device (Please Tick or Circle)									
1	2	3	4	5	6	7	8	9	10

Comments (If any):

Usability – How confidently can you use this device (Please Tick or Circle)									
1	2	3	4	5	6	7	8	9	10

Comments (If any):

Comfortability – How comfortable do you feel while using this device (Please Tick or Circle)									
1	2	3	4	5	6	7	8	9	10

Comments (If any):

Acceptability – Please rate your acceptance for this device (Please Tick or Circle)									
1	2	3	4	5	6	7	8	9	10

Comments (If any):