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2015 Physiol. Meas. 36 2069

(http://iopscience.iop.org/0967-3334/36/10/2069)

IOP Publishing | Institute of Physics and Engineering in Medicine Physiological Measurement

Physiol. Meas. **36** (2015) 2069–2088 doi:10.1088/0967-3334/36/10/2069

Multiple physical signs detection and decision support system for hospitalized older adults

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Received 8 January 2015, revised 21 June 2015
Accepted for publication 30 June 2015
Published 19 August 2015

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 patient workflow management. Moreover, expert systems have the potential to assist clinicians and improve their 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.

Vital signs monitoring systems are rapidly becoming part of today's healthcare delivery. 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 current study focuses on interpreting multiple physical signs and early warning for hospitalized older adults so that severe consequences can be minimized. Data from a total of 30 patients have been collated 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 hospitalized patients and transfers this information to a web-based software application for remote monitoring and further interpretation. Ultimately, this system is aimed to achieve a high level of agreement with clinicians' interpretation when assessing specific physical signs such as bradycardia, tachycardia, hypertension, hypotension,

hypoxaemia, fever and hypothermia 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 physician.

Keywords: physical signs, physiological parameters, early warning, decision support system, smart patient monitoring system and older adult monitoring

(Some figures may appear in colour only in the online journal)

1. Introduction

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 and storage and for generating alerts to other devices (Klingeberg and Schilling 2012).

Recent research is highly focused on the area of remote/mobile and wireless patient monitoring using body sensors, wireless devices and/or wearable systems. 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 (Chan *et al* 2008, Lau *et al* 2010). Such systems are being designed and developed for every possible healthcare scenario i.e. emergency departments and remote monitoring of indoor and outdoor locations (Cook 2012). 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 (Cook 2012).

Moreover, 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 (Reiswig 2011). To clarify the use of the terminology, we distinguish 'vital signs' such as the absolute (numerically defined) measurement of heart rate (HR), blood pressure (BP), pulse (P), and temperature (T) from 'physical signs', which we interpret as the state of abnormal vital signs, such as bradycardia, tachycardia, hypertension, hypotension and hypoxaemia. Whether an individual numerical 'vital sign' value constitutes an abnormal 'physical sign' will depend upon the individual and upon the clinical circumstances.

1.1. Need for a computerized vital signs monitoring system

There is increasing interest in potentially preventable causes of in-hospital morbidity and mortality (Vincent *et al* 2001). 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 (Kause *et al* 2004). It is reported that prior to cardiac or respiratory arrest up to 84% of patients have significant physiological deterioration (vital

signs) (Franklin and Mathew 1994). 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 (Franklin and Mathew 1994).

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 (Prytherch *et al* 2006). These points provide the 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 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 the 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 (Prytherch *et al* 2006). Some of the studies reported that as many as 80% of ward patients have physiological parameters outside normal ranges as much as the 24-hour preceding intensive care unit (ICU) admission (Goldhill *et al* 1999).

There is thus an argument for a reliable automated (computerized) early detection and vital signs monitoring system in hospitals' general wards. The current paper aims to present the development of a remote/wireless vital signs monitoring and early detection system in order to detect multiple physical signs in older adults in hospital ward settings.

2. Medical devices, data collection and protocols

2.1. Basic design functionalities

The key components consists of (1) the set-top box which wirelessly connects to medical devices and receives the patient's physiological data as well as audio/video with adaptive bandwidth of 16–2048 Kbps. (2) Physiological monitoring includes almost all vital sign collection devices: electrocardiography (ECG), heart rate (HR) monitor, blood pressure (BP), Pulse (P), blood glucose (Blood Glu.) meter, etc. (3) Audio/video functionality incorporates a high resolution camera, with pan, tilt and zoom transmits high quality data to medical professional in real-time. It uses advanced network communication such as: local access network (LAN), wider area network (WAN) and internet protocols and (4) security and privacy of patient information. The system 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 achieved 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 are also enforced, to protect patient data. Each patient profile is linked with a patient-assigned medical device (serial number and MAC address) only to receive medical data directly and store into the specific patient profile. Patients' data was collated with informed consent from hospitalized patients at the North Shore Hospital and Waitakere Hospital, Auckland, New Zealand on the older adults' wards, after seeking approval from the respective local and national ethical committees (NTX/12/EXP/073, Waitemata District Health Board 0980712176, and AUTEC 12/117). Ward-based medical staff identified appropriate patients and obtained written informed patient consent.

Figure 1. Wireless medical devices used for the proposed patient monitoring system.

2.2. Wireless medical devices used

Figure 1 shows wireless medical devices used in this research. The system has the capability of collecting multiple data simultaneously from multiple patients. A brief description of the devices shown in figure 1 is given below (number 1–5 refers to the medical device shown in figure 1);

(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 (CorScience 2015) 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 (Nonin 2015) is a wireless Bluetooth device which records oxygen saturation and heart rate continuously.
(4) Ear temperature: Omron's instant ear thermometer is an accurate and fast ear temperature measurement device.
(5) Body temperature: G-plus wireless remote body thermometer (G-max 2015) is a continuous body temperature wireless device.

2.3. Hospital setup and data collection

There were two critical aspects of data collection, the device optimization and maintaining the appropriate distance between the set-top box and the wireless (BT) devices. 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 walkways. The

Table 1. Mean values of the whole patient data.

Parameter	Mean value
Number of patients	30
Age (year)	82 year 1 month
Sex (M/F) %	57/43
BP (systolic/diastolic) (mm Hg)	125.15/71.81
Heart rate (bpm)	77.42 BPM
Oxygen saturation (SpO2)	96.12%
Blood glucose (mg dl^{-1})	134.79 mg dl^{-1} (7.48 mmol l^{-1})
Tympanic (ear) temperature	36.56 °C

distance and location of the data collector were 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. The practical setup for the real-time test bed during data collection and testing session was conducted at the Waitakere Hospital. The goal of the real-time data collection was to capture vital signs and related patient information/observation with a correct time-stamp, and to evoke suggestions from clinicians for making the prototype alarm more ergonomic.

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 blinded manual readings of the same parameters, using standard ward devices; and thirdly, very 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 patient's 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, pain complaints, activeness, response, visible mood and recent incident/improvement, restriction, special exercise/diet, etc, combined with real-time vital signs gave the interpretation model high accuracy and reliability.

2.4. Data statistics

Statistical information was found to be an important feature in developing a reliable interpretation model. Data trends from various viewpoints gave 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. 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 1 below shows the variety of statistical information related to the patient data collected. In the tables below blood pressure (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^{-1} (mg dl^{-1} divided by 18 gives mmol/l and mmol l^{-1} times 18 gives mg dl^{-1}) and Temp. is tympanic (ear) temperature in °C.

Table 2. 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 3. 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/A	N/A
Hypotension	N/A	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^{-1}	94–99%	36.5–37.5 °C

Normal ranges are adopted from the literature (McPhee *et al* 2010) 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.

2.4.1. Relationship between vital signs and physical signs. Table 3 shows the important relationship between the collected vital signs and their related possible physical signs. The relationship was established after consulting a medical expert (Professor of Geriatric Medicine) and widely accepted literature (McPhee *et al* 2010). This key relationship is adopted in the proposed vital signs interpretation model to detect various physical signs.

3. Vital signs interpretation

3.1. 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 2 shows the model overview with its key modules. This section discusses in detail the core modules (methodologies) integrated into the interpretation engine.

3.1.1. Individualized monitoring. The majority of systems used today have adopted a generalized 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) (Mitra *et al* 2012, MOTIVA 2015) and/or particular illness/health issue(s) (Taub *et al* 2011, Longo *et al* 2012). The proposed model has adopted individualized monitoring because of the fact that physiological parameters are different in each individual, hence threshold or SD

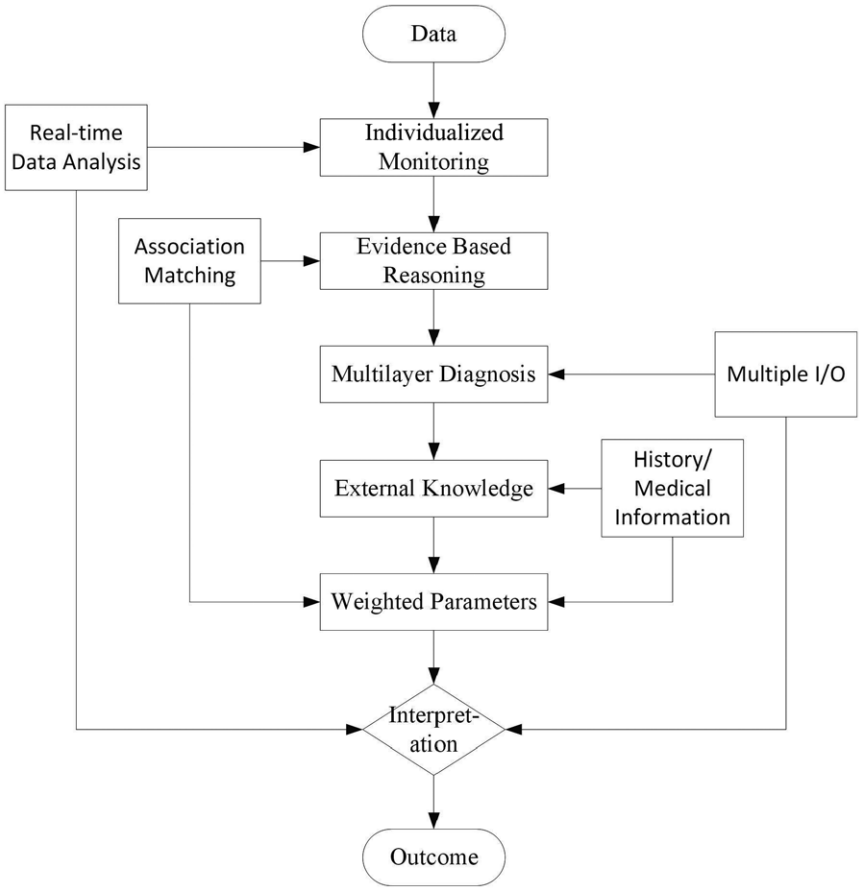

Figure 2. Overview of interpretation model.

based monitoring models often generate high false alarms (Imhoff and Kuhls 2006) and eventually reduce the reliability of the overall system.

The proposed model uses individual data for interpretation called 'individualized 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 individualized monitoring module is that its adaptive boundary limits will be changing throughout the monitoring phase. Every 10th recording, or every 10 min, 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 optimization).

Figure 3 shows the systolic blood pressure sample taken randomly from a patient's data to show the working of individualized monitoring. For every 10 recordings there is a window

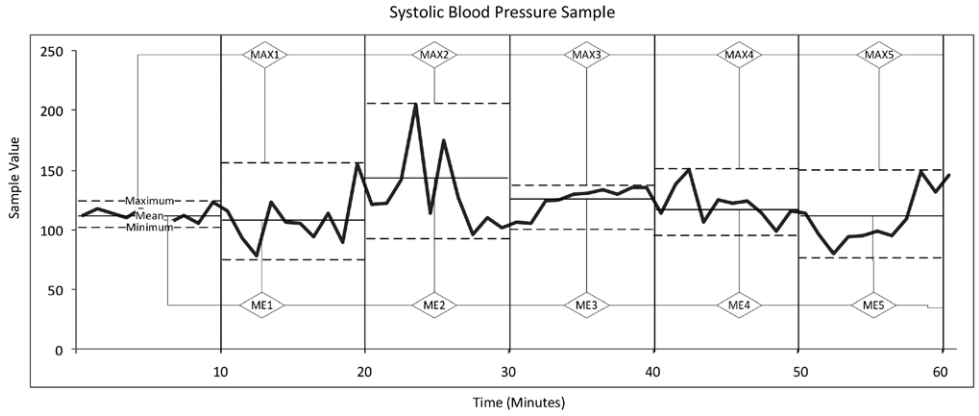

Figure 3. Systolic blood pressure sample for individualized monitoring.

to capture the adaptive limits as shown in figure 3. 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).

The manual data entry is performed by entering the scores (numbers) only to avoid the complexity of text and image analysis. The data of medical devices is the primary source for the rules engine and analysis however, the manual data entry makes it possible to limit the entries to the numbers only (based on the scope of this research).

3.1.2. Weighted parameters. A robust scoring mechanism is proposed in this module (figure 2), 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: hypoxaemia.
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.

Figure 4 shows the direct association between the vital signs and their related possible physical signs (bold ellipse) 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

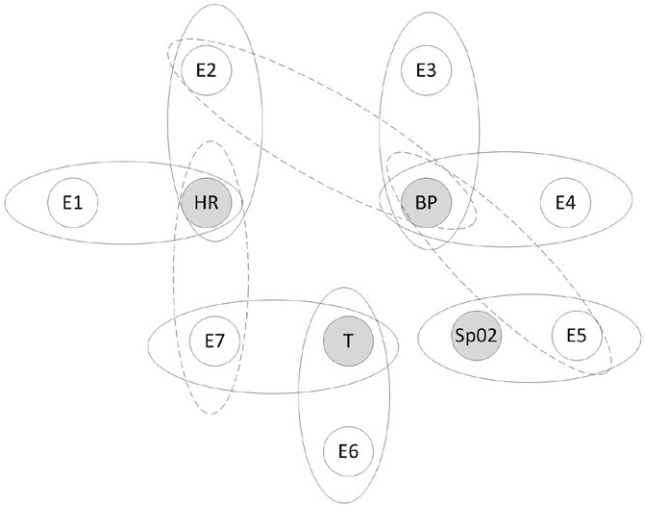

Figure 4. Second tier linking between the vital signs and physical signs.

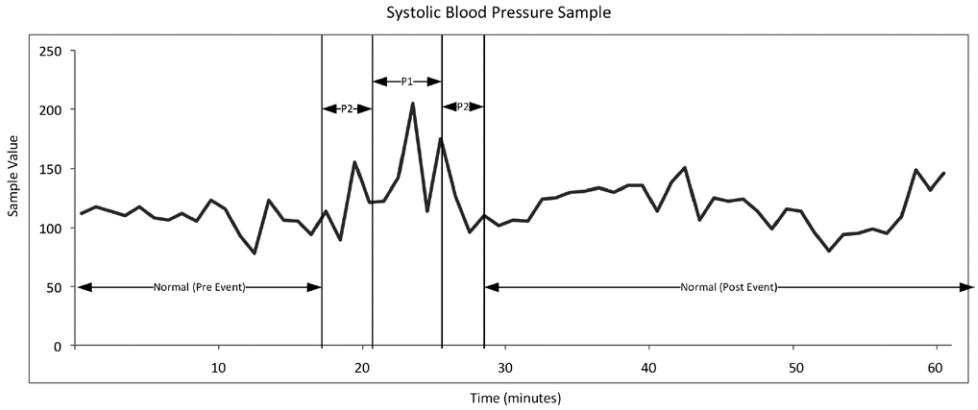

Figure 5. Multiple priorities based diagnosis.

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 have two layers of vital sign support, both direct (E2-HR and E5-SpO2) and indirect (E2-BP and E5-BP).

3.1.3. Multilayer diagnosis. Early detection of physical sign(s) can reduce adverse events (Kyriacos *et al* 2011, Griffiths and Kidney 2012, Baig and Gholam Hosseini 2013). 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 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

Table 4. Vital signs data handling and classification using two priorities.

Priority	Type of monitoring	Type of messages	Outcome message[a]
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

[a] 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.

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'.

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 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.

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. 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 4 shows vital signs handling according to the proposed two priorities.

3.2. 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 (individualized optimized 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 in this type of monitoring and 'diagnosis' (Sadegh-Zadeh 2000).

Figure 6 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

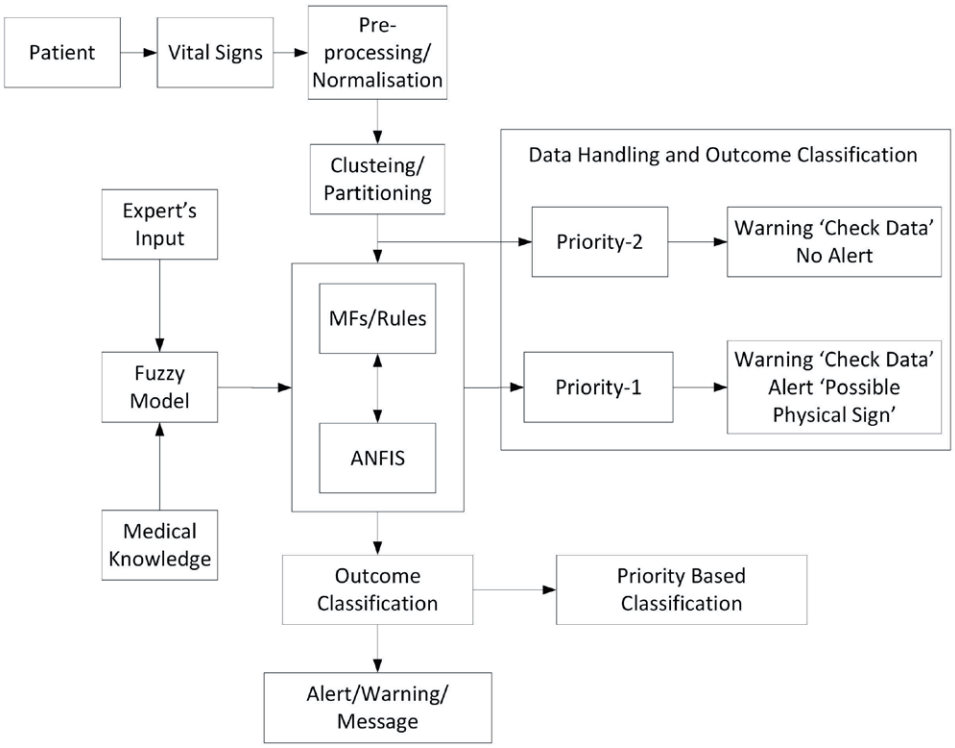

Figure 6. System model flow chart with data handling and outcome classification.

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.

3.3. 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 normalized 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 (Baig *et al* 2010, 2011a, 2011b, 2012, 2013). 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 7).

3.3.1. Layer 1: input layer (V_1, $V_2 \ldots V_n$). The vital data input obtained after performing the pre-processing and normalization, is now fed to the fuzzy neural network system. This layer is called input node and corresponds to one input variable.

3.3.2. Layer 2: clustering (c_1, $c_2 \ldots c_n$). Clustering is used to achieve a highly accurate and reliable medical data classification for the proposed expert system (event diagnosis, decision

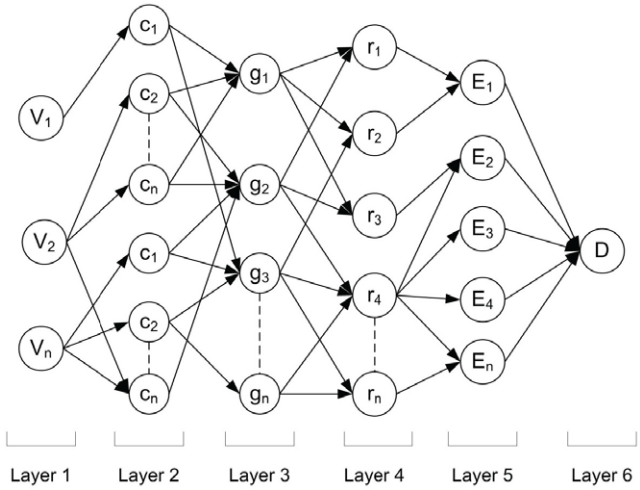

Figure 7. Six layer adaptive neuro fuzzy network designed for the proposed diagnostic module.

support or patient monitoring). It is simply known as the unsupervised classification of patterns, observations or data items into groups (clusters) (Sarkar and Leong 2001). Detail clustering used in the proposed system is discussed in the next section.

3.3.3. Layer 3: grouping ($g_1, g_2 \ldots g_n$). 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.

3.3.4. Layer 4: rules ($r_1, r_2 \ldots r_n$). 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) then (diagnosis is P2-bradycardia) (1)
(2) If (HR is VL) then (diagnosis is P1-bradycardia) (1)
(3) If (HR is H) and (BP is L/H) then (diagnosis is P2-tachycardia) (1)
(4) If (HR is VH) and (BP is VL/VH)) then (diagnosis is P1-tachycardia) (1)
(5) If (HR is H) and (BP is L) then (diagnosis is P2-hypotension) (1)
(6) If (HR is VH) and (BP is VL) then (diagnosis is P1-hypotension) (1)
(7) If (BP is H) then (diagnosis is P2-hypertension) (1)
(8) If (BP is VH) then (diagnosis is P1-hypertension) (1)
(9) If (HR is H) and (BP is L) and (SpO2 is L) then (diagnosis is P2-hypoaxemia) (1)
(10) If (HR is VH) and (BP is VL) and (SpO2 is VL) then (diagnosis is P1-hypoaxemia) (1)
(11) If (HR is H) and (T is H) then (diagnosis is P2-fever) (1)
(12) If (HR is VH) and (T is VH) then (diagnosis is P1-fever) (1)
(13) If (HR is L) and (BP is L) and (T is L) then (diagnosis is P2-hypothermia) (1)
(14) If (HR is VL) and (BP is VL) and (T is VL) then (diagnosis is P1-hypothermia) (1)

3.3.5. Layer 5: output sets ($E_1, E_2 \ldots E_n$). In this layer the output sets will be organized 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).

3.3.6. 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.

3.4. Physical signs extraction and classification

Vital signs have been categorized into two outcome priorities (table 4) 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 (Innocent and John 2004), 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.

3.4.1. Physical signs detection and working details. Patient physical signs are assigned as E1–E7 with priorities (P1–P2) for each of the physical signs, the detection and identification of physical signs with respect to one input, two inputs and all inputs when interpreting the physical signs are shown.

E1: bradycardia.
E2: tachycardia.
E3: hypotension.
E4: hypertension.
E5: hypoaxemia.
E6: fever.
E7: hypothermia.

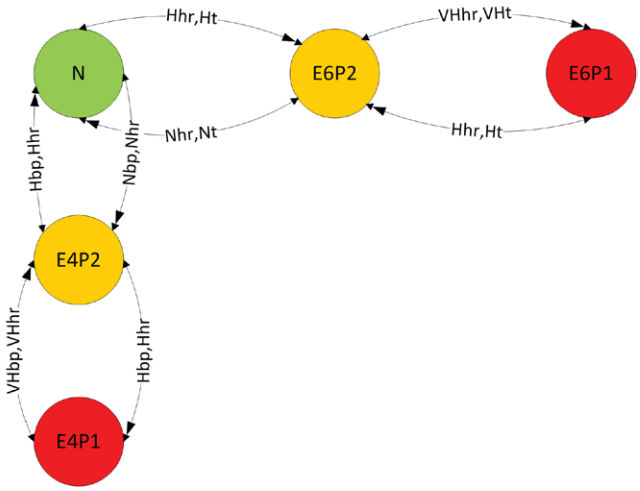

Figure 8. Possible hypertension (E4) and fever (E6) using two inputs with two priorities.

3.4.2. 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 8 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 blood pressure 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 8 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 and temperature are back to normal range for that particular data pattern (patient). This case has two inputs (HR and T) on which the interpretation is predicted.

3.4.3. Physical signs detection using all vital signs. Now, let us consider E1–E7 physical signs, depicted in figure 9, 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 9. 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. Prioritization of outcomes gives clinicians a higher degree of control over

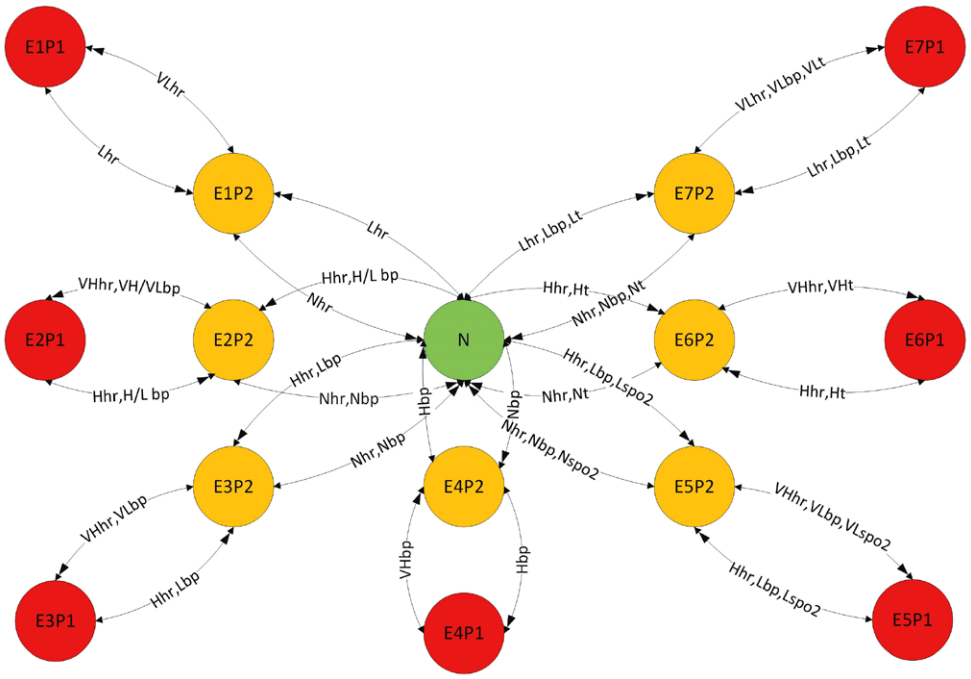

Figure 9. System working model with all possible seven physical signs using four vital signs and two levels of priority and a centre green normal state as the initial patient's condition.

the system's outcome because of two levels of priorities. This structure potentially provides a higher reliability and stability to compare with only single criteria for generating alarms.

The terms 'very high', 'high', 'very low' and 'low' are automatically/continuously optimized using the individualized 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 inputs HR and T as shown in the figure 9. In direct association with fever is the body temperature; hence in this case the T has more weight when predicting 'fever'.

The proposed system has been tested for both real-time as well as offline data. A multilayer concept has been introduced to enhance the overall reliability and accuracy of the proposed system. The multilayer approach has the potential of reducing the false alarms because early detection of physical sign(s) as the priority-2 warning does not generate alarm but only a warning. Then at the time of deterioration health event the priority-1 alarm will be activated and trigger the alarm. This mechanism is best utilized in this context by feeding a multiple input-output combinational relationships in real time.

4. Results and validation

Kappa analysis (Kundel and Polansky 2003) 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 (figure 10). 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

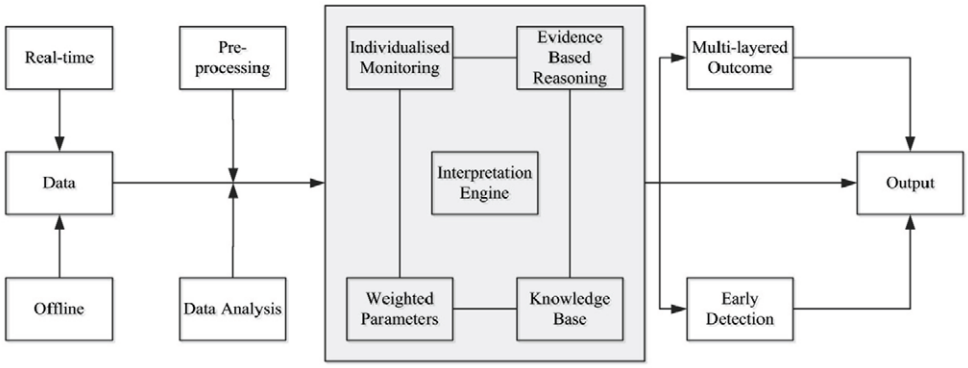

Figure 10. Block diagram overview of interpretation engine.

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 (Kundel and Polansky 2003).

4.1. 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 average, heart rate, oxygen saturation, ear temperature and blood glucose readings. Overall, a total of 1_{patient} X 3_{visits} X $4_{\text{data sets}}$ X $6_{\text{recordings}}$ = 72 recordings for one patient were collected. Finally, for 30 patients, a total of ($72_{\text{recordings}}$ X 30_{patients}) which is equal to 2160 recordings were collected.

The proposed system raised a total of 356 alarms and out 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 and compared with a medical expert's diagnosis. From another viewpoint, P2 (229) represents 64% of total alarms (356) when compared to 36% P1 (127), which suggests that for every P1 there was 1.8 P2, indicating that the proposed system successfully detects P1 early. The detection of P2 before and after P1 demonstrates that early detection of multiple physical signs as well as high predictability of the proposed system.

Table 5 below details the P1 alarms categorized according to the physical signs and compares it with the medical expert's diagnosis for the same data.

The results show 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 characterized as true negative (75) where the system and expert were both negative; this classification is defined in table 6.

Based on values from table 6, Kappa analysis was carried out using the standard 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

Table 5. 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

Table 6. 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

Table 7. 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

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; 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.

The overall kappa value is calculated as $K = 0.91$ and 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 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 to table 6 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.

4.2. 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 6) 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 normalized 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. Introducing the concept of priority 2 warning 'P2' was for two reasons. Firstly, for triggering the priority 1 alarm 'P1' and secondly to limit the false alarms so that clinicians could focus only on 'P1' alarms. The alarms generated by the proposed system achieved 95% accuracy in terms of clinical relevancy, when compared the outcome with the medical expert's diagnosis on the same data set. All alerts generated by the system were passed to the nursing staff for appropriate action, and it was found that 95% of them were true (compared to the traditional hospital guidelines) and valuable in patient care. It is expected that the proposed 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).

5. Discussion and conclusion

The developed vital signs interpretation system has shown that evidence-based expert diagnostic systems can accurately diagnose multiple physical signs in hospitalized older adults and could be useful in providing decision support to clinicians. The front end is designed for medical professionals so that they can use the system without any technical difficulties. 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% (Imhoff and Kuhls 2006). Chambrin *et al* (1999) and Tsien and Fackler (1997) reported the highest alarm rates in noisier environments, including simple threshold based systems (Chambrin *et al* 1999, Imhoff and Kuhls 2006).

The proposed decision support system may 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 medical professionals' needs and key clinical requirements. The other main focus was to minimize 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 different physical signs. Further work on the false alarms functionality of the proposed system using a wider inpatient population is required to demonstrate the reduction of false alarms.

Although, vital signs based hospital monitoring systems are still in the developmental stage and the realization process has only just begun (Pantelopoulos and Bourbakis 2010), the future work will help to fine tune the concept and bring forth the realization 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.

Conflict of interest statement

Authors declare no conflict of interest.

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