Current State of Critical Patient Monitoring and Outstanding Challenges

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Abstract

Technological advances in the fields of electronics and computer science have given rise to a considerable increase in the number of physiological parameters available to clinical staff for interpreting a patient’s state. However, owing to the limitations and flaws in current commercial monitoring devices, this has not resulted in a corresponding increase in healthcare quality.

This chapter analyses the reasons why clinical staff are not making full use of information from the monitoring devices currently in use in critical care units; a review is made of the most salient proposals from the scientific literature in order to address the imbalance existing between the amount of data available and the improvement in healthcare; and those problems for which suitable solutions have yet to be found and which have, up until now, hindered the applications of said proposals to clinical routine are analysed.

1. Introduction

The history of patient monitoring can be considered to date back to 1887, when the British scientist Augustus D. Waller made the first electrocardiogram (ECG) recording on a human being (Waller, 1887). The invention of the first commercial monitoring device is attributed to the Nobel Prize winner, Willem Einthoven, who in 1903 embarked on negotiations with the Cambridge Scientific Instruments Company to commercialise his “string galvanometer” for recording electrocardiograms (Einthoven, 1903). Since then, the list of advances made in commercial monitoring devices is endless, with these being especially prominent since the beginning of the 1970s. The invention of the microchip and the ensuing advances in the fields
of electronics and computer science have meant that the recording of a physical magnitude (a physical parameter in the case that concerns us), its subsequent conversion into a digital format, and its computer processing have become commonplace tasks. Consequently, there has been a considerable increase in the number of physiological parameters recorded from patients admitted to critical care units.

One could be forgiven for thinking that the more information there is available on a patient, the easier it will be for physicians to interpret the physiopathological processes that concur in each patient, and thus, the more efficiently the supervision task will be carried out. This, however, is not necessarily true: if the volume of data available exceeds the cognitive capabilities of physicians, they will have no option but to ignore some of those data that take them beyond the limits of their competence, which may lead them to commit errors. This situation is frequently aggravated due to the data being recorded from a patient admitted to a critical care unit often corresponding to situations that require a swift response (Jungk, 2002).

The only support that monitoring devices give to clinical staff for interpreting the patient’s state is threshold alarms; these are triggered when the value of a signal being monitored falls outside certain pre-established ranges that are considered normal. The selection of limits defining these alarms is subject to a compromise. Some limits give rise to a large number of false alarms, a high cognitive load for the healthcare staff, and, in the long-term, may lead to a lack of concern regarding the triggering of an alarm. In extreme cases, this may even result in healthcare staff occasionally disconnecting alarms (Mora, 1993). Tighter limits will give rise to a lower number of false alarms, but they increase the risk of not detecting real alarms, and thus, put the patient’s health in danger.

The availability of alarms capable of supplying higher levels of pre-interpretation for physiological variables would be extremely useful for healthcare staff. Such alarms would supply information with greater semantic content, and not only information on the membership or not of the instantaneous value of a physical parameter to a range of normality. In the bibliography on biomedical engineering, there are a good many proposals dealing with this problem. Nonetheless, in spite of all the work carried out along these lines, there are still a number of problems that have yet to be solved satisfactorily, and this has prevented these proposals from being implemented in clinical routine to date.
The present study analyses the principal shortcomings and limitations of threshold alarms and the problems which consequently afflict clinical staff. On the basis of this analysis, we shall define a framework for comparing different proposals for providing clinical staff with more effective assistance, and we shall compare the most salient proposals for tackling the problem of real-time patient monitoring. We shall then go on to consider those problems that have not been suitably dealt with by these proposals, and which must be resolved before their application in clinical routine. Finally, a series of conclusions on the work shall be given.

2. Patient monitoring: what is not working properly?

In critical care units, the physiological parameters of each patient are recorded by one or more bedside monitors. Among the most commonly monitored parameters are the 12 electrocardiogram leads, ST segment deviation, heart rate, respiratory rate, systolic, diastolic and mean blood pressure, blood oxygen saturation, encephalogram, intracranial pressure, partial pressure of expired oxygen, nitrogen and carbon dioxide, etc. Often, bedside monitor screens do not permit the simultaneous representation of all the physical parameters being recorded; rather they only allow a subset thereof to be viewed. Normally, between 4 and 8 parameters can be represented simultaneously. Also habitually shown on-screen is the instantaneous numerical value of the most relevant parameters, such as heart rate (HR) or blood oxygen saturation level (SpO2).

In the majority of current critical care units, all patients’ bedside monitors are connected up to central workstations, allowing the most relevant parameters and alarms triggered to be reviewed for all patients admitted to the unit. This enables healthcare staff to check on patients’ states without having to visit each bed in the unit individually.

In financial terms, the market for critical patient monitoring devices is substantial, since hospitals have no option but to invest heavily in this equipment. Consequently, it is highly attractive for companies, which compete fiercely for clients by incorporating constant innovations and improvements to their products. The most recent incorporations into state-of-the-art commercial monitoring devices include support for connecting a second, and even a third monitor, allowing more parameters to be viewed simultaneously; the capacity to store various hours of the patient’s physiological parameters and alarms triggered; significant reductions in size, and increased portability thanks to the use of TFT monitors; the possibility of transmitting data from the bedside monitor to the a central workstation via WiFi, thus
doing away with the need for cabling; and ubiquitous access to patients’ data via a Web interface. The number of parameters that some of these devices can record has also increased. Recent incorporations include body temperature, non-invasive blood pressure, various respiratory parameters, and up to six new ECG leads, giving a total of 18 (Wung, 2000).

Nonetheless, it would seem that these innovations and improvements have been guided more by aggressive marketing campaigns, with the aim of winning clients, than by the true needs of healthcare staff. Thanks to advances made in information and communications technologies, eliminating the need for cabling, supplying additional monitors, reducing the size of devices, providing more parameters or providing ubiquitous access to information via a web interface is tantamount to picking low-hanging fruit. Nevertheless, the main problem still faced by healthcare staff is same as it was 30 years ago: they have far too much information to be able to interpret it as swiftly as is needed, and the only support they have for interpreting this information (threshold alarms) is so unreliable that, at times, it may be more of a hindrance than a help. Consequently, it is doubtful whether the improvements incorporated into monitoring devices over recent decades truly enhance patient security, or even improve patient outcome (Boldt, 2002).

The bibliography on critical care includes a number of studies that attempt to determine the efficiency of threshold alarms. Habitually, there is a good deal of discrepancy in the results: Kestin et al. affirm that only 3% of all alarms indicate a real risk for the patient (Kestin et al., 1988), Tsien and Fackler place the rate of relevant alarms at 10% (Tsien, & Fackler, 1997), Chambrin et al. at around 25% (Chambrin et al., 1999), while Lawless sets it at 5% (Lawless, 1994). These discrepancies arise due to the studies having been performed in different settings (paediatric critical care units, operating theatres, adult critical care units, etc.) and the inconsistency regarding the criteria employed to define whether an alarm is “correct” or a “false positive”: some authors only consider an alarm to be correct if its triggering entails some type of therapeutic action, while for others it need only comply with the monitoring criteria that the alarm is supervising, even though it may have no bearing on the patient’s treatment. In spite of the discrepancy in the percentage of false positives among different studies, there is a consensus that this percentage is excessively high. Consequently, the effectiveness of auditory alarms is reduced notably (Edworthy, & Hellier, 2005), and it is not uncommon for the repeated triggering of an alarm to induce the healthcare staff to disconnect it (Mora et al., 1993; McIntyre, 1985).
On the other hand, the low expressive power of threshold alarms prevents healthcare staff from using them to monitor all situations of clinical interest that may appear in a patient. The ability to reason over the temporal evolution of a patient’s physiological variables (Giuffre et al., 1998; McIntosh et al., 2000) and to integrate information originating from various parameters into one single alarm (Tsien et al., 2000; Chambrin, 2001) would make it possible to automatically watch for the occurrence of situations that must be supervised currently by the healthcare staff.

Limitations on the expressive power of threshold alarms, along with the high number of false positives produced, are the main causes of the growing imbalance between the volume of data available on patients and the improvements that these data may yield in terms of healthcare quality. Hence the need for a new generation of alarms capable of providing enhanced support in the monitoring of pathological signs over a patient’s physiological variables.

3. Features of a new generation of alarms

In this section, we shall review the most salient works that provide techniques for addressing the flaws of critical alarms currently in use. All of these proposals can be considered as temporal abstraction techniques (Stacey and McGregor, 2007). Temporal abstraction consists in aggregating items of information, which evolve over time and which may be obtained on the basis of the data observed by the system, by means of a set of operations that progressively purge the data of those characteristics that are irrelevant for the task in question. Abstraction operations are characterised by being knowledge driven, heuristic by nature and by increasing the semantic content of the data over which they are applied.

In the present study, we shall only consider those temporal abstraction mechanisms whose input is one or more physiological variables sampled from the patient; which make it possible to work on-line over parameters with a high acquisition rate; and which have been applied, or may be applied, to generate alarms in a critical care unit. In the analysis of these proposals, five principal criteria will be employed: (1) the capacity to handle the vagueness and uncertainty inherent to the medical domain; (2) the capacity to reason over the temporal evolution of physiological variables; (3) the possibility of incorporating information originating from various parameters into one single alarm; (4) that they should permit the simple, intuitive editing of supervised monitoring criteria; and (5) the proposed warning mechanism for alerting healthcare staff of the triggering of the alarm.
3.1. Handling the uncertainty and imprecision

In order to determine the presence or not of an illness, physicians must deal with problems such as imprecision in measurements, errors and inconsistencies in data, the great degree of physiological variability between different patients (and even within the same patient), the difficulty of setting precise criteria for discerning between normality and abnormality, problems with the classification of borderline cases, disparity in the criteria applied by different physicians, the lack of a deep understanding of the underlying mechanisms of illnesses, and the uncertainty associated with verbally transmitted knowledge. Consequently, the presence or absence of an illness may often not be seen as a binary problem, rather as a matter of degree (Barro et al., 2002).

The aim of an alarm is to automatically identify signs of an illness that a patient may be suffering from; thus, alarms must reflect a degree of compatibility between the evolution of a patient’s physiological variables and the monitoring criteria that they are supervising, and they must show a gradual transition between those states that are considered to be clearly normal, and those considered to be clearly abnormal (see Fig. 1). On the contrary, threshold alarms show all or nothing behaviour, which leads them to make significant errors when the set of signals from the patient are on the border between being clearly normal and those that are not.

![Fragment of an HR recording from a patient admitted to an ICU. When does the tachycardia start?](image_url)
There are a number of solutions in the bibliography for handling uncertainty and imprecision. Haimowitz et al. (1995) present a technique for identifying patterns over a set of physiological parameters using a polynomial regression model to describe morphologies over the temporal evolution of a parameter. The polynomials may be of degree 0, 1 and 2, and their coefficients may be qualitative: {+, -}; or quantitative: a numerical value or a range of numerical values [min, max]. Each alarm is represented by means of a trend template which captures a set of relevant events and a set of transitions between them. Transitions are modelled by means of a partially ordered set of temporal intervals whose duration is represented by a pair of temporal distances - one minimum and the other maximum. Thus, it is possible to represent a certain degree of uncertainty in the temporal localisation of events. This technique as was employed in the development of the TrenDex patient-monitoring system.

Miksch et al. employ intervals over the range of values that physiological parameters may take to transform each instantaneous value into a qualitative description; and intervals over the magnitude of the parameter and over the temporal axis to classify trends in the parameters into a set of qualitative categories. The monitoring system then applies a set of rules obtained from clinical staff to propose a therapy (Miksch et al., 1996). As the authors of the aforementioned study point out, the problem of using intervals to handle uncertainty is that serious errors may be committed when classifying cases on the border between values considered normal and abnormal.

Combi & Chittaro (1999) present a model for representing multivariable patterns defined with the primitives “increases”, “falls” and “stationary”. All these primitives must always be evaluated over maximal intervals, it not being possible to specify a duration for them. These primitives may be combined with a series of temporal operators, such as “overlaps”, “meets”, “equals”, “during”, etc. The very linguistic nature of the primitives and the operators that combine them enables vagueness in the definition of patterns to be captured. Unfortunately, in real applications, the vagueness obtained as a consequence of this completely qualitative description has proved to be excessive.

Statistical techniques have also been used as a tool for handling vagueness and uncertainty (Davies et al., 2003; Gather et al., 2006; Imhoff et al., 1998). The great drawback for the application of these types of techniques in the medical domain is that healthcare staff require explicit knowledge of statistics in order to adapt them to each monitoring context (Imhoff et
al., 1998). Thus, taking a proposal of these characteristics beyond a pilot scheme is highly complicated.

In the medical domain, definitions of normality and abnormality are often based on heuristic knowledge and experience. Hence, fuzzy set theory, a tool of proven value in handling and representing this type of knowledge, would appear to be one of the tools most suited to representing the medical knowledge upon which alarms are based. Moreover, this formalism enables a balance to be struck between a completely crisp definition of the monitoring criteria and a completely qualitative one.

Until the mid 1990s, fuzzy logic played a relatively minor role in medical expert systems. Even though the aim of these systems was often to represent and reason over imprecise information, formalisms other than fuzzy set theory were normally opted for. Good proof of this is given by MHTP (Larizza et al., 1995), ICM (Sittig and Factor, 1990), PATRICIA (Moret-Bonillo et al., 1993), VIE-VENT (Miksch et al., 1996), the intelligent monitoring system of Westenskow et al. (1992), InCare (Koski et al., 1994), TrendDX (Haimowitz et al., 1995), Resume (Shahar y Musen, 1996) and SIMON (Dawant et al., 1993). Nevertheless, since the mid 1990s, fuzzy set theory has been the formalism most often resorted to: ARTAA (Guez and Nevo, 1996), the ventilation system of Becker et al. (1997), DSS (De Graaf et al., 1996), the monitoring system of Lowe et al. (1999), the intelligent alarm system of Oberli et al. (1999), SUTIL (Vila et al., 1997), the anaesthesia control system of Shieh et al. (1999), DiaMon-1 (Steimann et al., 1996), the intelligent alarm system of Otero et al. (2007) GUARDIAN (Drakopoulos and B. Hayes-Roth, 1998), and the intelligent ventilation system of Belal et al. (2005).

If fuzzy logic has not had a greater presence in medical expert system from the outset, it has probably been due to the fact that the technology it required was not available: the price to pay for its power in representing and handling knowledge is the high computational cost of operations in which fuzzy entities play a role. With the increase in computational capacity in computers, the use of fuzzy logic no longer adversely affects the efficiency of the system, and hence it is currently the most widely used formalism in medical expert systems.
3.2. Reasoning over the temporal evolution of the physiological variables

Threshold alarms are simply triggered when the instantaneous value of one single variable either belongs or not to a given range of normality. Thus, any artifact that may give rise to a value outside this range will trigger the alarm. Artifacts caused by patients’ movements are undoubtedly the principal motive for false alarms in a critical care unit.

Nevertheless, if we analyse the temporal evolution of a parameter, we can identify many artifacts, and thus prevent them from being identified as false positives. By way of example, when healthcare staff view the SpO2 recording shown in figure Fig. 2, they will know that the sharp falls to a null value are due to temporary disconnections of the pulseoximetry sensor (in all probability, due to patient movement) and do not represent a life-threatening situation for the patient, as it is impossible for this parameter to vary so abruptly. On the other hand, making it possible to reason on the temporal evolution of a variable means that alarms can be created to supervise monitoring criteria, such as trends, endowed with a greater semantic content than a simple threshold.

The GUARDIAN monitoring system, based on the proposal by Drakopoulos & Hayes-Roth (1998), represents each alarm by means of a set of measurements (e.g. the value of the parameter and its first and second derivative) taken over the temporal evolution of the patient’s physiological parameters. For each of these measurements, a fuzzy value has been previously defined indicating the degree of similarity between the measurement and the monitoring criterion. Matching is carried out using a segmentation algorithm which processes the signal backwards from the current instant. The algorithm stores the initial and final instants of each segment in order to evaluate the temporal constraints between different segments.

Jungk et al. (2002) present an intelligent alarm system to aid anaesthetists. The physiological variables recorded are transformed into linguistic variables on the basis of a set of fuzzy partitions defined over both the magnitude of the variables and their trends. The magnitudes of the variables are assigned labels, such as “high”, “good” and “low”, while trends are assigned labels such as “increasing”, “increasing slightly”, “decreasing”, etc. Thus the alarms consider not only value of the parameter, but also its evolution. These linguistic variables
comprise the input to a set of rules that assign another linguistic variable (whose value may be “good”, “slightly bad”, “bad” or “very bad”) to the evolution of each parameter.

Figure 2 During the eight minutes of the SpO2 recording in the figure, the threshold alarms were sounding for over one minute.

Charbonnier, & S. Gentil, (2007) present an alarm system based on trends that capture information on the temporal evolution of a signal in a semi-quantitative manner. The matching of each trend is triggered using a fixed threshold; once trend matching has been launched, the temporal evolution of the signal is matched with a qualitative set of symbols, such as “increasing”, “decreasing” and “stable”. The matching algorithm presented operates on-line, although in order to perform the qualitative matching with trends, the data need to be processed with a certain delay, which may be of up to 20 seconds.

DiaMon-1 (Steimann, 1996) employs fuzzy trends to describe trends over the temporal evolution of a single parameter. Each fuzzy trend represents the deviation admissible in the temporal evolution of a physiological parameter which is compatible with the trend, and the degree of compatibility of a sequence of samples from the parameter is obtained as the lesser of the degrees of membership of the set of samples to the fuzzy trend.

The idea of using fuzzy trends, albeit not necessarily with the same mathematical formalism as that proposed by Steimann, has been employed by other authors (Belal et al., 2005; Lowe et al., 1999; A. Otero, et al., in press a). In a similar manner to qualitative trends (Charbonnier, & S. Gentil, 2007; Miksch et al., 1996), fuzzy trends enable vagueness to be captured in both the temporal dimension and the magnitude of a parameter (see Fig. 3). Nevertheless, a fuzzy trend shows a gradual transition between those evolutions that are
clearly normal and those that are clearly abnormal, at the same time as it provides greater control over the level of imprecision to be used when describing the evolution of the parameter.

Figure 3 Graphical representation of one of the fuzzy trends employed by the MFTP model (A. Otero, et al., in press a).

3.3. Integrating information originating from various physiological parameters

Common sense would seem to dictate that the more physiological parameters recorded on a patient (i.e. the more information there is available on a patient), the more reliable the interpretation of his/her state and evolution should be. Nonetheless, this is not necessarily the case in critical care units: given that each threshold alarm oversees the temporal evolution of one single physiological parameter, the greater the number of physiological parameter that are measured, the more false alarms will generated. Having alarms capable of integrating information originating from various parameters may enable artifacts to be identified when the behaviour of one or more of them is not consistent with all the others. It would also make it possible to reduce the margins of abnormality for the events identified over each parameter,
maintaining the number of false positives within reasonable levels, thanks the integration of information.

Another advantage would be the possibility of creating alarms based on a set of findings which, considered independently, are irrelevant, but which, if they appear related with other findings appearing over the temporal evolution of other parameters (which, independently, may also be irrelevant), may supply evidence of physiopathological processes of clinical interest. For example, a slight increase in a patient’s HR or a small drop in blood pressure (BP) are events which, independently, are innocuous and irrelevant. Nevertheless, if both occur simultaneously, they may constitute a symptom of hypovolaemia or an embolism. These types of alarms provide strong diagnostic evidence of the occurrence of the illness they are monitoring, given the substantial quantity of information they incorporate.

Clinical staff currently use multi-parametric criteria in patient supervision, enabling them to identify pathologies at early stages, before they are life threatening for the patient (Chambrin, 2001; Tsien et al., 2000). The events that form part of these multi-parametric criteria are often too weak to be monitored using current threshold alarms, resulting in clinical staff having to oversee their occurrence with no type of support from the monitoring devices. The enormous quantity of parameters being monitored, the limited number of healthcare staff available, and the fact that this an arduous, tiresome task means that these multi-parametric criteria are not continuously overseen for all those patients in critical care units, it only being possible to monitor them in those situations in which their occurrence is more likely.

One such situation is the dialysis of a bed-ridden patient. This procedure is often carried out using a catheter placed intravenously via the femoral vein. The displacement of large quantities of blood to the dialysis unit may provoke a hypovolaemia in the patient. The concurrence of a slight rise in HR with a small decrease in BP supplies strong evidence of the onset of this pathology. Another risk inherent to this procedure is that when the catheter is introduced, blood clots in the femoral vein may be released, and may block the capillaries in the lungs, giving rise to an embolism. The formation of clots is especially likely if the patient has been bed-ridden for a long period of time. The appearance of this pathology over the physiological variables habitually monitored in a critical care unit is similar to that of hypovolaemia, but in this case the events described above concur with a fall in SpO2.
When proceeding with the dialysis of a patient, the physician is continuously monitoring the evolution of his/her physiological variables --especially at the commencement of the procedure. If either of the aforementioned patterns appears, the physician will probably react immediately by providing the patient with a volume overload, and in the case of hypovolaemia, increasing the fraction of oxygen inspired. These two procedures involve no risk to the patient, even when neither of the abovementioned pathologies is present. Nonetheless, when they do occur, acting so swiftly significantly reduces the threat for the patient.

Hypovolaemia and embolism are two pathologies that, with lower levels of probability, may occur at any time, without there being any clear triggering cause. Nevertheless, it is simply not possible to pay similar levels of attention to that shown at the commencement of dialysis throughout the patient’s entire stay in the critical care unit. Hence the advantages of having alarms capable of overseeing these types of criteria.

In the bibliography on biomedical engineering there are a number of proposals for creating multi-parametric alarms. Some consider the instantaneous value of two or more parameters to determine whether an alarm is triggered or not. In Orbeli et al. (1999) a fuzzy inference system (FIS) is employed to integrate information originating from various parameters into one single alarm. For each of the parameters recorded from a patient, the compatibility with five linguistic labels is calculated, these being: “extremely low”, “low”, “normal”, “high” and “extremely high”. These data are fed into an FIS whose rules have been obtained from the clinical staff. The FIS is capable of handling missing information by employing a set of rules acquired to this end. In the setting of anaesthetics, a number of fuzzy rule-based systems capable of integrating information from various parameters have also been developed (Becker et al., 1997; Schecke et al., 1991; Shieh et al., 1999).

Neural networks are another formalism that has been used to integrate instantaneous information from various variables into one single alarm (Guez, & Nevo 1996; Maglaveras et al., 1998). The disadvantages of using this type of technique in the medical domain include its black-box behaviour and the fact that training data are not always available.

Although the integration of instantaneous values from various physiological variables into one single alarm is a step in the right direction, this type of solution does not have sufficient expressive capacity to describe all monitoring patterns employed by physicians. By way of
example, the embolism and hypovolaemia patterns cannot be captured properly with these approaches. In the bibliography are a number of works that enable trends, and even more complex morphologies, occurring over the temporal evolution of various parameter to be related in one single alarm. The works by Haimowitz et al. (1995) and Drakopoulos & B. Hayes-Roth (1998) make it possible to describe temporal relations, modelled by means of intervals in the former case, and through possibility distributions in the latter, between morphologies identified over different parameters.

In (Lowe et al., 1999) the proposal of (Steimann, 1996) is extended, by taking notions borrowed from (Haimowitz, & Kohane, 1995) to allow trends occurring over different parameter to be related. In order to do so, a group of fuzzy trends is grouped in a trend template, in a similar way to the proposal of (Haimowitz et al., 1995). The temporal layout of each template is defined relative to another template within which the first is integrated - using a fuzzy temporal duration to do so - and each template may contain a set of sub-templates. A template containing no sub-templates is equivalent to a Steiman fuzzy trend. The main expressive limitation of the proposed model is that each template may only be related temporarily with its sub-templates. In the clinical domain, temporal relations between events are often of paramount importance for discerning between one set of findings that are pathological and another set of similar findings that are not.

The Multivariable Fuzzy Temporal Profile (MFTP) model is presented in (Otero et al., in press a). This model represents the temporal evolution of a set of parameters, using fuzzy constraints between a series of significant points; i.e., points from the temporal evolution of the system which are of special relevance for the physician. These constraints limit the increase in magnitude, temporal duration, and slope between each pair of points situated over a single parameter, and the increase in magnitude and temporal duration between significant points situated over different parameters. Within each parameter, the temporal evolution between each pair of significant points is limited by a fuzzy trajectory, whose specific mathematical expression may take a number of different forms, depending on the nuances of natural language employed in the description of the section (Félix et al., 2003). In this proposal, matching is carried out hierarchically, imitating the mental abstraction processes of clinical staff when identifying patterns. Thus, for example, to identify the hypovolaemia pattern on the basis of the sampled signal, we search for moderate increases in HR and moderate decreases in BP. These findings correspond to an initial abstraction level. It is then
verified whether the findings in the first abstraction level fulfil a set of relations (to be approximately simultaneous) in order to identify the global pattern, hypovolaemia, which corresponds to a second abstraction level. This matching procedure enables clinical staff to be provided with detailed explanations regarding why the pattern has come about, or not (for example, because even though there has been a moderate increase in HR there has been no moderate increase in BP). Items of information may also be reused between patterns: Those findings that are generated in the first abstraction level to identify the hypovolaemia pattern, may be reused to identify the embolism pattern.

3.4. Permitting the simple, straightforward editing of monitoring criteria

The physiological variability among human beings means that monitoring criteria used to oversee the occurrence of a pathology in one patient may not necessarily be suitable for supervising the same pathology in a different patient. The monitoring criteria must thus be adapted to the specific context of each patient. The lack of a Gold Standard to define precisely how to carry out this individualisation of monitoring criteria means that, to date, patient monitoring is still somewhat closer to a craft than to an exact science. Consequently, two different physicians often use different criteria in supervising the same patient, without it being possible to assert that the criteria of one are more suitable than those used by the other. It is simply the case that each physician wishes to be alerted on different deviations from normality.

A good number of the proposals included in the bibliography on biomedical engineering for the creation of intelligent alarms ignore this problem. In these proposals, the individualisation of monitoring criteria would require the assistance of a knowledge engineer, which would have to acquire the new monitoring criteria from the physician and implement them.

A number of proposals tackle this problem by incorporating contextual information into the definition of alarms, and by modifying the monitoring criteria on the basis thereof. This contextual information is frequently represented by means of rules (Miksch et al., 1996; Moret-Bonillo et al., 1993; Dawant et al., 1993). Another solution is to use automatic learning with the aim of adapting the monitoring criteria to each patient (Maglaveras et al., 1998; Silvent et al., 2004). Both solutions suffer from the same problem: the monitoring criteria finally used to supervise the patient are not transparent for healthcare staff. We do not
consider a monitoring system in which healthcare staff cannot revise the monitoring criteria they are using and, if they so desire, edit them, to be viable. Automatic learning also has the additional drawback that some pathologies, and hence their associated signs, are highly infrequent, due to which it may not be feasible to obtain sufficient training data, especially if, owing to the great degree of physiological variability, the data must be obtained from the patient we wish to supervise.

Those proposals in the bibliography that employ rules assume that the knowledge upon which these are based will be obtained linguistically from clinical staff (Becker et al., 1997; Jiann et al., 1999; Orbeli et al., 1999, Schecke et al., 1991; Shieh et al., 1999). In practice, the projection of linguistic knowledge onto the rules must be carried out by a knowledge engineer. None of these techniques proposes solutions for verifying the consistency and accuracy of the knowledge acquired, which renders the monitoring systems vulnerable to errors due to the incorrect interpretation of linguistic knowledge on the part of the engineer, or errors in its projection onto the rules. On the other hand, in order to incorporate new knowledge, it is often necessary to perform implementation work, a task which once again cannot be performed by healthcare staff.

If we intend to implement a proposal for creating alarms in clinical routine, the alarms it provides must be easily understandable for healthcare staff, who must be able to interpret and edit the content of these alarms easily. If the intervention of a knowledge engineer is needed to acquire the monitoring criteria or to generate recognition procedures, the project is doomed to progress no further than a conceptual test. To our way of thinking, failure to provide a suitable response to this problem is one of the main reasons why, in spite of the efforts made by the biomedical engineering community, commercial monitoring devices continue to employ threshold alarms, a solution which enables healthcare staff to modify monitoring criteria in a simple easy manner, without the need for assistance.

In (Drakopoulos & Hayes-Roth, 1998) a formal language is proposed for defining alarms, but the authors themselves acknowledge that the language is a bottleneck in knowledge acquisition. The solution they propose, even though it has never been implemented, is a development of a graphical interface in which the physician would trace the temporal evolution of the physiological parameters with a mouse and, employing automatic learning techniques, the system would learn the monitoring pattern. A similar solution is employed in (Steimann, 1996). In this case, a graphical interface is proposed in which the physician, over
the occurrence of the trend we wish to describe, defines a temporal interval during which it is completely possible for the pattern to commence, and a second temporary interval outside of which it is completely impossible for it to start. Using both intervals, a possibility distribution is created and projected over the rest of the samples of the evolution, proposing a membership function for each one of them. The fuzzy trend which will describe the pattern is calculated as the envelope of all the membership functions.

Both the solution proposed by Drakopoulos & Hayes-Roth and that proposed by Steimann recognise a fact that is widely ignored in the bibliography: the knowledge that must be acquired to create alarm is not of a linguistic nature, rather visual. It is learnt visually through experience in clinical routine, and applied in a visual manner. In effect, this knowledge is often expressed linguistically, owing to the lack of more suitable mechanism. But any human will feel more comfortable using a pencil and paper to describe the evolution of a temporal series than a set of sentences whose interpretation is always subjective. The idea of Drakopoulos & Hayes-Roth of learning a pattern on the basis of a set of prototypes drawn by the user is interesting, although just how it could be implemented in practice is not clear. Even though it makes use of visual techniques, the solution proposed by Steimann is a touch ad hoc, and it is not clear how it could be generalised.

We believe visual metaphors to be the ideal solution for acquiring knowledge relating to alarms. Thus, in the MFTP this problem is resolved using TRACE (Otero et al., in press b), a graphical tool which uses the graph of the MFTP as a visual metaphor for eliciting knowledge. The form of this graph is reminiscent of that of the pattern being defined, and any changes the physician makes in the alarm definition are reflected immediately in the shape of the graph, supplying immediate visual feedback on the monitoring criteria and enabling errors in the definition to be identified simply (see Fig. 4) On the basis of the graph, TRACE automatically generates the recognition procedures for the described pattern, rendering the intervention of a knowledge engineer unnecessary for generating a new alarm, or for editing already existing criteria.
Figure 4 TRACE’s representation of the hypovolaemia pattern. The form of the MFTP graph is reminiscent of the shape of the hypovolaemia pattern, and padlocks represent constraints limiting evolution of parameters.

3.5. Supplying suitable warning mechanisms

Momtahan et al. carried out a study in a critical care unit in which they recorded a total of 23 different alarms where no other alarm was activated. They then asked healthcare staff to identify the alarms. The rate of alarms identified correctly was 39% (Momtahan et al., 1993). Loeb, et al., asked 44 anaesthetists to identify 19 alarms that had been recorded beforehand; in this case the rate of alarms identified correctly was 34% (Loeb, et al., 1992). In a similar study carried out among a hundred members of healthcare staff with different occupations (physicians, nurses and respiratory therapists), Cropp et al. obtained correct alarm identification rates of between 40 and 50%, depending on the occupation of those under study and whether the alarms were critical or not (Cropp et al., 1994).
The enormous quantity of alarms currently available in critical care units means that currently it is practically impossible for clinical staff to recognise the audible warning associated to each alarm. Thus, these warnings do not completely comply with their aim, leading some physicians to even question their usefulness (Biot, 2003). In light of this situation, adding further auditory warnings to represent each of the new alarms in a hypothetical intelligent patient supervision system would not seem to be a good idea. This system could potentially oversee a large number of pathologies: in addition to abnormal values in the physiological variables, in a similar way to how current threshold alarms work, it could monitor increasing and decreasing trends over the physiological variables, and more complex patterns, such as those of embolism or hypovolaemia. Expecting healthcare staff to be capable of distinguishing the sounds corresponding to each alarm is simply unrealistic.

One possible solution is the use of sonification (the science that studies the conversion of data into sound) to improve current auditory warnings (Watson, & Sanderson, 2004). In sonification, each of the dimensions of the data being monitored is assigned an acoustic parameter, such as pitch, loudness, speed, harmonic content, etc. Applied to patient monitoring, the sound of a heart beating faster and faster could be used to indicate an rise in HR, or sound of a person breathing slower and slower to indicate a fall in breathing rate. Speech synthesis is yet another interesting alternative, although the implications of giving verbal notification of patient’s pathologies needs to be studied. One potential drawback of both sonification and speech synthesis is that they would both contribute to increasing sound pollution levels in critical care units. A number of studies have shown that the current levels of sound pollution are already capable of causing stress, circadian rhythm disturbance and sleep deprivation in patients (Kahn et al., 1998).

Another interesting notion is that of employing alternative warning mechanisms, such as vibro-tactile displays (Jessie et al., 2005; Ng et al., 2008). These studies make use of wrist straps and belts which produce different types of vibrations, depending on the alarms that have triggered them. Although this is still at a very early stage, the ideas proposed are interesting.

None of the principal alarm generation proposals analysed in this chapter provides an alternative to the current auditory warnings, or ideas to improve on them. And this is in spite of the high semantic content of some of the alarms proposed, and the specific nature of certain techniques requires special consideration in this sense. For example, a good proportion of
these techniques use fuzzy logic and calculate some level of compatibility between certain fuzzy monitoring criteria and the temporal evolution of the patient. In these systems, when warning of the triggering of an alarm, information should be supplied on the compatibility between the monitoring criteria and the evolution of the patient. Warning about all alarms, or warning about only those alarms with a level of compatibility over a given threshold, would diminish the benefits of having employed a fuzzy approach.

Proposals do exist for improving the warning graphics currently in use, which habitually consist of information flashing on bedside monitors. Jungk et al. (2002) have created a user interface to show a patient’s state in which a set of rectangles are employed to present information on the physiological variables. In some cases, the rectangle’s height corresponds to the value of a physiological variable, while in other cases, each of the two dimensions of a rectangle are used to show two related variables. The rectangles appear in red if the values of the variables imply a life-threatening risk (alarm situation), otherwise in green.

In (Oberli et al., 1999) textual descriptions are used to report on which alarms have been triggered and why. This simple, effective mechanism for reporting on the patient’s state is particularly suitable for rule-based monitoring systems, and could easily be extended to take advantage of speech synthesis.
A number of studies propose visual metaphors for highlighting those fragments of the patient’s physiological variables demonstrating compatibility with the monitoring criteria, in order to attract the attention of healthcare staff (Lowe et al., 2001; Otero et al., in press b). To do so, they use colours and/or tracing the signal with a thicker line (see Fig. 5). One advantage of this technique is that no additional space is required on the bedside monitor screens (always a scarce resource) for showing information relating to alarms: it will always be necessary to show the temporal evolution of physiological variables.

Table 1 is a summary of the characteristics of some of the principal alarm creation proposals reviewed herein. The first four columns indicate, respectively, the mechanism the proposal uses to handle the vagueness and uncertainty characteristic of the medical domain; temporal reasoning capacity; whether or not it is capable of integrating information from multiple parameters; and the proposal for the acquisition of monitoring criteria. The fifth column indicates whether the authors propose some type of warning mechanism adapted to the specificities of their alarms. The sixth briefly describes the proposal's mathematical basis; and
the seventh indicates whether or not a pilot experiment has been carried out in a medical unit, implementing a monitoring system based on the proposed alarms in parallel with those alarms that are currently available. Even in those cases in which such an experiment was carried out, they were limited and over a short term.

4. Discussion

There are two principal reasons why none of the proposals presented herein has progressed beyond the pilot experiment stage. The first is that the vast majority of techniques completely ignore or fail to propose a suitable solution to the problem of knowledge elicitation. The physiological variability among patients, along with the fact that patient monitoring is a craft that lacks specific guidelines for adapting monitoring criteria to each patient, means that two different physicians will often use different criteria for monitoring the same patient. Thus, expecting physicians to place their faith in certain monitoring criteria generated automatically by a computer does not seem feasible, however much contextual information may have been taken into account in the process, if they cannot revise them and, if considered opportune, edit them.

If an alarm generation technique is to be employed in clinical routine, it is paramount that the healthcare staff should understand how the alarms function, and should be able to edit their monitoring criteria, without the need for assistance. The intervention of a knowledge engineer in the acquisition of knowledge, or for carrying out some type of implementation task, will effectively prevent the proposal from progressing beyond the pilot experiment stage. In this sense, we personally have opted for visual metaphors that supply immediate feedback on the monitoring criteria being described.

The second reason why these proposals have yet to succeed in knocking the threshold alarm off its perch is the lack of exhaustive studies on their introduction into clinical routine. In effect, authors often demonstrate that their alarms have greater expressive power and/or a lower rate of false positives than threshold alarms, but there are still a good many questions that remain unanswered. Initially, the new alarms will have to exist side by side with threshold alarms. What form must this coexistence take? Will it be possible at some moment in time to substitute all threshold alarms with the new proposal?
<table>
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<tr>
<th>Authors</th>
<th>Handle vagueness and uncertainty</th>
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Table 1: Summary of the comparison of a number of the most relevant proposals in the bibliography
This does not seem very likely: a threshold is effectively the swiftest manner of warning of a total failure in an organ (e.g. a cardiac arrest). Given the seriousness of these illnesses, an instant warning is imperative; hence it would not seem to be a good idea to employ trend-based techniques (which always involve a certain delay in warning of events) to identify them. So, how many and which of the threshold alarms may be substituted by those of the new proposal?

Also, how much will it cost to train healthcare staff to learn to use the new alarms, and how long will it take to define each one of them? The greater expressive power of alarms will require more time to train healthcare staff and to define each alarm. It may well be the case that the benefits obtained from new alarms do not offset the increased complexity and the time required for the definition and, thus, healthcare staff may opt not to use them. On the other hand, taking into account that these alarms are more complex, how often will errors in definition come about, and what will be their consequences?

In order to respond to these questions, the new alarms need to be tested in pilot experiments. And this is not easy. On one hand, all the legal and social implications deriving from the introduction of experimental monitoring devices into the critical care unit need to be resolved: compliance with regulations affecting the hardware that may be used in these units; obtaining permission from the hospital and, possibly, from the health authority on which the hospital depends; guaranteeing the confidentiality of recorded data by means of cryptography; obtaining permission from patients to carry out the experiment, etc.

On the other hand, the technical problems deriving from the introduction of the new system in parallel with the already existing one will need to be solved, the principal problem being the real-time acquisition of data from monitoring devices. One solution is to capture data from the critical care unit intranet: if the commercial monitoring system has a central workstation, communication between this and the bedside monitor usually takes place via an Ethernet network. To access the data, we need to know the communication protocol employed. These protocols tend to be proprietary, and companies are usually reluctant to supply them; moreover, their implementation and debugging are tedious tasks. Nevertheless, this solution, which the present authors have tested in SUTIL (Vila, et al., 1997), has the advantage of providing real-time access to data.
Another alternative is to resort to commercial solutions which provide specific hardware for the acquisition of physiological parameters via analogical outputs or the RS 232 port on bedside monitors (Biopac, 2008; ADInstruments, 2008). The downside of this alternative is access to data in real time: in the case of the solution supplied by ADInstruments, this feature is not available. The company Biopac does provide a proprietary API based on a Windows dll which gives real-time access to data, but the API has very limited functionality and is tiresome to use.

Another problem which may lie behind the scant number of pilot experiments carried out and the limited range within which they have been performed, is the considerable cost in terms of time and resources that they give rise to. This means that many research groups do not have the resources necessary to tackle it, or they are unwilling to make the investment required: on a research level, the benefits deriving from efforts spent in resolving legal matters, negotiating with companies and the hospital, and the technical problems deriving from data acquisition are scant or null.

5. Conclusions

From the field of biomedical engineering a number of techniques have been proposed for addressing the flaws and limitations of threshold alarms. The expressive power of these proposals ranges from the identification of qualitative trends, or the integration of instantaneous values from various physiological variables, to the description of complex patterns comprising arbitrary morphologies over the temporal evolution of various parameters. The result, in all cases, is alarms with greater expressive power than threshold alarms, and a considerably lower rate of false positives.

Nevertheless, there are still a number of problems to be resolved before any of these proposals may be applied to clinical routine. Worthy of special mention among these is the development of techniques for the acquisition and validation of alarm monitoring criteria. In these developments, Artificial Intelligence and Intelligent Data Analysis will play a very prominent role, given that these operations are driven by human knowledge. The development of warning mechanisms, beyond visual warnings, used to draw attention to the triggering of an alarm and transmit all of its semantic content is another open problem. In the near future many advances will be made in this field by incorporating intelligent user interfaces capable of adapting themselves to the particular monitoring goals of each patient and to the current
state of the patient. New gadgets like wireless headphones—which will enable the use of natural language for the generation of warnings—or vibro-tactile display—that enable the use of more senses besides sight or hearing to convey information to caregivers—will likely revolutionize the way in which monitoring devices generate warnings.

Pilot experiments need to be performed with the new alarms to study the implications deriving from their introduction into critical care units. Agents based architectures will play a prominent role in the development of the prototypes required for these experiments, In addition to providing a robust framework for building these systems, agent based architectures permit the rapid and simple testing of new monitoring techniques—agents—and the undoing of the new changes if they have proven not to be good ideas. However, unlike the traditional agent-based systems, complying with the strong real-time requirements imposed by patient monitoring will be a significant challenge due to the large amount of low-level data that needs to be processed: just the monitoring of ECG and EEG in one patient may produce up to 8000 samples per second.

Besides pointing out technical challenges for the development of the new monitoring systems, pilot experiments must permit the study of problems such as the higher costs of training healthcare staff, the ratio between the benefits obtained from the new alarms and the greater effort required in their definition, the adaptation of proposed warning mechanisms, and how the new alarms should coexist with the current ones. These are problems which may invalidate an alarm generation technique if suitable solutions have not been provided. And the only way of testing the solutions proposed is through pilot experiments. In this sense, researchers would benefit greatly from support from commercial companies, on both technical and economic levels.

The new monitoring systems should make a strong emphasis on the use of medical communication standards such as HL7 (Dolin et al., 2001), enabling the interoperability of multiple information systems—emergencies, clinical consultations, radiology, pharmacology, critical care units, etc.—. These systems must also emphasize the provision of ubiquitous monitoring, both intra and extra-hospital, especially for patients suffering from chronic illnesses such as cardiac patients or those suffering from chronic obstructive pulmonary disease. The increase in life expectancy and the increasing aging of the population are other factors driving the need for ubiquitous monitoring. In this sense, the ever increasingly cheap
biosensors and the small –but powerful- computing devices such as PDAs or smart phones will provide great opportunities.

Patient monitoring is a fascinating field where there are still many problems to be solved, and where even relatively small advances may give rise to considerable benefits in healthcare quality. Providing solutions to these problems requires multidisciplinary teams with specialists in sensors, signal processing, user interfaces, artificial intelligence and medicine. We would urge researchers to get involved, and help to tackle these unsolved problems.

6. Key Terms and Their Definitions

Physiological variable: temporal series representing the evolution of a physical magnitude related with the patient’s physiopathological state.

Bedside monitor: commercial monitoring device used in critical care units to record, view and supervise the evolution of physiological variables.

Threshold alarm: mechanisms used by bedside monitors to notify clinical staff each time the value of parameter leaves a pre-established range.

Intelligent alarms: for the purposes of the current work, any alarm which significantly improves the performance of threshold alarms.

Patient monitoring: the acquisition and viewing of a patient’s physiological variables, with the aim of verifying his/her physiopathological state.

Therapeutic action: any action performed by healthcare staff with the aim of leading a patient towards the desired state.

Knowledge elicitation: the obtaining of knowledge required to carry out a task from an expert in the application domain.

Patient supervision: activity consisting of verifying a patient’s physiological state on the basis of the information available on him/her, and leading him/her to the desired state by means of therapeutic actions.
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