Guideline for Patient Monitoring and Medical Alarm Systems in hospitals

Note for readers: the translation of the Dutch Guideline is slightly changed and shortened, as terminology in Dutch is different from English and therefore, more details and definitions were needed in the Dutch guideline compared to its English translation.

Aim and scope of the Guideline

The aim of the guideline is to describe the requirements and considerations for safe medical alarm management in a critical care setting in hospitals. The medical alarm system must be safe for the patient, easy to use for healthcare professionals (HCP), and easy to implement and manage in the alarm infrastructure for clinical engineers[1]. Two practical tools are developed to support hospitals in the design and implementation process of a medical alarm system:

1. "Basic set of requirements for a (distributed) medical alarm infrastructure".
2. "Process guide for using medical alarm systems safely".

The guideline addresses the following questions:

2. Definitions, scenarios and medical alarm systems and their infrastructure
   2.1 What is patient monitoring and what are medical alarm systems?
   2.2 How does the care scenario influence the extent of the medical alarm infrastructure?
   2.3 Which legislation, standards and norms apply to medical alarm systems and their infrastructures?
3. Current situation and bottlenecks experienced when using medical alarm systems
   3.1 What is the variation between departments in a hospital and between hospitals?
   3.2 Which bottlenecks are experienced in medical alarm systems?
4. Optimal medical alarm infrastructure: advice for process design and technical design
   4.1 What are the requirements and wishes for the medical alarm infrastructure?
   4.2 How can the design of the medical alarm system be adapted to the intended care scenario?
   4.3 How can the medical alarm care process be organized optimally and safely?

Finally, a summary and conclusion are provided in Chapter 5.

Outside the scope of this guideline, are alarms without a medical purpose (non-medical alarm infrastructure; Fall Detection Systems (for example in nursing wards) and remote monitoring (e.g. in the home situation or in nursing homes). In addition, certain areas were outside the area of expertise of the guideline panel, like legal and ethical matters and therefore these aspects are not addressed in the guideline.

Intended readers

This guideline is intended for all clinical engineers[1] and health care professionals (HCP) involved in procurement, technical design and clinical implementation of (distributed) medical alarm systems in hospital settings.

Guideline panel

The Dutch Society for Medical Physics (NVKF) initiated the guideline. The guideline was developed by a multidisciplinary guideline panel, consisting of representatives of all relevant specialisms involved in monitoring patients in the hospital in the Netherlands. In addition, the Netherlands Patient Federation, Foundation Child & Hospital (Stichting Kind & Hospital), IC Connect, Neo4Care and an ethicist were consulted.

[1] E.g. medical physicists, biomedical technologists, engineers, medical technicians, medical ICT experts

Table 1. Members of the guideline panel

Panel member	Function	Institute	On behalf of
Ir. Carla Kloeze	Medical physicist	Catharina Hospital Eindhoven	NVKF
Dr. ir. Bärbel van den Berg	Medical physicist	Medisch Spectrum Twente hospital, Enschede	NVKF
Dr. Michelle Westerhuis	Gynecologist	Catharina Hospital Eindhoven	NVOG
Drs. Ferry Hersbach	Cardiologist	Diakonessen Hospital, Utrecht	NVvC
Dr. Jan Willem Kuiper	Pediatric intensivist	Erasmus University Medical Center, Rotterdam	NVK
Drs. Rene Hagenouw	Anesthesiologist	Erasmus University Medical Center, Rotterdam	NVA
Prof. dr. Diederik Gommers	Intensivist	Erasmus University Medical Center, Rotterdam	NVIC
Drs. Pauline Buscher-Jungerhans	Anesthesiologist-intensivist	Rijnstate Hospital, Arnhem	CMIO network
Dr. Dunja Dreesens	Senior advisor	Knowledge Institute of Medical Specialists	Kennisinstituut
Drs. Erik Koomen	Anesthesiologist-Pediatric intensivist	University Medical Center Utrecht UMCU, Utrecht	NVA
Prof.dr.ir. Carola van Pul (chair of the panel)	Medical physicist	Maxima Medical Center, Veldhoven; Eindhoven University of Technology, Eindhoven	NVKF

2. Definitions, scenarios and medical alarm systems and their infrastructure

2.1 What is patient monitoring and what are medical alarm systems?

The clinical status of patients in a hospital is often monitored by keeping track of the individual physiological parameters, such as heart rhythm, saturation and blood pressure. This is done either by periodic manual checks and measurements or with a patient monitoring system that continuously measures these parameters. If one or more parameters exceeds a predefined threshold an alarm signal – audible or visible- is generated to trigger the health care professionals (HCP) into action at the patient's bed side.

In clinical practice, different forms of patient monitoring are used depending on the medical purpose. To ensure a uniform terminology in this guideline on medical alarm systems, the guideline panel follows the definitions from the norms for medical devices (see section 2.3) but needs the following definitions to distinguish different care scenarios:

- **Patient monitoring**: the automated and continuous measurement of vital parameters and generation of alarms (auditory or visual) when predefined thresholds ('the alarm limits') are exceeded with the purpose of ***warning the HCP of potentially critical patient conditions***. Immediate action on the alarm is needed by an HCP. The alarm is repetitive until the HCP has taken action.
  - An example: bedside monitoring of multiple vital signs of a patient in an intensive care setting in which alarms are distributed to a central viewing/monitoring station.
- **Signaling** (or: early warning systems): repeated (intermittent) measurements of a set of parameters to detect a change in the patient's condition that requires treatment policy changes but does not pose an immediate danger to the patient (this distinguishes it from patient monitoring).
  - An example: periodical measurement of oxygen saturation in a general nursing ward to determine the proper care policy for the patient; Another example is the use of the Early Warning Score (EWS (1)).
- **Spot check**: determining physiological values of a patient, for diagnostic purposes usually, which do not require an immediate intervention, but provide healthcare professionals information regarding treatment optimization.
  - An example: a blood pressure measurement in an outpatient clinic.

As mentioned, patient monitoring requires the alarms to always reach a HCP. If the responsible HCP is not in the vicinity of the patient, an (ICT) infrastructure can be used to distribute the alarm from the patient to the HCP. This infrastructure includes all technical components that transmit an alarm from the alarm generating device to the HCP. In this guideline we therefore define:

- **Medical alarm system:** the alarm functionality is used to monitor the patient's condition in a critical care setting in which an HCP needs to take immediate action in case of an alarm
- **Medical alarm infrastructure**: all technical components in this medical alarm system together, that enable the generation of an alarm at the bedside monitor, the transmission of the alarm to the central viewing/monitoring station and from there (if applicable) to a mobile device of the responsible HCP, with the intended use to immediately trigger the HCP into action.

- Example: a patient monitor alarm system that sends critical alarms to a mobile device is considered a medical alarm system. On the other hand, an EWS score made visible in an Electronic Medical Record (EMR) is not an alarm and the EMR servers are not part of a medical alarm infrastructure. If an alarm is made visible in an EMR and the module of the EMR has medical alarming as intended use (requiring immediate response of HCPs), the system may be considered a medical alarm system, and this guideline is then applicable.

2.2 How does the care scenario influence the extent of the medical alarm infrastructure?

The specific design of medical alarm systems and their infrastructure depends on the patient category and on the department where monitoring takes place (e.g. (neonatal) intensive care unit (ICU), nursing ward, operating room (OR), or obstetric ward). Patient monitoring can be arranged in different ways, depending on the desired care setting. In an 'open bay' setting, with all patients in one room, a direct overview of all patients is easily available for the HCP without the need for complex technical solutions. However, nowadays critical care is increasingly provided in single-person patient rooms, to provide privacy for the patient and family and to reduce the risk of infections. However, for the HCP this means that the patients cared for may be in several separate rooms without direct overview of the patients. In such cases, more sophisticated medical alarm infrastructures are often used to provide the HCP with direct feedback on any deterioration of the patient. Figure 1 outlines several care scenarios with possible alarm systems:

A. In an open bay unit, there are several patients in one large room, each patient with his/her own patient monitoring device. The HCP is usually in the room and can see and/or hear all alarms directly.
B. In an open bay unit, a central monitor may be added to provide additional overview and information to the HCP, if required by the clinical condition of the patient population. This central monitoring station shows the vital parameters and the alarms of several patients at the same time and has an overview purpose.
C. In the situation of single-person room care, vital parameters and alarms are visible on the monitoring device in the room. Since the HCP regularly works outside the patient room or in another patient room as well, vital signs and alarms must also be available outside the patient room. For this often a central monitoring station, located centrally in the department is used. Usually, interbed communication is also used in this situation, meaning that alarms of one patient give a (visual) alarm on another patient's monitoring device which can be viewed by the HCP directly on that monitor.
D. In single-person room care as shown in C, it may be necessary to transmit vital signs and alarms to a mobile device carried by a HCP to ensure that the right/appropriate HCP is always informed of an alarm of his or her patient.
E. The same care setting as D, but without a central station. Alarms from medical devices are sent directly to a mobile device.

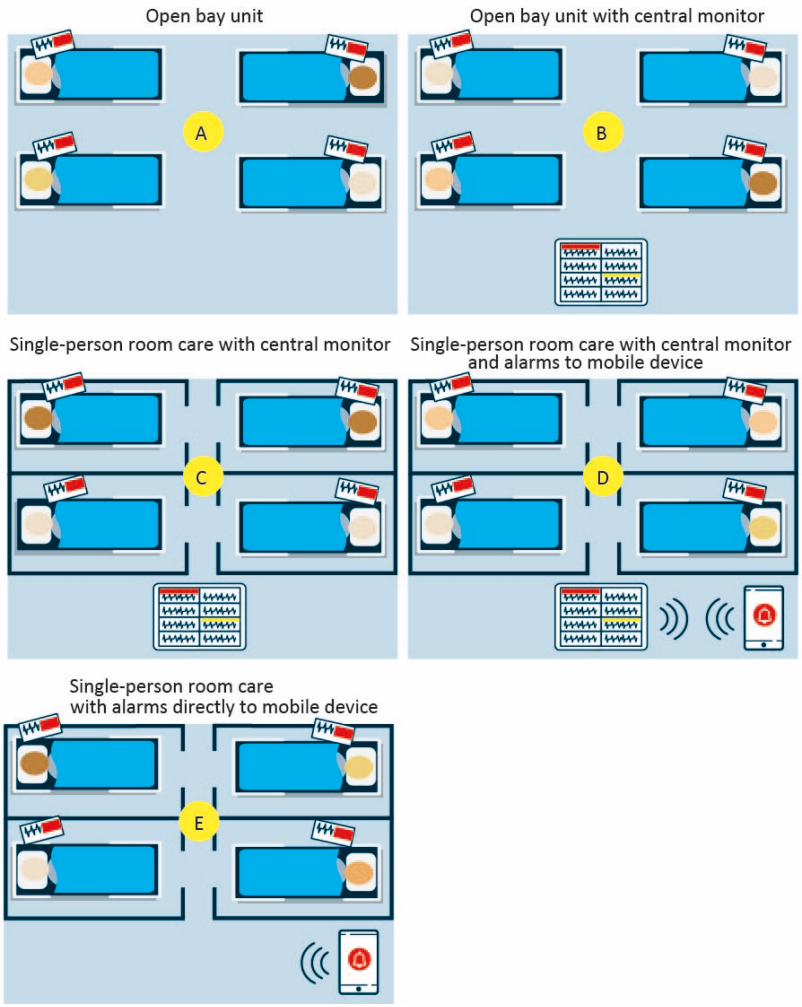

Figure 1. Examples of common care scenarios where alarms are visible in different positions:
A. Open bay unit with alarm visible on the patient monitor.
B. Open bay unit with alarm visible on the patient monitor and on a central station.
C. Single-person room care with alarm visible on the device and on a central station.
D. Single-person room care *with alarm visible on the device, central station and via ICT infrastructure on a mobile device.*
E. Same care setting as D, but without a central station in which alarms from medical devices are sent directly to a mobile device.

In these care scenarios, different alarm system infrastructures are used to send an alarm from a patient to a HCP. A few common systems are shown in Figure 2 and their use discussed below:

1. A **Nurse Call System (NCS)** consists of a button that the patient can press to receive help from a HCP. The HCP is alerted that someone in a room needs help. This alerting of the HCP typically is effectuated by lighting up an indicator light on the outside of the patient room, or by displaying a notification on a central screen or on a HCP's mobile device. The HCP can only see that there is a call from a specific room but does not receive information about the patient's condition at that time. The NCS is not a medical device and is therefore not covered by this guideline. If a combined NCS/MCS (see following point) is used, it may be considered a medical device.
2. A **Medical Call System (MCS)** consists of one or more medical devices, connected to the alarm system using a specific so-called nurse call output port (without alarm information). When a medical device generates an alarm, a break to alarm signal is generated, creating an “alarm on” message in the available alarm infrastructure. The alarm message typically results in an indicator light lightning up on a central location or sending an alarm message via an ICT network to a mobile device of a HCP. The alarm signal does not contain any further information on the cause of the alarm or the patient's clinical conditions. These kinds of systems

are often only intended to give a notification, not an alarm, to provide additional information to the HCP. If the infrastructure is deployed to monitor the patient in a critical care situation or to send a critical alarm from a life-supporting medical device to a HCP, it should be regarded as a medical device. In that case it is part of the medical alarm infrastructure, which is covered by this guideline.

3. A **Medical Alarm System (MAS)** consists of one or more medical devices, linked to a medical alarm infrastructure using a server. In this system, alarms and their associated contextual information, such as information about the type of alarm and urgency, is sent to the HCP. Often life supporting medical equipment, such as ventilators, are also linked to the MAS for alarm distribution. This system is intended for patient monitoring, so it is considered a medical device and is covered by this guideline. The different systems can coexist in a care scenario. This is illustrated as an example for an ICU room in Figure 2.

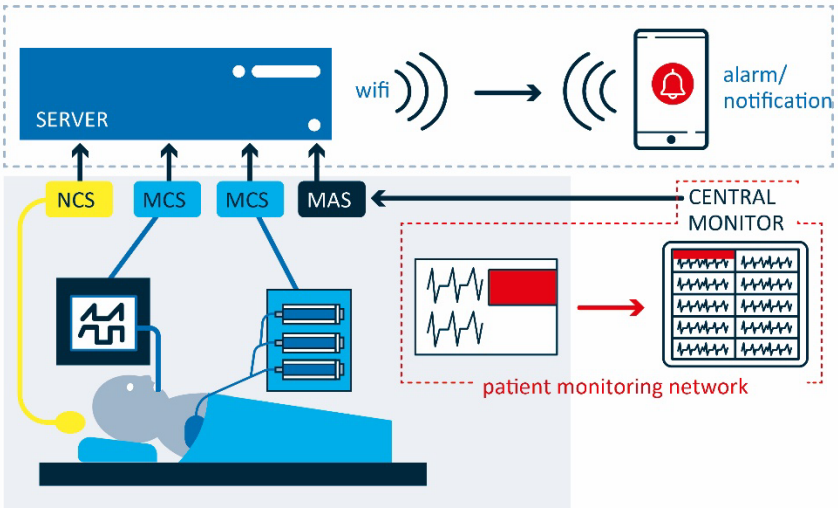

Figure 2. Example of a possible situation in a patient room with various alarm systems (care scenario D in Figure 1): the patient's vital parameters, such as heart rhythm and saturation, are measured with a clinical patient monitor, and both signals and alarm conditions are shown on a central monitor. The central monitor can send alarms via the MAS to a server to a mobile device. Alarms can be viewed in an App on a mobile device. The patient bell to the NCS is shown in yellow (NCS). The MCS is a 'box' inside the patient room that can receive the alarms from a nurse call port on the medical device, like a ventilator and a perfusor as shown, and pass them to a server (blue).

Conclusion

The care scenario determines the design and associated workflow of monitoring patients as well as the setup of the medical alarm systems and its technical infrastructure. In an open bay care scenario, fewer components in the infrastructure may be needed to provide safe care while a more extensive alarm infrastructure may be required for patients who are cared for in single-person rooms. This is further elaborated on in Figure 3 of this guideline.

2.3 Which legislation, standards and norms apply to medical alarm systems and their infrastructures?

The Medical Device Regulation (MDR) is the main European legislation for medical devices. Both vendors and hospitals should comply with it. Patient monitoring systems with the intended use of 'monitoring vital parameters' must be classified as a medical device and must be categorized with risk classification IIa or even IIb when “the nature of the variations of those parameters is such that they can lead to immediate danger to the patient, for example variations in the performance of the heart, respiration and activity of the central nervous system”. Classification IIb also applies to patient monitoring systems “intended for diagnosis in clinical situations where the patient is in imminent danger”. (2) Software that influences or helps with making a medical decision is also classified as a medical device (typically risk classification IIb or III within MDR).

Hence, depending on definition of intended use, a complete medical alarm infrastructure (MAS and MCS) may be classified as a medical device, but it is also possible that only separate components are classified as a

medical device by the vendors, and the hospital takes responsibility for combining the components in the hospital infrastructure.

Standards applicable to the medical alarm infrastructure can be divided into specific standards for individual components, such as NEN-EN-IEC 60601-1-8 (3), which specifically deals with alarms on medical devices. There are also standards that apply to the entire medical alarm infrastructure and define the interaction between the various components in the infrastructure (e.g. NEN-EN-IEC 80001-2-5 distributed alarms (4), risks & alarm management in networks). Some standards are older and not always adapted to the rapidly changing healthcare, with single-person rooms and increasingly mobile patients and HCPs. New standards on interoperability (such as the ISO/IEEE 11073 SDC Health informatics device interoperability standards) (5) are developed to define standards for the interoperability between different systems (from different vendors). This offers perspective to integrate alarms from multiple medical devices in a medical alarm infrastructure. This allows for hospitals to be more flexible in choice and composition, without sacrificing safety to deliver alarms adequately to the HCP. The multitude of components, design possibilities and involved parties means that the development of a single standard for the entire alarm infrastructure is still complex and a long way off.

Conclusion

Medical alarm systems must comply with the appropriate legislation (in the EU this is the MDR), if the intended use of the medical alarm infrastructure concerns monitoring of vital parameters of the patient. If variations in these parameters can pose a risk to the patient, the medical alarm system needs to be classified as a medical device with risk classification IIb. The alarm infrastructure can be certified as a whole, but it is also possible to build the infrastructure from separate components as long as each component guarantees interoperability, preferably complying with the ISO/IEEE 11073 SDC standard.

3. Current situation in the Netherlands and bottlenecks experienced when using medical alarm systems

This chapter is based on a literature review, workshops with caregivers, clinical engineers, and a workshop with patients.

3.1 What is the variation between departments in a hospital and between hospitals?

Patient monitoring and medical alarm systems are used in departments where HCPs need real-time information of the patient's vital parameters, such as heart rhythm, respiratory rate, oxygen saturation or blood pressure. These parameters are tracked over time using medical devices, that generate alarms if a threshold value is exceeded. This type of monitoring is for example used in the intensive care unit, the operating room, children's wards and delivery rooms where both mother and unborn child are monitored.

The guideline panel sent out a survey to all Dutch hospitals to gain insight in the current use and design of (distributed) medical alarm infrastructures. From the answers to the survey, it was concluded that not only alarms from patient monitoring systems but also alarms from perfusor pumps and ventilators are distributed in their medical alarm systems. Because the HCP is not always in the vicinity of the patient, many Dutch hospitals use additional technology, such as advanced ICT systems, which forward an alarm (via a wireless network) to a caregiver's mobile device. Internally, a hospital may even have multiple types of alarm systems for different care settings in the various departments and thus there may be a lot of variation in the systems and their components. It became clear that hospitals add components to an existing system at different moments in time, and that various components have difference maintenance and life cycles, hence complicating the replacement policy on such systems. In conclusion, there is a lot of variability with respect to the technical components, architecture design, implementation, quality and reliability of medical alarm systems in Dutch hospitals.

3.2 Which bottlenecks are experienced in medical alarm systems?

For years, alarm-related risks have been highly ranked on the international top 10 health technology hazards lists that are provide by the ECRI (6-8). Serious alarm-related risks are ranging from failures to detect a critical situation, for example in case of incorrect settings of the patient monitor; via alarms being lost in the system,

e.g. due to malfunctioning of technical components or incorrect handling of the alarm distribution system; to not responding to alarms in case of alarm fatigue of HCPs. Alarm fatigue may arise in situations where many vital parameters are monitored continuously. When alarms go off too often in non-actionable situations, the HCP may become desensitized and may not adequately respond to the alarms anymore (9). Thus, the chance of missing a clinically relevant alarm increases, leading to potentially unsafe situations (10) (8, 11-13).

From workshops and survey, the main bottlenecks from the patients' perspective, HCPs' perspective and technical perspective were identified and they are listed below.

Patients' perspective

Patients and their relatives want to receive adequate and safe healthcare. They indicate that they find it reassuring that medical alarm systems are used to alert a HCP in case of a critical situation by distribution of alarm signals. The biggest bottlenecks experienced by the patients are:

1. Alarm signals cause audible and visible signals in the patient's room near to the patient. This situation disturbs the patient who needs rest to recover, it disturbs their sleep and causes stress to patient and also his/her relatives and may have a negative impact on the patient's health situation. The patient usually cannot turn off the alarm. In rooms with multiple beds, the nuisance experienced is even greater because alarms from one patient are also disturbing the other patients and relatives in the room.
   It is important to limit sounds and lights near to patients. By automatically turning down an alarm sound or turning it off when the HCP is not in the room and by limiting flashing light signals in the patient's field of vision, the patient will be disturbed less often, and relatives are not unnecessarily worried.
2. Alarm settings may not match the patient's clinical situation, particularly if no patient-specific alarm settings are used. This may lead to under- or over-detection. The first may lead to critical situations, the latter to an alarm and thus sound overload. Both are not desirable.
   There is a need for adequate (personalized) alarm settings. To adjust the alarm settings, the HCP must be trained how to adjust them and have the authority to do so. Attention is needed to prevent over-monitor, thus to also choose to stop monitoring parameters if they are not considered relevant for clinical interpretation anymore, following the patient's needs during the clinical process.
3. The purpose of alarming and how alarms are handled by the HCPs are not always adequately explained
   A hospital admission is a stressful situation for both patients and their relatives. Stress can be increased by alarms of which the patient or the relative does not know the urgency or importance. The patient and relatives may also experience stress due to inconsistencies in alarm handling between HCPs (e.g. different response times) or changes of alarm limits without explanation.
   Appropriate explanation to the patient and his/her relatives of the purpose of monitoring and the way the alarm is handled by the HCP can reduce stress significantly. Particularly if alarms are seen remotely, it is desirable to explain to the patient and family that the caregiver is aware of all alarms and will act accordingly. The Dutch Patient Federation recommends supplying this explanatory information on the medical alarm system via various media; like a brochure with the basic explanation (in different languages), but also using graphics, video and/or oral explanation.
4. Monitoring using sensors attached to the patients can cause discomfort and also mobility constraints experienced by the patients. They can greatly disturb the patient's comfort and affect the patient's recovery. In addition, monitoring systems allow to view physiological parameters and alarms of multiple patients on the same display, and some patients see this as a violation of privacy.
5. There is a need for less obtrusive sensors and wireless sensors, provided that they are sufficiently robust. In addition, privacy aspects need to be considered in implementing medical alarm systems, choosing between the necessity for patient safety and privacy.

Healthcare professionals' perspective

In a critical care setting, highly complex care is provided, supported by a multitude of medical technologies. HCPs' tasks (care for the patient) are interrupted by secondary tasks, such as responding to alarms. Both technology as well as user interaction with a medical alarm system is complex and human factors play a major role (9, 14). When implementing medical alarm systems not only choosing robust technology is important, but

also the organization of the clinical processes, implementation strategy and the work culture. In particular, the large number of alarms that are often not actionable leads to an unnecessary burden on the HCP, who can experience stress and alarm fatigue as a result. Thus, alarm fatigue can pose a risk to the patient because there is less adequate response to alarms (6). Excess alarms may arise due to incorrect alarm thresholds with respect to the patient's clinical situation, to measurement errors or to a lack of robustness of the measurement itself.

The biggest bottlenecks experienced by HCPs are:

1. Uncertainty about responsibilities in the entire process of alarm handling and management.
2. It is important to explicitly state who is responsible for which task – both at the hospital level and at the department level. Think about the responsibilities of the doctor, the nurse, management but also of the support staff and/or alarm system supplier. Although it is not possible to develop one generic responsibility structure for all hospitals, the guideline panel recommends defining and document the responsibilities for the local situation in a hospital.
3. Too many non-actionable alarms occur. This situation worsens when the system has limited ability to set and filter alarm limits. When purchasing new medical alarm systems, it is important to choose a system that allows to adjust alarm thresholds to the patient's needs. The options for filtering alarm types on urgency must be included in the list of requirements. Training (at the start, but also period retraining) is needed to ensure that the HCP has sufficient knowledge on how to set alarm thresholds.
4. Uncertainty about how to escalate alarms if a HCP cannot act on the alarm immediately.
5. If a caregiver is nursing a patient and cannot respond to an alarm from another patient, the alarm signal should be forwarded (automatically) to an available HCP who can attend to the alarm (like a buddy HCP in the nursing unit). It is important to design a local process for adequate handling of the alarm signal for various possible care situations.
6. Insufficient (factual) insight into alarm management.
7. Many systems still lack a dashboard to analyze the number and type of alarms as well as their distribution. A dashboard is useful to optimize the alarm pressure in a unit to prevent alarm fatigue.
8. Systems are not well adjusted to support the care process.
9. Alarm urgency may be perceived differently by HCPs than by manufactures of the medical equipment: a critical alarm of a patient monitor may in clinical practice need a different urgency than a critical alarm from a perfusor pump. It is important that the medical alarm system allows for re-defining which type of alarms are necessary for adequate care for their patients and what actions should be taken by the HCP.

Technical perspective

The survey distributed among clinical engineers shows that technicians set high standards when purchasing new medical alarm systems. New systems should comply with applicable legislation (see section 2.3), however the engineers also stress that hospitals need to be allowed to replace the current used alarm systems gradually in order not to require immediate large costs for replacement.

The requirements for a medical alarm system and the individual components within the infrastructure are included in the Tool "Basic set of requirements for a (distributed) medical alarm infrastructure".

The biggest bottlenecks experienced by clinical engineers are:

1. Technical management can become complex, particularly for historically grown alarms systems consisting of separate components added over time. If the individual components have different lifetimes, replacement budget may be available at different moments in time.
   It is therefore important that hospitals have an up-to-date overview of the technical state of the medical alarm system as a whole as well as its individual components. In the rapidly changing ICT and healthcare landscape it is desirable to make a multi-year investment plan for the medical alarm system and its infrastructure.
2. The lack of full redundancy in many medical alarm systems, usually in one or a couple of components. A single point of failure design of individual components may result in a complete system failure and thus impose a risk to patients.
   High availability is critical for medical alarm systems. Backup systems for critical components that can take over its role directly are important, but redundancy may also cause unexpected problems because of the

complexity in interaction within the alarm system. The components, software versions for example, of medical alarm system and also the use of the ICT infrastructure needs to be well documented in order to provide adequate support in case of problems. A technical risk assessment needs to be performed multidisciplinary in consultation with suppliers and the various technical departments. Possible failure modes of the system as well as in the user processes should be identified and risk mitigation measures proposed. Emergency procedures need to be in place and need to be known by HCPs in case of a system failure (and need to be regularly trained).

3. Lack of real-time insight on the functioning of the full alarm system.
   When transmitting alarm signals, there is not always an acknowledgment of receipt of alarms between send and receive components in the medical alarm system. As a result, alarms may get lost without the user being informed. Timely identification of problems is needed to adequately warn the user but also the clinical engineers in case of problems. For this, monitoring of the functioning of all components in the medical alarm infrastructure end-to-end is necessary, called 'medical alarm infrastructure monitoring, or chain monitoring'. Performance of this infrastructure monitoring system should also be checked during maintenance.
4. Uncertainty about the roles and responsibilities of involved technical support services.
   Since alarm system often consists of building-related parts, medical devices and ICT components, usually several technical support services are involved in the management and maintenance of medical alarm systems. It is not always clearly documented who is responsible for which part of the technical aspects management and who should respond if there is a malfunction. To ensure a safe system and adequate service, the responsibilities for support for each part of the medical alarm system should be well documented. A hospital may decide to outsource the technical support and maintenance. In this case, clear agreements for support between hospital and supplier are essential.

Conclusion

Different clinical care situations may need different monitoring systems, varying in technical design, complexity and possibilities. The guideline panel recommends hospitals to identify bottlenecks in their local situation and to conduct a risk assessment in a multidisciplinary group consisting of HCPs (doctor and nurse) as well as clinical engineers, both on clinical and technical aspects of the medical alarm system. Users must be aware of local emergency procedures in case of a malfunctioning system or system component. It is important that good maintenance and support services are defined and documented for the medical alarm system and its components. It is desirable to receive input from patients and their relatives about their experiences with medical alarms during their stay at a care unit in to learn the patient's needs concerning medical alarm systems. Finally, hospitals are advised to make a multi-year investment plan for all components in the medical alarm system to ensure continuity of usage/use.

4. Optimal medical alarm infrastructure: advice for process design and technical design

4.1 What are the requirements and wishes for the medical alarm infrastructure?

Patient perspective

The patient wants a safe and silent alarm infrastructure that gives reliably alarms the caregiver (and not disturbing the patient) about the state of the patient. Several requirements are already mentioned in section 3.2. Developments towards a reduction of alarms and their sounds and lights, e.g. individualized rather than generic alarms for a whole population, are encouraged but must of course be safe. In addition, patients individually may have different needs on the information they like to receive. The Dutch Patient Federation stimulates the development of 'family centered care' monitors, in which the patient and his/her next of kin can chose which information remains visible to them on the screen when the healthcare provider/professional is not in the room. However, this functionality is not yet available. In particular, the representatives of patient organizations emphasized the importance of providing information to the patient and his/her next of kin (see section 3.2). The patients and their relatives like to receive proper information about the medical equipment that is used and the need for it to alarm. For children, animations or illustrations may help. Explanation that an alarm is always seen by an HCP, even if they are not in the room, and why an alarm not always requires HCPs to

come to the room instantly is deemed very important to avoid unnecessary anxiety among patients and their relatives. Patients would like to see confirmation when the caregiver has seen an alarm, so they don't have to worry about this. Patients and relatives also find it important that it is not openly visible to the entire department how the patient is doing. Finally, patients would like to have their resting times taken into account in the care process, e.g. to not perform disturbing measurements (like non-invasive blood pressure) if possible. The industry is asked to develop new sensors that are more comfortable and, for example, wireless so they are less restrictive of the patient's range of motion.

HCP perspective

HCPs indicate that to them the most important requirement is that they can safely rely on the system, with a high uptime and no failures. Should the infrastructure nevertheless fail partially or completely, timely informing the HCP is essential, so that the emergency procedure can start immediately. It is important that a priority (for example in the form of color or sound) can be set for each type of alarm. There must be a minimum of non-actionable alarms to avoid alarm fatigue. HCPs prefer medical alarm infrastructure that can be tailored to their individual tasks: for example, nurses want information on the patients they care for, while a doctor may like to see an overview of all patients on the ward. Alarms should come with additional information, like urgency and value of vital signs at that time, or even, for example, a camera view on the patient, to gain immediate insight into the patient's clinical condition at the time of the alarm.

Alarms preferably follow the HCPs: the alarm remains in the room as the HCP is present, and when the HCP leaves the room, the alarm is automatically sent to the mobile device of the HCP and no longer goes off at the patient’s bedside. Furthermore, the HCP should be able to alert a colleague directly for assistance, using the same alarm system. It must be possible to easily transfer all alarms to a colleague to take over alarm handling in case care tasks prevent adequate alarm response. The settings in the system and the assignment of patients to the HCPs must take place in a simple manner. When designing the alarm infrastructure and work process, hospital-wide considerations must also be considered, for example rules about hygiene when using mobile devices.

Technical perspective

From a technical perspective, a medical alarm infrastructure that is reliable with a high availability (‘uptime’) is most important. The technical specialists indicated in the survey that systems must comply to applicable legislation (MDR), and if intended for medical alarms of vital parameters, they must meet the classification for patient monitoring (in EU this means CE with risk classification IIa or IIb).

In addition, it is required that components in medical alarm infrastructure are interoperable, preferably meet the standard for interoperability (IEEE 11073 SDC), which better guarantees the reliable transmission of alarms in the infrastructure. For high uptime, redundancy of critical components in a medical alarm infrastructure is advised.

It is also considered important to have options for analyzing alarms (dashboards), for filtering alarms before transferring them to mobile devices of healthcare professionals and possible other methods to distribute alarms in different ways. Moreover, it must be possible to perform regular updates of the components in the medical alarm infrastructure (e.g. to meet the information security requirements), without impacting the care process and without long downtimes. It is desirable to have a development and test environment in which upgrades (or alarm filter settings) can be tested without endangering the 'real' clinical environment to implement upgrades and changes in a safe way.

Conclusion

There are many requirements for medical alarm systems and their infrastructures, but not all requirements and wishes can be met currently in all hospitals because of already existing alarm infrastructures and the lack of budget to replace them immediately. When purchasing a new (or part of a) medical alarm infrastructure, it is recommended to define a set of requirements, by a multidisciplinary team of HCPs and clinical engineers, taking into account the patient population, local work process and local circumstances. The guideline panel has developed the tool “Basic set of requirements for a (distributed) medical alarm infrastructure” that can be used to define the local set of requirements. It should be noted that the tool is giving requirements only for the

alarm system aspects, of course other functional requirements for the separate components in the system (such as on a clinical patient monitor) are therefore not included and should be then defined locally.

4.2 How should the design of the medical alarm system be adapted to the intended care scenario?

A medical alarm system and its infrastructure will have to be adapted to the needs of specific care departments (15). For an intensive care with single-person room care, more components may be included in an alarm infrastructure than in an open bay general ward. The care scenario will determine the work process, ward design and technical requirements and components, as illustrated in Figure 3. There is no 'one size fits all'.

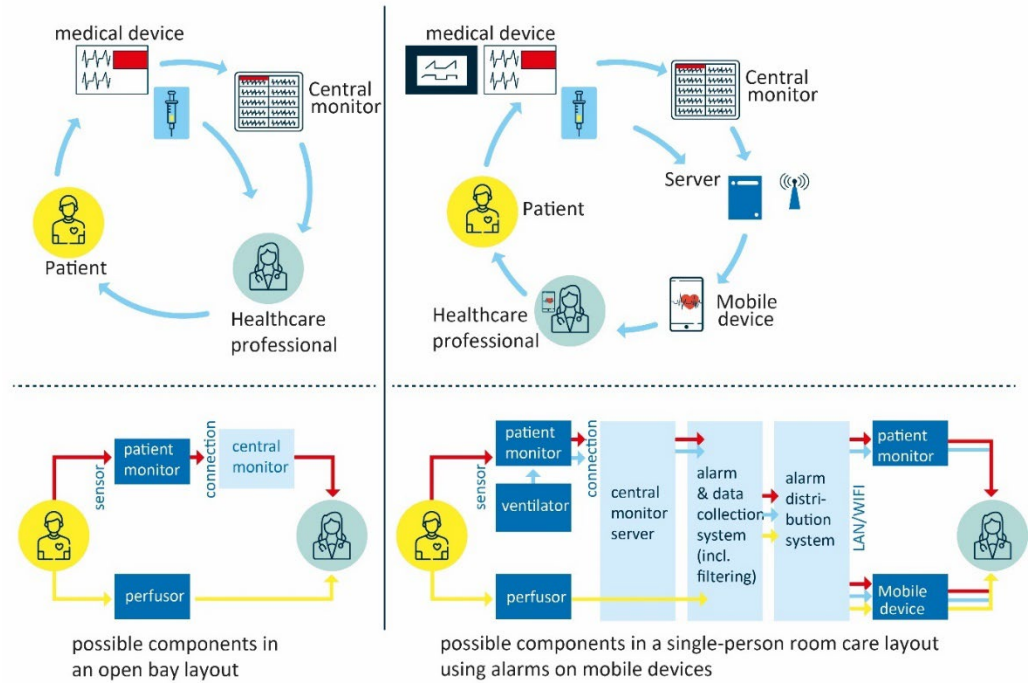

Figure 3. Schematic representation of the components of the alarm infrastructures in the two care scenarios/settings 1B and 1D from figure 1.
The left part of the image shows an example of an open bay ward in which the only medical devices in the alarm system are the patient monitor, the perfusor pumps and a central post. The alarm from the patient monitor is sent to a central monitor. The perfusor pump alarm can immediately be noticed by the HCP (for example as an audible alarm). The HCP can then respond to the alarm by going to the patient. In the block chain (lower part of the figure) are thus three technical components visible.
The scenario on the right shows an example of a more complex alarm system as often used in a single-patient room care setting. In this example, a ventilator is connected to a clinical patient monitor to transfer the alarms. Alarms from the ventilator and monitor are sent then to the central monitor and via the ICT system to a mobile device of a HCP. For the perfusor pumps, a direct connection to the alarm distribution system is shown. Such a complex infrastructure requires more technical components. Central is the alarm collection and distribution system (possibly consisting of several servers) to collect, filter and distribute the alarms to the HCP via Wi-Fi or LAN.

<u>Conclusion</u>

The care scenario and work process determine the design of the medical alarm system and its architecture. The technological system needs to be designed in such a way that it fits the clinical requirements and optimally guarantees patient safety. The choice of components of the medical alarm infrastructure should depend on choices in the intended process of alarm handling and the local possibilities, such as integration within the ICT infrastructure.

4.3 How can the medical alarm care process be organized optimally and safely?

Many publications are available on improving alarm handling in the healthcare process, with a focus on the improvement of the organization of 'medical alarm management'. Such as the ECRI Alarm Safety Handbook (8), various reviews (16-18) and (many) other scientific articles (16-22). The ECRI Alarm Safety Handbook (8) contains a practical strategy and tools to increase alarm safety. It provides strategies to prevent alarm fatigue

and to reduce the number of alarms. Alarm-related risks can be reduced by, among other things, organizational, technical and care process measures. Effective measures mentioned in ECRI and mentioned papers include:

- Deploying the correct sensors or disposables and the correct protocol of application.
- Adequate setting of the patient monitor and alarm urgency, for example by using protocols for patient-specific alerting.
- Training of users in the correct use of the medical alarm infrastructure.
- Taking workflow aspects into account, like positioning critical patients closer to the central point of HCPs.
- Preventing "over-monitoring" and define when the monitoring of physiological signals or the entire monitoring may be stopped.

A multidisciplinary team may be needed to analyze alarms and workflow in a department and develop a proposal for improvement in alarm management, taking into account department-specific scenarios and patient categories. By including feedback from patients, their needs can be taken into account, such as minimizing disturbances of the patient and their loved ones.

Conclusion

The work process needs local optimization in every department by using a PDCA-cycle, by a multidisciplinary team. From literature, but also from other hospitals valuable input can be gathered to include in the PDCA-cycle. Work processes must be optimized or safe and effective medical alarm management. The panel has developed a tool **"process guide for using medical alarm systems safely"** for this purpose, which can be used to check which local processes are already present and which can be implemented to improve safety. The guideline panel recommends using the ECRI Alarm Safety Handbook as a starting point.

5. Conclusions and recommendations

The guideline panel has carried out an extensive analysis of medical alarm systems and their infrastructure and their current use in Dutch hospitals. It may be concluded that there is no uniform best solution. The design of an alarm system depends on the local situation and therefore always requires a tailor-made adaptation for optimal performance, though it was possible to provide a general strategy to develop a well-designed medical alarm infrastructure. To be able to use medical alarm systems safely, the entire process around patient monitoring and alarm handling must be analyzed and optimized. A tool to support this is found in the "Process guide for using medical alarm systems safely". In addition, the safety of the current medical alarm systems can be increased by technical measures. This may require the purchase of a new system (or components). The guideline panel has developed a tool "Basic set of requirements for a (distributed) medical alarm infrastructure" that can be used when purchasing new systems.

The main recommendations (summarizing all recommendations from the previous chapters):

1. Prevent an excess of (clinically non-actionable) alarms that can cause anxiety for the patients and those close to them. Correct deployment of patient monitoring is required, by monitoring a minimum set of vital parameters (instead of a maximum set), using clinically relevant limit values for the individual patient; and monitor only during the period that this is medically necessary.
2. Inform patients and their relatives about the medical equipment, the necessity and meaning of alarms. Explain how alarms are seen by the HCP and why a HCP does not always come immediately to the room in the event of an alarm. Discuss with the patient any questions they have about the alarms.
3. Investigate bottlenecks of using medical alarm systems in the local situation, using the information from Chapter 3. Conduct a risk assessment with a multidisciplinary team to formulate risk-reducing measures. These can be both process-oriented and technical. Make sure to choose an adequate technical design for the medical alarm infrastructure and implement adequate work processes.
4. Optimize – in steps – the work process in each department by means of a PDCA cycle, in a multidisciplinary team. Include the input from patients. Use the tool "Process guide for using medical alarm systems safely".
5. Draft a multi-year investment plan to replace medical alarm equipment in a timely manner. For a new system to be purchased, draft a set of requirements with a multidisciplinary team of HCPs and clinical engineers, and use the Tool "Basic set of requirements for a (distributed) medical alarm infrastructure".

6. When using medical alarm infrastructures, regard these as a medical device and ensure that these devices comply with the applicable legislation (in Europe this is the Medical Device Regulation (MDR)). In the case of critical care patient monitoring a CE with risk classification IIb is compulsory.

References

1. Alam N, Hobbelink EL, van Tienhoven AJ, van de Ven PM, Jansma EP, Nanayakkara PWB. The impact of the use of the Early Warning Score (EWS) on patient outcomes: a systematic review. Resuscitation. 2014 May 01;85(5):587-94.
2. Medical Device Regulation - regulation (EU) 2017/745, (5th of April, 2017).
3. International Standard I6. Medical Electrical Equipment— Parts 1–8: general requirements for safety—collateral standard. General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. 2005. Report No.: 60601-1-8.
4. International Electrical Commission. Application of risk management for IT-networks incorporating medical devices - Part 2-5: Application Guidance - Guidance on distributed alarm systems. 2013.
5. Kasparick M, Schlichting S, Golatowski F, Timmermann D. New IEEE 11073 Standards for interoperable, networked Point-of-Care Medical Devices. Conf Proc IEEE Eng Med Biol Soc. 2015 Aug;2015:1721-4.
6. Keller JP,Jr. Clinical alarm hazards: a "top ten" health technology safety concern. J Electrocardiol. 2012;45(6):588-91.
7. ECRI institue. TOP 10 HEALTH TECHNOLOGY HAZARDS, 2014
8. ECRI Institute. The Alarm Safety Handbook; 2014.
9. Edworthy J, Hellier E. Alarms and human behaviour: implications for medical alarms. Br J Anaesth. 2006 Jul;97(1):12-7.
10. Sendelbach S, Funk M. Alarm fatigue: a patient safety concern. AACN Adv Crit Care. 2013;24(4):378-8.
11. Jones K. Alarm fatigue a top patient safety hazard. CMAJ. 2014 Feb 18;186(3):178,4696. Epub 2014 Jan 13.
12. Kenny PE. Alarm fatigue and patient safety. Pa Nurse. 2011 Mar;66(1):3, 22.
13. Ulrich B. Alarm fatigue: a growing problem. Nephrol Nurs J. 2013;40(4):293, 346.
14. Lange K, Nowak M, Lauer W. A human factors perspective on medical device alarms: problems with operating alarming devices and responding to device alarms. Biomed Tech (Berl). 2016 April 01;61(2):147-64.
15. Koomen E, Webster C, Konrad D, van der Hoeven J, Best T, Kesecioglu J, Gommers D, de vries W, Kappen T. Reducing medical device alarms by an order of magnitude – a human factors approach. Anaesthesia and Intensive Care. 2020.
16. Bach TA, Berglund L, Turk E. Managing alarm systems for quality and safety in the hospital setting. BMJ Open Qual. 2018;7(3):e000202.
17. Kane-Gill SL, O'Connor MF, Rothschild JM, Selby NM, McLean B, Bonafide CP, et al. Technologic Distractions (Part 1): Summary of Approaches to Manage Alert Quantity With Intent to Reduce Alert Fatigue and Suggestions for Alert Fatigue Metrics. Crit Care Med. 2017 Sep;45(9):1481-8.
18. Winters BD, Cvach MM, Bonafide CP, Hu X, Konkani A, O'Connor MF, et al. Technological Distractions (Part 2): A Summary of Approaches to Manage Clinical Alarms With Intent to Reduce Alarm Fatigue. Crit Care Med. 2018 01;46(1):130-7.
19. Curry JP, Jungquist CR. A critical assessment of monitoring practices, patient deterioration, and alarm fatigue on inpatient wards: a review. Patient Saf Surg. 2014 Jun 27;8:29,29. eCollection 2014.
20. Paine CW, Goel VV, Ely E, Stave CD, Stemler S, Zander M, et al. Systematic Review of Physiologic Monitor Alarm Characteristics and Pragmatic Interventions to Reduce Alarm Frequency. J Hosp Med. 2016 Feb;11(2):136-44.
21. Konkani A, Oakley B. Noise in hospital intensive care units--a critical review of a critical topic. J Crit Care. 2012 Oct;27(5):522.e1,522.e9.
22. Varisco G, van de Mortel H, Cabrera-Quiros L, Atallah L, Hueske-Kraus D, Long X, et al. Optimisation of clinical workflow and monitor settings safely reduces alarms in the NICU. Acta Paediatr. 2020 October 13.