Smart patches in mass-casualty incidents

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Abstract. The favourite Macedonian greeting for birthdays and new births is: "Be alive, healthy and happy". Mass-casualty incidents severely endanger them all mainly due to the unavoidable overcrowding where treating of one patient might threaten the welfare of those who are also waiting for treatment. The prevention of such situations during emergencies and disasters is fixed by efficient emergency triage process. The triage identifies life threatening conditions and their severity and determines whether the patient needs an urgent intervention or not. Objectivity of judgment is crucial and depends primarily on the patients' heart rate, respiratory rate, oxygen saturation, and blood pressure. Smart patches keep track of all these vital parameters. They are an affordable emerging technology remotely connected to healthcare institutions. To be massively used, their drawbacks need to be carefully identified and reduced as much as possible. The goal of our research was to detect which are the major ethical challenges of this emerging technology and to propose solutions that will avoid them. To accomplish the goal, four research questions were identified, thoroughly reviewed, and the results of the ethical analysis were highlighted for each question. They embrace privacy, security, reliability, responsibility issues and the usefulness of smart patches. Based on the review, we propose recommendations for the development of new patch-like devices that will support the efficient detection of respiratory and cardiovascular changes of triage-labelled victims, without interfering with human rights and dignity.

Keywords: Bio-medical ethics, Mass-casualty incidents, Wearable devices

1 Introduction

In the last years, everyday life has become very fragile. Recent European floods; deadly Asian, Peruvian and Hispaniola earthquakes; North India landslides; North Pacific and Indian Ocean tsunamis; and the COVID-19 pandemic have posed significant risks to life. They place "a significant demand on medical resources and personnel" (Lee, 2010). If early diagnosis is crucial to prevent organism failure and death caused by the virus (Zhai et al, 2020), efficient triage systems are critical to prevent mass-casualty incidents due to emergencies and disasters (Bazvar et al, 2020). There are many different triage systems and methods. START (Simple Triage and

Rapid Treatment) is a simple system that is sufficiently effective to be used by lightly trained emergency response personnel (Gebhart and Pence, 2007).

Innovations in wireless communications and low-power electronics have contributed to the creation of effective wearable medical devices that support monitoring of vital signals (Khan et al, 2016). Fabricated of flexible and lightweight materials, they are less irritable for people who wear them. The results obtained from their sensor systems are wirelessly connected with the healthcare institutions.

Many new multifunctional smart patches have proven their efficiency, accuracy and relevance for advanced healthcare (Hwang, 2018). Their diagnostic abilities can lead to more personalized care, and give instant feedback of patient's condition, before it becomes serious and life threatening. Faster the reaction is, greater are the chances to safe victim's life.

Unfortunately, frequent malware attacks against wireless sensor networks (Queiruga-Dios, 2016) and severe ransomware attacks against hospitals (Spence, 2017) can seriously endanger the security and reliability of health monitoring, threatening the health of already vulnerable patients. Apart from security problems, privacy of medical data has also been compromised (Ching and Singh, 2016). These problems affect smart patch devices similarly to all other wearable devices.

To overcome their occurrence, particularly during mass-casualty incidents, considerable attention should be paid to invent technical measures that will minimize the risk of threatening patient's life, instead of saving it.

Discrimination in providing a medical care is another problem (Williams, 2019). This is the first ethical challenge of the prospective emergency triage. Medical and biomedical ethics should "respect for autonomy, beneficence, nonmaleficence and justice" (Aacharya, 2011).

Based on these initial premises, the goal of our research was to investigate the following questions:

1. Can continuous monitoring of the essential health parameters become a privacy and security threat for their users?
2. Do smart patch devices ethically challenge the emergency triage more than traditional medical devices?
3. If smart patches fail to accurately present the health condition of the triage labelled victims due to technical or cyber challenges, who will be held liable for negligence?
4. If smart patches are approved in the triage process, who and how should make the decisions whether the triage-labelled victim can use them or not?

To answer the defined research questions, smart medical patches, their advantages and disadvantages were thoroughly researched, aiming to define technical and ethical recommendations for developing new patch-like devices that will be accurate, reliable and efficient. Thanks to their wide availability and affordable price, these medical devices will be able to reduce the detection time of respiratory and cardiovascular changes of the triage labelled victims, which are crucial in high-stress situations, such as mass-casualty incidents.

2 Related work

Emergency department triage aims to improve the quality of emergency care by quickly sorting patients to determine priority of further evaluation of care (Aacharya et al., 2011). During mass-casualty incidents, it is affected by massive overcrowding, thus it is crucial to decide who needs immediate treatment and avoid the two extremes: undertriage or underestimation of the severity of the patient's condition, and over-triage, i.e. assigning a higher acuity rating than necessary (Fernandes et al., 2005).

Depending on the observable vital signs, demographics, medical history and the injured part of the body, patients are classified with one of the five-level triage categories: resuscitation, emergent, urgent, semi-urgent, and non-urgent (ClayWilliams, 2020). Within the triage system, they get a visible triage tag with four colours: green for minor injuries; yellow for non-life threatening injuries that can get a delayed treatment; red for life threatening injuries that need an instant treatment; and black for expected death that need a pain medication only (Coleman et al., 2011).

START is a simplified triage strategy that is suitable for mass-casualty incidents. It is designed to identify problems that could cause death to the patient within one hour, typically breathing problems, head injury or significant bleeding. The next step is the need of observing if the victim is hemodynamically stable (if the blood pressure and heart rate are stable) before he/she is transported to a hospital. The idea is to use a specific design of a smart patch that includes electrocardiogram (ECG) and photoplethysmogram (PPG) sensors, providing easy calculation of heart rate, respiratory rate, oxygen saturation (SpO_2), and blood pressure (Lehocki et al, 2021). To be massively used, it has to be available, cheap, reliable and with few side effects. (Santos et al, 2018).

During some life-threatening situations, blood circulation is limited to the torso and head and thus monitoring blood oxygenation from finger can result in corrupted blood saturation reading due to poor blood circulation (Schreiner, 2010). Integration of PPG sensor into patch device placed on the chest reduces the delays of SpO_2 measurement by several seconds comparing to finger-based sensor, which is of great importance in emergency situations.

In 2014, IEEE standard for wearable cuffless blood pressure measuring devices was introduced (IEEE, 2014). They are embedded in the Internet of Medical things applications, enabling flexible, accurate and continuous and non-invasive blood pressure monitoring (Ibrahim & Jafari, 2019).

Smart patches, as wearable electronics can be equipped with different biosensors and can be used in different situations. They provide an opportunity for everyone to own personal healthcare systems. Most of the smart patches are self-powered with wireless transmission ability to monitor the temperature and motion status of individuals (Shi, 2017).

3 Ethical challenges of medical smart patches

Following four subsections elaborate the research questions defined in the introduction of this paper in more detail aiming to deduce how to decrease the probability of future occurrence of the perceived ethical challenges of medical smart patches used in the emergency triage system.

3.1 Can continuous monitoring of the essential health parameters become a privacy and security threat for their users?

Collecting data is an issue that needs special attention. Whenever possible, the data is kept locally and used with no recording. The main approach in developing multisensory wearable patch-devices is to maintain the functionality within the device. If the parameters can be obtained using the patch memory and processing power, no data is recorded but only their momentarily heart and respiratory rate values, needed for the triage process. However, the remaining two parameters, SpO_2 and BP, need further data processing on a mobile device – tablet or on a remote server. The first approach uses a Bluetooth connection to the sensor and the tablet serves as a platform to the model for SpO_2 and blood pressure estimation, so the data stay locally on the tablet (Fedor, 2021).

Privacy and confidentiality of medical devices should be carefully safeguarded to avoid accidental disclosure of sensitive health information (Berlan and Bravender, 2009). Unfortunately, most wearable medical devices keep the collected data in their original form without any encryption (Vijayalakshmi et al., 2018). They continuously monitor the changes of patient’s condition and send them remotely to computers in medical institutions for further processing (Vijayalakshmi et al., 2018).

Remote monitoring systems are still not appropriately secured allowing access to transmitted sensitive data and enabling their interception, generation or modification (CISA, 2021). Sun et al. (2018) claim that healthcare organizations are usually indifferent about security and privacy, forgetting that they produce a vast amount of highly sensitive data (Sun et al., 2018). According to their review, major privacy and security challenges are related to insecure networks, rather light security protocols, and insufficiently protected data sharing. To prevent capturing of sensitive medical data, they suggest encryption in the phases of their storing, accessing, searching and transferring. Additionally, they recommend trusted third party auditing and data anonymization. Their impression that “more successful exploration is needed” is vital for the embedded remote medical devices.

How do poor protection of stored data and vulnerable communication affect smart patches? Smart patches are self-adhesive or tattooed on patient’s skin, thus they cannot be accidentally lost or stolen. This is their great advantage to traditional wearable medical devices. However, they use the same data transfer MQTT protocol for remote communication as IoT (Montgomery et al., 2018). The authentication is either optional or not encrypted, making the protocol “highly susceptible to man-in-the-middle attacks” (Combs, 2022). Since 2014, around 90 vulnerabilities of this protocol have been identified (Combs, 2022). This might be one of the major reasons why in September 2021, more than 60 million fitness tracker records of Apple and Fitbit users were compromised, revealing many private non-medical information (McKeon, 2021).

Vulnerable data transfer protocols and observed risks of massive data breaches prove that continuous monitoring of essential health parameters might cause accidental disclosure of confidential medical information that are collected in smart patches. This undesirable challenge is additionally amplified by the fact that most patients trust that their personal information is well protected (Cilliers, 2019).

Synergy of inevitable continuous monitoring of the triage-labelled victims, privacy and security risks and patients' lack of awareness about these risks might obstruct massive use of smart patches during mass-casualty incidents.

3.2 Do smart patch devices ethically challenge the emergency triage more than traditional medical devices?

The major challenge of mass-casualty incidents is the unavoidable overcrowding. It inevitably causes delays in providing care or prioritization of some patients, which threatens the welfare of clinically urgent patients who have wait for a treatment (Aacharya et al., 2011). Wearable medical devices, including smart patches are part of the pre-hospital triage and they are crucial to determine patients' flow when clinical needs exceed capacity of emergency departments (Aacharya et al., 2011). Their obligation is to comply with the four principles of biomedical ethics: autonomy, nonmaleficience, beneficience and justice (Hall & Smithard, 2021).

The principle of respect for autonomy is the right of a patient to accept or reject medical treatment, even when the patient has lost consciousness (Gillon, 1994). The decision is based on patient's personal values, fears and beliefs (Aacharya et al., 2011). To overcome the problem, good physician - patient communication should be established, which is difficult in emergency cases. Those patients who accept medical treatment usually become impatient, hindering the treatment of other patients and challenging the principle of nonmaleficience.

Nonmaleficience can be simplified with the principle "do no harm", and it is part of the Hippocratic Oath (Aacharya et al., 2011). In overcrowded mass-casualty situations, the obligation of emergency department is to provide the reasonably best care without discrimination and ill intent from the medical staff. Unfortunately, high stress situations usually worsen patients' psychological state, which includes "stress, fear, feeling neglected or not being taken care of" (Aacharya et al., 2011).

Beneficence is also part of the Hippocratic Oath and represents a moral obligation to contribute to the benefit and well-being of people (Aacharya et al., 2011). One of the main challenges of this principle in the mass-casualty situation is overtriage, i.e. overestimation of the urgency and incorrect prioritization of less urgent patients to those who need more urgent care. Overtriage triggers inefficient use of medical staff and resources, increasing the cost and reducing the effectiveness of urgent care.

Justice is related to distributive justice realizing the ethical values of equality, utility and priority to the worst-off (Marlink, 2017). Although triage systems strive to equally and justly distribute all the resources, in overcrowded situations, patients will get “a fair share based on appropriate criteria and principles” (Aacharya et al., 2011).

Review of metrological properties of wearable medical devices discovered that there is still not a standard test protocol for their validation (Cosoli et al., 2020). Accuracy of wearable heart rate monitors in cardiac rehabilitation is inferior to accuracy of clinical electrocardiographic monitors (Etiwy et al., 2019). Additionally, they may be affected by transmission failures caused by “communication channel disconnection, power loss, power off, and interruption of user biometric information sensing” (Lee, 2021). Finally, wearable devices are prone to failures (Koydemir, 2018).

These reliability problems significantly affect the four principles of biomedical ethics. Although autonomy is not explicitly disturbed, nonexistence of an accurate information about patient’s health condition, if such an information exists, seriously devastates the remaining three principles: nonmaleficience, beneficence and justice. Autonomy depends on the patient’s awareness of own health state. All the data stored on medical smart patches are accessed by the clinicians only (GlobalData, 2109). It means that patients do not know their current state. It is actually a double-edged sword: on one hand, lack of knowledge about a critical health state keeps the patient calm and prepared to wholeheartedly collaborate with the emergency department, on the other, lack of information affects the feeling of helplessness and increases panic, even when there the condition is not life-threatening.

It is extremely difficult to determine whether medical smart patches ethically challenge the emergency triage more than the traditional ones. They are still in their infancy, and their reliability is still developing. Their major advantage is that they are affordable, widely available and accurate enough to support the emergency department triage and reduce overcrowding of mass-casualty incidents.

3.3 If smart patches fail to accurately present the health condition due to technical or cyber challenges, who will be held liable for negligence?

Nash (2021) examines the liability threats resulting from smart devices hacking emphasizing the lack of comprehensive legislative framework to improve their security. He claims that many manufacturers deliver solutions with embedded security vulnerabilities (Nash, 2021). He also examines product liability associated with product failures or defects, stressing that “failures in technology can result in direct physical discomfort, harm and mortality” (Nash, 2021).

Liability of medical smart devices in Europe is regulated according to Regulation 2017/745 (EUR-Lex, 2017). Although not explicitly stated, liability of smart patches, which use nanoparticles refers to manufacturers. According to this regulation “such devices should be subject to the most stringent conformity assessment procedures” (EUR-Lex, 2017). Together with manufacturers, all stakeholders in the supply chain may also be subject to liability.

Typical side effects of wearable devises to patients’ health include: headaches, dizziness, discomfort, and musculoskeletal disorders (Xue, 2019). None of these symptoms have been registered in smart patches. Due to their minuscule dimensions, safety concerns embracing awkward postures, forceful exertions, physical fatigue, and mental vibration are not applicable to smart patches (Schall et al., 2019). A small problem can be the durability of the sensor and the risk of damaging the smart patch by sweating. Whenever failures occur, smart patches create a potential risk of harming patients (Parimbelli, 2018). Their medical liability in the emergency triage predominantly refers to manufacturers and to medical staff. Manufacturers include knowledge engineers, system developers and maintenance engineers. Medical staff consists of physicians, nurses, and the hospital that is responsible for monitoring the results. For communication failure, responsibility passes on the network service provider. In all these examples, the patient is excluded. The patch is attached to the patient's chest while the patients are in need of medical attention. The patch can be used only if it becomes a part of an emergency medicine protocol, so it is agreed upon the utilization of the patient's data. Patients do not interact with the patch, unless they intentionally remove or destroy them. In such case, they use their autonomy right to refuse medical care, and are therefore no longer part of the emergency triage.

3.4 If smart patches are approved, who and how should make the decisions whether the triage-labelled victim can use them or not?

In the beginning of COVID-19 pandemic, most health systems prompted rapid transition towards virtual care. Wearable smart medical devices played a vital role in self-diagnosing of coronavirus and enabled observing of the health condition of people with visible signs and symptoms. During this massive and long-lasting mass-casualty incident, people with mild or moderate symptoms managed to recover without hospitalisation, preventing the instant collapse of health care system. They could rely on the devices they already had or purchased online. The only prerequisite for such brave decision was the ability to get access to available medical smart devices.

Similarly, to most wearable accessories available on the market, medical smart patches are affordable, so the first prerequisite for their widespread use during masscasualty incidents is met (Omerov et al. 2021). Their penetration is still limited to developed countries, mainly due to network availability and regulatory constraints. However, it is expected that global patient monitoring market will increase tremendously, with a projected value of 30 billion US$ by 2026 (Businesswire, 2022).

Although used by almost one quarter of US population, very few wearable medical monitoring technologies are FDA-approved (Phaneuf, 2022). It is expected that their compliance with existing legislation will soon increase, enabling their broader adoption for real-time monitoring of health conditions, which is a key requirement for improving the survival rate during mass-casualty incidents.

If they are approved, the decisions whether the patient can use them or not should be made without introducing any kind of discrimination (Camporesi & Mori, 2021). According to Montgomery et al. (2018), profiling algorithms and techniques for selecting the eligible candidates and usually biased, enabling discrimination on the basis of "ethnicity, gender, sexual orientation, age, community, or medical condition". During mass-casualty incidents, biased profiling methods should be either avoided as much as possible providing all people with an equal opportunity for real-time monitoring and urgent medical treatment, whenever their health is endangered.

High affordability of medical smart patches makes every person an eligible candidate for their use. If affected people are mentally able to make their own decisions, they should decide whether to get the smart patch or not, using their principle of autonomy (Zdravkova, 2017). Otherwise, the decision should be made by their relatives, if any, or by the medical staff, obeying the principle of beneficence and justice, which is guaranteed by the triage protocol of smart patches (Jaigirdar et al., 2019). It will guarantee the right to equality and non-discrimination.

4 Conclusions

In the coronavirus era, patient monitoring market has significantly increased. Smart medical devices have supported the health sector, preventing exceeding of hospital resources. They enabled real-time monitoring of various physiological signals.

Smart patches are affordable wearable sensor-based devices used in the medical industry. They are integrated into the wider concept of Internet of Medical Things (IoMT) and consequently, experience many technologies and user-related concerns and challenges, embracing privacy, security and reliability barriers (Loncar-Turukalo et al., 2019). So far, these challenges obstruct the massive adoption of smart wearables. Hopefully, several technological giants started investing in the creation of accurate, reliable and affordable smart medical devices. They are experienced to apply the four principles of biomedical ethics by design.

Privacy and security protection will be significantly improved by developing a more sophisticated data transfer protocol for remote communication. In such case, continuous monitoring of the essential health parameters will not harm privacy and security of collected and transmitted medical data.

Additionally, to protect the patients, a written informed consent should be signed by the patient or by the personal representative (Nakikj and Mamykina, 2017). The signed form is a legal document that will keep the physicians in the loop and let them go ahead with the treatment.

Standardisation of smart wearables will contribute to their higher reliability. It should be supported by innovative technologies, inventive materials and highly developed deep learning methods. The synergy between various technologies embedded in the creation of these devices will bypass the most common software bugs and hardware failures. They will gain more trust, which will contribute to faster approval by legal authorities. In such case, manufacturers will be obliged to obey the legal norms and reduce the risk of liability challenges.

By reducing multiple technological barriers, smart patches will become a reliable partner in the emergency triage systems. They will mitigate the inevitable panic level during mass-casualty incidents. Relying on their diagnostic power, health care system will be relieved without initiating any ethical challenges. Supported by new protocols, they will provide “the right care, at the right time, via the right medium” (Croymans et al., 2020).

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