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PAPER

Designing an Ethical and Secure Pain Estimation System Using AI Sandbox for Contactless Healthcare

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ABSTRACT

Pain estimation in patients having communication difficulties is vital for preventing adverse consequences such as misdiagnosis, delayed treatment, and increased suffering. Traditional pain assessment tools relying on observer-based ratings and patient self-reporting are hampered by subjectivity and the need for continuous human monitoring, which have the potential to lead to inaccurate or delayed pain estimation. This paper presents an extensive literature review, a conceptual framework, and a systematic procedure for helping researchers develop a contactless, multimodal pain estimation system that leverages AI-based automation of standard pain assessment tools and scales within an AI sandbox environment. Our proposed concept aims to improve the efficiency of traditional pain estimation systems while reducing subjectivity and physical contact. This approach offers potential benefits, such as more accurate and timely pain assessment, reduced burden on healthcare professionals, and improved patient experiences. Moreover, the integration of the AI sandbox allows researchers and developers to experiment with AI models, algorithms, and systems safely and securely, ensuring that AI systems are reliable and robust before deployment. We also discuss potential challenges and ethical considerations related to the use of AI in pain estimation, emphasizing the importance of addressing these concerns to ensure the safe and responsible integration of this technology into healthcare systems. The paper lays a foundation for future research and innovation in pain management, ultimately contributing to better patient care and advancements in the field.

KEYWORDS

pain detection, AI sandbox, pain tools, ethical AI, contactless

1 INTRODUCTION

Accurate pain assessment is crucial for effective pain management in clinical settings. The widely used methods for assessing pain in patients rely on self-reporting of their pain level. For this purpose, a number of standard tools are used. For example, the Numeric Rating Scale (NRS) has been validated as a measure of pain intensity in populations with different types of pain [1]. However, it is only applicable to

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patients who can verbalize their pain intensity. Visual Analogue Scale (VAS) is a psychometric measuring instrument that uses a straight line to represent pain intensity, with the endpoints labeled as "no pain" and "worst pain imaginable". However, it requires clear vision and may be challenging for some patients, such as children and mentally challenged patients [2]. Functional Pain Score (FPS) assesses pain by associating numbers with functional impairments. It provides a more objective indicator to help clinicians understand how pain affects a person's life. The Wong-Baker pain scale has been validated and has good test-retest reliability. However, it may not be suitable for children or adults who do not understand its vocabulary [3]. Iconic Pain Assessment Tool (IPAT) is a web-based instrument for the self-report of pain quality, intensity, and location in the form of a permanent diary [4]. However, it shares the same limitations due to being a self-report system. Similarly, several other self-report pain scales such as McGill [5], Mankoski [6], brief pain inventory [7], and descriptor differential scale [8] all require patients to verbalize their pain intensity, which is not suitable for the type of the patients under discussion.

The self-reporting tools have limitations in infants, patients with cognitive impairment or dementia, and critically ill patients receiving mechanical ventilation or sedation. They require patients to understand pain ratings and accurately interpret the experience of noxious stimuli as painful events [2]. For these patients, behavioral pain assessment tools are widely used, which are based on observing the patient's physiological parameters and body expressions to determine the level of pain. Several behavioral pain scales exist such as for infants (e.g., NIPS [9], CRIES [10], FLACC [11]), for elderly people with severe dementia (e.g., PACSLAC [12], DOLOPLUS2 [13], PAINAD [14]), and for critically ill and/or unconscious patients (e.g., BPS [15], CPOT [16], NVPS [17]). However, behavioral pain assessment tools are subjective and rely on observer-based methods, which can lead to inter-rater variability and inconsistent treatment of patient pain management [18], [19]. The mentioned limitations entail objective and reliable pain assessment tools. Not only must these tools be robust, they must also be portable and interactive to facilitate ease of use, requiring minimal setup or calibration effort.

Automated pain estimation through physiological data has been extensively studied to improve pain assessment and management [20]. A myriad of AI-driven techniques has been employed for pain estimation using uni- and multi-modal approaches. Most of these techniques utilize facial expression recognition as a strong indicator of pain intensity [21]–[23]. The facial features and landmarks or geometric features obtained from the mouth area are used to estimate the intensity of the pain (Jerritta et al., 2022). Analysis of conversations between patients and medical professionals in emergency triage has also been used to identify pain intensity [24]. Similarly, combining vocalization with facial expressions has also emerged as a promising technique for infant cry and pain estimation [25]. However, at a practical and commercial level, automatic, real-time pain estimation is still in infancy. Painchek [26] is the first and only clinically validated pain estimation tool based on a smartphone app-based device that combines a facial expression assessment component with input from five other domains (voice, movement, behavior, activity, body) to yield a pain score for application in geriatric and pediatric settings. However, this system is not fully automatic. After identifying a facial micro-expression, the app requires completing the checklist in other domains to calculate a numerical pain score. It also requires clinical competence on tool's contents, domains and descriptors [26].

It is crucial to recognize and address the safety and ethical risks associated with the development and deployment of an AI-driven system to minimize the potential harms [27], [28]. In the context of European ethics guidelines for trustworthy AI [29], one of the primary safety concerns with an AI-driven solution is reliability and robustness [30], particularly in a safety-critical application such as pain estimation. Ensuring that the pain estimation system operates securely and accurately under various conditions and circumstances is essential to prevent catastrophic failures.

There are several types of contactless healthcare monitoring systems, including camera-based, radio frequency-based, and wearable sensors [31], [32]. Recent research has focused on developing non-contact sensors that can monitor vital signs such as respiratory rate, oxygen saturation, heart rate, and body movement [31], [33]–[35]. These sensors are based on technologies such as deep learning, artificial intelligence, and the Internet of Things [33]–[35]. Some examples of contactless healthcare monitoring systems include TeleVital, a non-contact health assessment system that uses a webcam to measure vital signs [34], and RhythmEdge, a low-cost, deep-learning-based contactless heart rate estimation system [35]. Researchers have also developed non-contact monitoring systems for human physiological signals and body movement, which use custom-designed low-cost accelerometers and phased-array Doppler sensors [31], [32].

Recent advances in contactless healthcare technology have enabled mobile-based screening tools that can measure vital signs and provide health risk assessments using mobile and desktop devices. Anura™ is a video-based contactless health monitoring technology that can measure vital signs and provide health risk assessments using only a smartphone video camera [36]. Contactless human activity recognition using deep learning with flexible and scalable software-defined radio has been developed to assess and contrast deep learning approaches [37]. Mobile telehealth facilitates the contactless and real-time interaction of healthcare professionals, doctors, and patients for patient diagnosis, case discussion, decision-making, and personalized medicine. Remote patient monitoring (RPM) using non-invasive technology could enable contactless monitoring of acutely ill patients in a mental health facility [38].

The potential benefits of these technologies include the ability to monitor patients remotely, which can reduce the burden on healthcare systems and improve patient outcomes. Patients can receive care from the comfort of their own homes, which can be especially beneficial for those who are unable to travel to healthcare facilities. These technologies can also provide real-time monitoring of vital signs, which can help healthcare professionals detect and respond to health issues more quickly.

However, there are also potential drawbacks concerning ethics and security. The most important ethical issues of medical IoT include security, access control, and privacy [39]. Organizations capable of continuous surveillance via IoT devices must consider ethics and its effects. When devices connect to the internet, users have no true privacy. Organizations can monitor consumers through smart devices, including homes, appliances, cars, wearables, and water and gas meters. The vendors can monitor and track conversations, locations, timing, actions, and behaviors through interconnected wireless devices. Despite the promise of ambient intelligence to improve the quality of care, the continuous collection of large amounts of sensor data in healthcare settings presents ethical challenges, particularly in terms of privacy, data management, bias and fairness, and informed consent [40]. Patient data security is a challenge in telehealth monitoring, which jeopardizes patients' health information without an end-to-end encrypted communication service [41].

Ethical risks in the development of an AI-enabled pain estimation system, involving bias, fairness, transparency, and accountability [42], require addressing potential biases in training data to prevent discriminatory outcomes and promote fairness. Ensuring transparency allows users to understand AI decision-making processes, fostering trust and facilitating ethical issue resolution. Accountability, involving clear responsibility lines, redress mechanisms, and regulatory frameworks, holds AI developers and users responsible for their systems' ethical behavior.

The potential safety and ethical risks associated with the development and deployment of an AI-enabled pain estimation system underscore the importance of a controlled environment where the system can be thoroughly tested and validated before deployment. In this way, regulatory and ethical standards can be upheld, and potential risks and negative consequences can be minimized [43]. Moreover, the demand for multi-stakeholder collaboration has grown, with policymakers in an increasing number of countries implementing mechanisms such as regulatory sandboxes. This underscores the significance of knowledge sharing across technology and jurisdiction in a rapidly evolving field [44].

To devise an efficient automated pain estimation system, we advocate the utilization of an AI sandbox environment. This environment integrates multi-modal features—spanning visual, audio, and physiological aspects discernible through audio-visual indicators—ensuring a holistic pain assessment. This environment should encapsulate AI-driven pain hierarchical classification algorithms [45], [46], sophisticated facial recognition capabilities, and the ability to collect vital signs using contactless methods, eliminating the need for physical contact. Leveraging the AI sandbox ensures that the AI system effectively fuses data pertaining to the well-accepted behavioral pain scales from diverse sources to deduce an encompassing assessment of a patient's pain. A pivotal realization in holistic pain estimation is recognizing the intertwined nature of physical and emotional pain indicators [47], [48]. As such, the AI must be adept at recognizing micro facial expressions, variations in body posture, and even subtle vocal cues. Given that the well-accepted behavioral pain scales encompass these subtleties, it's crucial to base the AI-driven pain estimation on them. By doing so, we leverage their evidence-backed, structured approach, supporting the AI system with a scientifically validated foundation. Beyond accurate pain measurement, integrating the system within an AI sandbox also underscores the need for rigorous pre-deployment testing and ensuring important concerns like data security and privacy are met.

AI's potential in healthcare, especially in pain estimation systems, is undeniable. As we advance, the field is witnessing myriad defensive technologies designed specifically to counter the security and privacy challenges associated with AI. For instance, methods like detection and filtering, data provenance, and standardized management are enhancing data collection integrity. Coupled with this, image reconstruction, quality monitoring, and data randomization are steps toward augmenting data processing security and quality. During the AI model's training phase, certified defenses ensure robustness, while a range of technologies caters to the needs of the inference and integration stages [49]. Moreover, the evolution of Fog-assisted or edge computing architectures is noteworthy. They pave the way for a secure healthcare data collection and transmission system while ensuring efficiency through low computational demands and optimal compression rates [50]. We believe that these technological advances not only make AI-driven pain estimation systems secure but also heighten their accuracy, which is paramount in healthcare scenarios.

In this paper, we introduce a conceptual framework aimed at crafting a secure, automated system for pain estimation. This system utilizes non-contact sensing methods grounded in standard pain scales and tools. The proposed model is not only deeply rooted in robust theoretical foundations, but also offers a systematic pathway to the development of an AI sandbox for non-contact pain estimation. This AI sandbox serves as a controlled and safe experimental space for testing AI-driven applications before they are deployed. This study provides a blueprint for researchers, healthcare professionals, policy makers, and technology developers to create and implement secure, non-contact AI systems for pain estimation.

The structure of this paper is as follows: Section 2 offers a comprehensive review and critical analysis of current automated pain detection techniques. In Section 3, we delve into the theoretical aspects of AI sandbox, illustrating its significance in crafting AI healthcare applications. Section 4 outlines the systematic process for creating an AI sandbox dedicated to non-contact pain estimation. It delves into the specifics of the AI sandbox development, pain detection tools, data collection methods, pertinent modalities, cues, pain indicators, and the various pain scales used. It also expands on the development of a computational and sensing platform and the methodologies employed in pain estimation. Additionally, it delves into the crucial topics of data protection, privacy, and how AI decisions are explained. In Section 5, the focus shifts to the evaluation and validation procedures for the pain estimation system. Ethical considerations surrounding this field are discussed in Section 6. Section 7 identifies potential hurdles and challenges that might arise during system implementation. Finally, Section 8 wraps up the paper with conclusive remarks.

2 RELATED WORK

Recent research on automated pain estimation utilizes one or a combination of three types of modalities: audio, visual, and physiological. Different cues related to these modalities have been used, which are listed in Table 1. These modalities can be further divided into behavioral and non-behavioral. While the former represents the direct, contactless measurements of modalities, the latter represents a contact-based approach.

Table 1. Overview of different modalities and cues for assessing emotions

Signal Type	Modality	Cues	Description
Behavioral	Audio	Crying, moaning, groaning, gasping, and sighing	Audible sounds of distress or discomfort
	Video	Facial expressions	Visual cues of emotions displayed on the face
		Body gestures	Physical movements conveying emotions
		Facial skin temperature	Temperature changes on the face indicating emotional states
Non-behavioral	Physiological	ECG, EEG, HRV, SCL, EMG, fINRs, fMRI, RR, BP, HR, SCR, STemp, SIP, GSR, PPG, BM, BVP, HRG	Signals that provide information on the body's physiological state

Notes: **ECG:** Electrocardiogram, **EEG:** Electroencephalogram, **HRV:** Heart Rate Variability, **SCL:** Skin Conductance Level, **EMG:** Electromyogram, **fINRs:** Functional Near-Infrared Spectroscopy, **RR:** Respiratory Rate, **BP:** Blood Pressure, **SCR:** Skin Conductance Response, **STemp:** Skin Temperature, **SIP:** Sweep Impedance Profiling, **GSR:** Galvanic Skin Response, **PPG:** Photoplethysmogram, **BM:** Body Movements, **BVP:** Blood Volume Pulse, **HRG:** Heart Rate Gain.

Recent research has investigated several modalities for automated pain estimation. These modalities have been used in unimodal as well as multimodal methods. Facial Expression Recognition (FER) and physiological signals have been predominantly used for automated pain estimation, either separately or in combination. While facial expressions are consistently associated with pain and convey most of the pain-related information as compared to other behavioral indicators [51], the physiological signals are strongly related to the autonomic nervous system's role in pain response [52]. Since addressing more modalities gives better insight into pain and its varieties, a number of different combinations of multimodal methods have been investigated.

Table 2 details the methods employed for automated pain estimation in the past few years. It can be seen that methods based on physiological signals have been widely used for pain estimation. Especially, EDA has predominantly been used in both unimodal and multimodal approaches. FER is the primary modality in contactless approaches, which highlights the importance of visual cues and the potential of leveraging computer vision techniques for pain estimation. Fewer approaches utilize audio-based modalities, which entail further exploration and research. Though contact-based approaches have been prevalent, the growing number of contactless studies suggests an increasing interest in developing non-intrusive methods for pain estimation. Though heart rate, heart rate variability, and respiration rates have been traditionally used as contact-based modalities, the recent advancements in computer vision have paved the way for measuring them using a contactless method called remote photoplethysmography (rPPG) [53]. The physiological cues, shown in the visual modality column of Table 2, have been measured through contactless methods. Figure 1 shows the frequency of each distinct modality combination used for automated pain estimation.

Table 2. Existing pain estimation methods and the modalities used

	Reference	Visual	Physiological
CONTACT-BASED METHODS	Korving et al., 2022 [57]	–	EDA
	Kong et al., 2021 [58]	–	EDA
	Kong et al., 2021 [59]	–	EDA
	Kong et al., 2020 [60]	–	EDA
	Chen et al., 2022 [61]	–	EEG and fINRS
	Erdoğan et al., 2020 [62]	–	HR, BP, STemp
	Al-Qerem et al., 2020 [63]	–	HR, BP, STemp
	Hassan et al., 2020 [64]	–	EMG, ECG
	Lopez et al., 2018 [65]	–	SCR, HR
	Thiam et al., 2020 [66]	–	EDA, EMG, ECG
	Pouromran et al., 2021 [67]	–	EDA, EMG, ECG
	Bellmann et al., 2020 [68]	–	EDA, EMG, ECG
	Badura et al., 2021 [69]	–	EDA, EMG, RR
	Lopez et al., 2019 [70]	–	fNIRS
	Santana et al., 2019 [71]	–	fMRI
	Truong et al., 2020 [72]	–	SIP, PPG, EEG, GSR
	Vu et al., 2022 [73]	–	SIP, PPG, EEG, GSR
	Gouverneur et al., 2021 [74]	–	ECG, EDA, EMG
	Kasaeyan et al., 2021 [75]	–	ECG
	Walter et al., 2020 [76]*	FER, BM	HR, EDA
	Casti et al., 2020 [77]*	FER	HR, SCR
	Xu et al., 2019 [78]	FER	EDA
	Khan et al., 2023 [79]	–	BVP
	Yang et al., 2021 [80]	FER	HR, RR, GSR, STemp, BM
	Winslow et al., 2021		RR, HRV

(Continued)

Table 2. Existing pain estimation methods and the modalities used *(Continued)*

	Reference	Visual	Physiological
CONTACTLESS METHODS	Xin et al., 2021 [81]*	FER, BM	–
	Wu et al., 2023 [82]	FER	–
	Morabit et al., 2021 [83]	FER	–
	Aydın et al., 2023 [84]	FER	–
	Semwal et al., 2020 [85]	FER	–
	Lee et al., 2020 [86]	FER	–
	Thuseethan et al., 2020 [87]	FER	–
	Alghamdi et al., 2022 [88]	FER	–
	Bargshady et al., 2020 [89]	FER	–
	Rudovic et al., 2021 [90]	FER	–
	Fontaine et al., 2022 [91]	FER	–
	Thiam et al., 2020 [68]	FER	–
	Rathee et al., 2022 [92]	FER	–
	Huang et al., 2022 [93]	FER, HRG	–
	Souza et al., 2021 [94]	FER, HR	–
	Castillo et al., 2020 [77]	FER, HR	–
	De Sario et al., 2023 [95]	FER	–
	Liu et al., 2018 [96]	FER	–
	Wu et al., 2022 [97]	FER	

Note: *Methods using vocalizations.

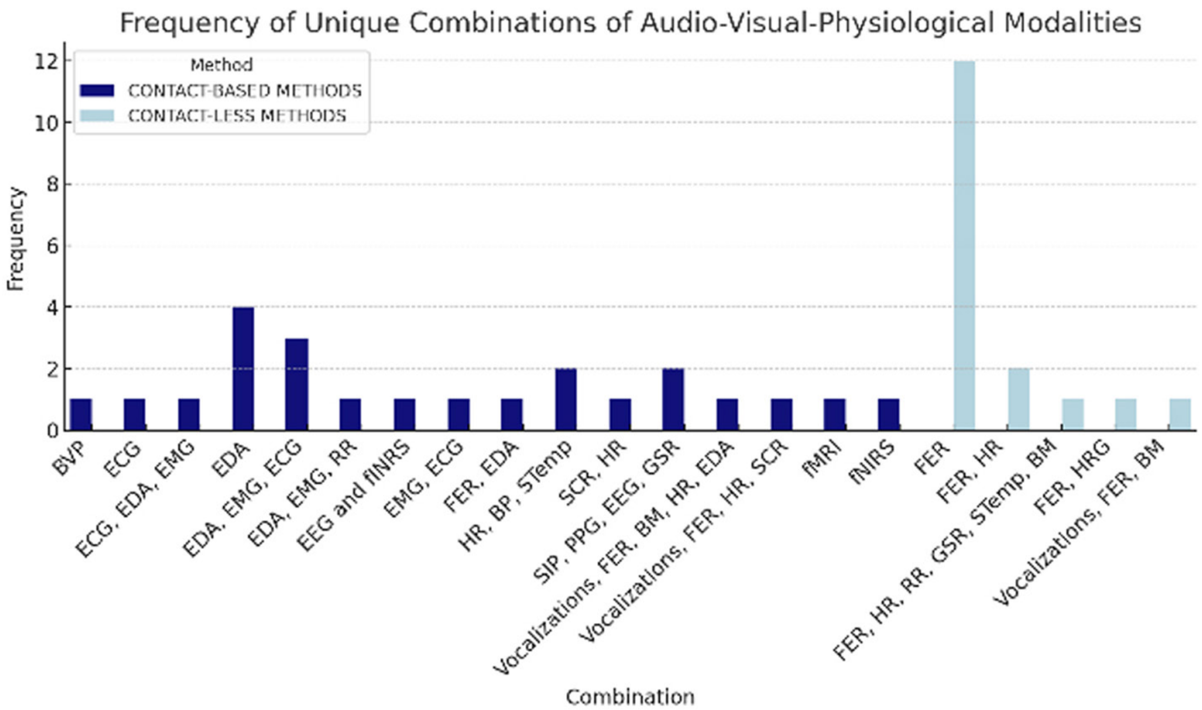

Fig. 1. Frequency of the modalities used in automated pain estimation

The growing interest in contactless methods is due to the fact that the methods depending on wearable and contact-based sensors come with several drawbacks. Continuously wearing sensors can cause discomfort, potentially affecting patient compliance. Furthermore, these methods typically entail specialized lab settings or particular subject postures, adding to the limitations of their applicability [54]. Therefore, ambient monitoring can offer a superior approach to pain estimation, addressing the limitations of wearable and contact-based sensors. In addition, research on automated pain estimation signifies the importance of using multiple behavioral cues instead of single ones [55], [56] to better capture the subtleties of pain. By seamlessly gathering various physiological and audiovisual signals without direct contact and employing machine learning for analysis, it presents a more practical and feasible solution for this pressing issue. Hence, behavioral-based pain indicators are preferable as they utilize contactless sensing (such as cameras). Additionally, behavioral-based parameters can be monitored continuously for the desired time duration without causing any discomfort to the patient.

While a large part of the relevant literature utilizes only FER or physiological signals for pain estimation, the effectiveness of using these methods independently is debatable. Some studies show that several factors such as fear, anxiety, and psychological stress can affect physiological measurements [98]–[100]. Additionally, it has also been found that a lack of changes in vital signs does not necessarily imply an absence of pain [101]. Similarly, due to the subjectivity of FER and its variation from person to person, estimating pain levels accurately solely on FER can be difficult [83]. Additionally, factors such as facial paralysis (e.g., locked-in syndrome [102]), cultural differences, individual differences, and context also affect FER [103]. Therefore, it is essential to incorporate a diverse range of behavioral cues and employ multimodal models when developing AI-enabled pain estimation methods.

There are certain limitations of AI-enabled pain estimation methods which need to be addressed for clinical use. A common limitation is that these methods usually collect data based on a pain stimulus or a pain-inducing protocol applied to healthy individuals, which may not fully represent real-world pain experiences. The majority of the pain estimation methods also lack clinical validation in a clinical environment and/or are based on data collection from a smaller sample size which raises questions on generalization. Some methods are even limited to a single pain type (e.g., should pain) and do not address other pain types.

The existing techniques only provide a preliminary classification of pain [104] and do not make full use of standard, well-validated behavioral pain assessment tools designed specifically for critically ill patients who are unable to effectively communicate their pain levels. While it is evident that a myriad of multimodal combinations has been used for pain estimation, their efficacy is difficult to ascertain without a rigorous clinical evaluation, especially when they are not based on well-validated subjective pain scales. Some AI-enabled methods have attempted to automate the manual pain estimation scales, e.g., FER based on Prkachin and Solomon Pain Intensity (PSPI) scale [105], [106]. However, PSPI only evaluates active facial action units along with their intensities and assigns a score; therefore, its efficacy for critically ill, unconscious, or patients on ventilation cannot be ascertained, pain estimation of such patients requires more modalities to be observed such as compliance with the ventilation. To the best of our knowledge, no study addresses the automation of behavioral pain scales for patients with communication difficulty (or inability). These pain scales have been validated through rigorous clinical trials and serve as standards for the mentioned conditions. Also, they do not rely on a single pain indicator (such as FER), but comprise a diverse set of pain indicator items including facial expressions, body movements, and vocalizations, to name a few.

Finally, the lack of transparency in AI-enabled automated pain estimation techniques is also a major concern, as it makes it difficult to understand how the system arrives at its conclusions. Developing more transparent models that provide clear explanations of how they make their assessments could increase trust in these systems and improve their usability in clinical settings.

In this context, a potential solution is to combine traditional observer-rated pain assessment tools with AI-enabled techniques to improve pain assessment accuracy and reduce the limitations of these methods. Despite their subjective ratings, these tools still serve as a reliable criterion for pain [15], [107]. Hence, the observer-based criterion of these pain assessment scales can be converted to an AI-enabled system to reduce inter-observer variability in pain assessment, which is a major limitation of observer-rated scales. At the same time, it may result in a more objective measure of pain, which is particularly useful in cases where the self-report methods are no more valid due to the patient's cognitive or communication impairments. In addition to that, real-time and continuous monitoring of pain can be ensured, which can help in detecting pain episodes otherwise missed by intermittent assessments. More importantly, the burden on healthcare staff could be significantly reduced, eliminating the need for their availability to perform frequent pain assessments.

To address these limitations, it is essential to develop an AI-driven pain estimation system that operates within an AI sandbox environment and utilizes a wider set of modalities for a more nuanced estimation of pain. By incorporating the AI sandbox, the system allows researchers and developers to safely experiment with pain estimation models and algorithms, ensuring that the pain estimation techniques are reliable, robust, and optimized before deployment. This innovative approach provides an objective measure of pain that can reduce inter-observer variability, objectifying the standard observer-rated pain assessment tools, and offering a real-time, continuous measure of pain for critically ill patients. The AI sandbox integration ensures the mitigation of potential risks and the recognition of inadvertent consequences before the pain estimation system is broadly adopted.

3 AI SANDBOX

An AI sandbox is a controlled virtual environment that allows researchers, developers, and organizations to experiment with AI models, algorithms, and systems safely and securely [108]. By simulating real-world scenarios and conditions, AI sandboxes enable users to test, validate, and optimize AI solutions without risking unintended consequences, ensuring that AI systems are reliable and robust before deployment. The importance of an AI sandbox lies in its ability to mitigate potential risks and uncover unintended consequences before AI systems are widely adopted. By providing a controlled environment, AI sandboxes allow developers and researchers to fine-tune algorithms, identify biases, and rectify potential safety issues without exposing users or society to harm.

The development and deployment of an AI-enabled pain estimation system necessitate an AI sandbox to test the system on diverse datasets and simulate different patient populations. This allows researchers to identify any biases or inaccuracies in the AI system's diagnostic capabilities, such as a tendency to inaccurately estimate pain in specific demographic groups. By refining the pain estimation models and algorithms, it can be ensured that the system is both accurate and unbiased before being deployed in actual clinical settings.

4 CONCEPTUAL FRAMEWORK FOR CONTACTLESS, MULTIMODAL PAIN ESTIMATION WITHIN AN AI SANDBOX ENVIRONMENT

4.1 Overview of the concept

A multimodal, real-time pain estimation system combines multiple data sources and signals, utilizing visual and auditory modalities. This includes a combination of visual data such as stature, gait, facial expression, ambient sounds, and dialogues. The sensing setup of the system comprises sensitive microphones and cameras which can provide high-quality and accurate data even under low-light conditions or occlusion. The data associated with the pain indicators is collected from various clinical and hospital settings and is subsequently used to develop and train multimodal models [109] that can detect pain and discomfort. Spatio-temporal analysis can be applied that takes into account both spatial and temporal information of the video feed to improve estimation accuracy. The vision models are developed to detect facial expressions, upper limb movements, and body postures, while the audio models are developed to detect pain sound input and compliance with ventilation. In addition, the efficacy of a multimodal, unified model for pain estimation is worth investigating. This model takes all the modalities as input and translates them into a pain value, providing a more accurate assessment of pain intensity.

Based on the acquired values of the pain indicator, the system predicts a pain value representing the pain intensity on the pain assessment scale. To address data privacy and protection, robust mechanisms for data anonymization and protection are developed in compliance with GDPR. Finally, narrative and visual explanations of the AI decisions are generated to give further insights into the AI decisions. This enhances transparency and trust in the system and provides valuable information for healthcare providers to make informed decisions about patient care.

An important aspect of the pain estimation system is its development and deployment within an AI Sandbox before its implementation in a real clinical setting. The steps involved in the development of the pain estimation AI sandbox are detailed in the next section.

4.2 Development of pain estimation sandbox

Implementing an AI sandbox for the pain estimation system involves two phases, as shown in Figure 2. The first phase involves creating a controlled and isolated environment tailored for the development of pain estimation models. The primary objective is to maintain data privacy, security, and regulatory compliance throughout the development process. This involves selecting a secure and compliant computational infrastructure that ensures scalability, flexibility, and adherence to healthcare regulations. Implementing stringent access controls is crucial to limit data access to authorized team members only, protecting sensitive patient information.

Healthcare data must be securely stored, with encryption and de-identification measures in place to maintain compliance with data protection regulations [89]. AI sandbox systems should utilize a "privacy by design" concept encompassing a range of legal, privacy, and security policies and measures to ensure the necessary protection of personal health data. At the heart of the sandbox's security lies encryption. Every piece of data, whether at rest within the system's storage mechanisms or in transit between system components, is encrypted. The choice of advanced encryption standards, such as Advanced Encryption Standard (AES-256) [110] for data-at-rest and the Transport Layer Security (TLS) [111] protocol for data-in-transit, ensures that even if malicious entities gain unauthorized access, deciphering the actual patient information remains a complex challenge. These encryption standards are widely recognized for their resistance to cryptographic attacks on healthcare data and are pivotal in maintaining the confidentiality of the data [112], [113].

Ensuring the integrity of healthcare data is also vital [114]. By employing cryptographic hash functions, such as SHA-256 which is widely used for ensuring healthcare data integrity [115], or its advanced variants such as [116], the system can ascertain that the data, once stored or transmitted, retains its original state when later retrieved or received. Any discrepancy in the hash values would serve as a red flag, indicating potential data alteration. Further supporting this is the use of digital signatures, which not only promise data integrity but also its authenticity [117]. Any modifications post-signature application would render the signature verification process void, signaling a breach in data integrity.

Beyond encryption and data integrity verification, the AI sandbox is fortified with multiple safeguards to ensure data fidelity and privacy. A critical component here is data de-identification. Before any data enters the sandbox, personally identifiable information is either masked or replaced with pseudonyms, ensuring that individual users remain anonymous [118]. This de-identification process, coupled with role-based access control, guarantees that only authorized personnel with a legitimate purpose can access the data, and even then, the data they access doesn't compromise patient privacy.

To continually assess the system's resilience against threats and vulnerabilities, regular security audits are conducted. These audits, complemented by threat modeling [119], [120], ensure that the system remains prepared for both known and emergent security challenges. Threat modeling, in particular, is instrumental in understanding the assets at risk, the potential threats to these assets, and the risks associated with those threats. And, in the unforeseen event of a security breach, a well-defined incident response plan is in place, outlining the precise steps to be taken, from data recovery strategies to communication plans and legal considerations.

Network segmentation is also essential to isolate the AI sandbox from production environments, preventing potential security risks from affecting clinical systems. At the same time, continuous monitoring and logging of activities within the sandbox helps detect potential threats and ensures ongoing security and compliance.

Establishing backup and disaster recovery plans safeguards the AI sandbox against data loss or system failures. For instance, having a plan in place to restore EHRs from secure backups in case of a cyberattack or system failure ensures the continuity of healthcare services. Conducting regular audits and risk assessments helps identify and address vulnerabilities or non-compliance issues, further enhancing the security and reliability of the AI sandbox.

The second phase involves creating the AI sandbox, which comprises several crucial steps to develop and refine the models pertaining to predicting pain indicators and estimating pain. Data preparation is the cornerstone of effective AI models. In healthcare, this step entails the collection, preprocessing, and anonymization of EHRs while adhering to data protection regulations, such as HIPAA or GDPR [121]. For instance, personal information replaced with pseudonyms and data encryption can be employed to maintain privacy and security.

Monitoring and iterating the models is essential for continuous improvement. In the pain estimation system, this involves collecting various types of feedback, such as analyzing key performance indicators like accuracy, sensitivity, and specificity for classification models (e.g., for facial expression recognition) and R-square score and root mean square error for regression models (e.g., estimating the pain level), gathering input from medical professionals, and conducting pilot studies in real-world healthcare settings. Additionally, error analysis should be performed, and feedback should be obtained from doctors, nurses, and pain management experts. These insights can help identify areas for improvement, allowing the models to be refined to better align with real-world scenarios and user expectations.

Implementing version control and collaboration tools is vital to ensure effective teamwork and maintain a history of model development [122]. Using version control systems and collaboration platforms helps manage changes, track progress, and facilitate collaboration among healthcare professionals across all steps of the development process. This aids in maintaining a streamlined workflow while developing and refining pain estimation models. The team working on the pain estimation system might use a version control system to track changes to the models' code and a project management tool to coordinate tasks and communication among team members.

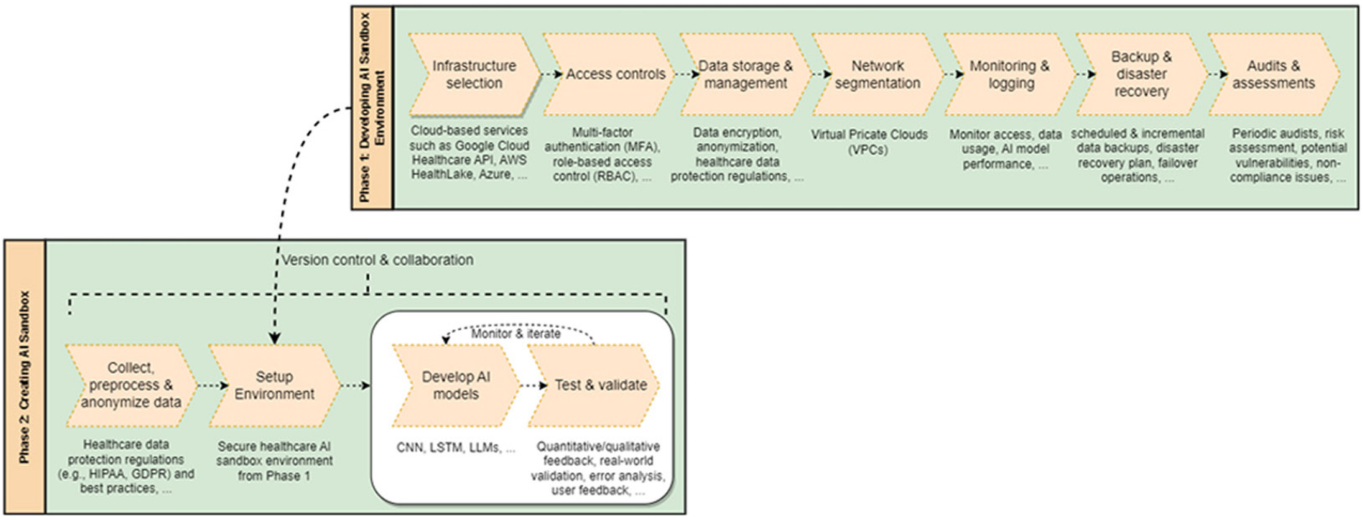

Fig. 2. Phases of implementing pain estimation sandbox

4.3 Selection of a pain assessment tool

The focus of our study is the patients with communication inabilities or difficulties. Such patients comprise infants, critically ill and/or on ventilation, and patients with cognitive impairment or dementia. Some widely used pain assessment scales separately address these target groups. These pain scales utilize a diverse range of pain indicators to address the communication impairment of the patients. Besides using facial expressions as pain indicators, these scales also utilize other behavioral indicators such as body movements, compliance with ventilation, vocalization, breathing patterns, and upper limb movements. Each indicator has a certain number of associated behaviors which describe the intensity of the pain related to it. Each pain behavior is assigned a score. The total score of all the pain behavior represents the pain intensity. A higher score indicates a higher level of pain [123]. Table 3 shows the pain indicators related to each cue in BPS and COPT scales. It can be seen that the data of the pain indicators is multimodal (audio, visual). Pain indicators such as facial expressions, upper limb movements, and body movements can be obtained by analyzing the images captured by cameras. Similarly, the pain indicators data related to compliance with ventilation can be obtained by audio modality. Table 3 summarizes the widely used pain assessment scales for our target groups.

Table 3. Standard pain assessment scales and their indicators

Targeted Group	Pain Assessment Scale	Pain Indicators/Items
Infants	NIPS	Facial expression, cry, breathing patterns, arm movements, leg movements, and state of arousal [124]
	CRIES	Crying, oxygen requirement, changes in vital signs, facial expression, and sleep state [10]
	FLACC	Facial expression, leg movement, activity, cry, and consolability [125]
Elderly people with severe dementia	PACSLAC	Facial expressions, verbalizations, body movements, changes in interpersonal interactions, changes in activity patterns, mental status changes, changes in intake of food or fluids, changes in sleep patterns, changes in body care and grooming, and changes in vital signs [126]
	DOLOPLUS-2	Facial expression, body language, verbalization, consolability, changes in habits, mental confusion, autonomy, sleep disorders, appetite, and social interactions [127]
	PAINAD	Breathing, negative vocalization, facial expression, body language, consolability [128] (Herr et al., 2004)
Critically ill and/or unconscious patients	BPS	Facial expression, movements of upper limbs, and compliance with a ventilator [129]
	CPOT	Facial expression, body movements, muscle tension, and compliance with the ventilator [130]
	NVPS	Facial expression, body movements, muscle tension, compliance with the ventilator, and vocalization [131]

4.4 Designing and developing a contactless sensing and processing platform

This section discusses the development of a contactless sensing and processing platform for pain estimation.

Integration of multimodal sensors. The sensing component of the contactless pain estimation system comprises visual and auditory sensors to capture pain indicator data. The data related to facial expressions, upper limb movements, compliance with ventilation or vocalization, body movements, and muscle tension is collected by a network of visual sensors. This includes two high-resolution RGB cameras and one near-infrared (NIR) camera. The RGB cameras capture color information, while the NIR camera enhances the system's ability to operate under low-light conditions and provides additional depth information. This setup also ensures comprehensive coverage of the patient's face and upper body, enabling more accurate estimation of pain indicators under low-light conditions commonly found in clinical settings.

All cameras are equipped with high-resolution image sensors to provide detailed images of the patient's face and upper body. The RGB cameras operate in the visible light spectrum, while the NIR camera captures images in the near-infrared spectrum, enabling it to function effectively in low-light conditions. The NIR camera can be installed at the head of the bed, slightly above one of the RGB cameras. The angle should be such that the NIR camera captures a direct view of the patient's face and can pick up the minute changes in facial expression that could be indicative of pain. The RGB cameras are positioned at different angles, such as one at the head of the bed, one at the foot of the bed, and one on each side. The side RGB cameras should be ideally aligned with the patient's midsection. This configuration addresses the issue of occlusion, capturing various views of the patient's face and upper body. The images from multiple visual sensors are combined to form a more complete representation of the patient, resulting in a more accurate and reliable pain prediction system.

For auditory sensing, a sensitive microphone is positioned near the patient's head to record sounds associated with pain, such as vocalizations, coughing, or changes in breathing patterns. The microphone captures compliance with the ventilator or vocalization, e.g., the pain indicators in the CPOT scale. To assess body movements and muscle tension without contact, the system relies on advanced computer vision techniques (e.g., [132]) to analyze the visual data from the RGB cameras. By tracking the patient's upper limbs and body posture changes, the system can evaluate body movements and muscle tension indicators, e.g., in the CPOT scale.

Real-time processing and computing platform. The data captured by the multimodal sensors is sent to a processing and communication platform that runs data pre-processing, fusion, and pain prediction algorithms. While onboard processing in smart visual sensors (cameras) can be advantageous, processing power and other essential parameters must also be taken into account. If the optimal setup consists of homogeneous or heterogeneous image sensors without onboard processing capabilities, a compact, energy-efficient, and processing-efficient computing platform is integrated with the image sensors to effectively run machine learning algorithms. The other factor to be considered for the computing platform is its small form factor, as it is intended to be a compact point-of-care device. A trade-off between computational efficiency and energy consumption must be found.

The camera network sends the captured images to the computing platform. The images captured from the heterogeneous setup are resized and registered using a suitable feature-based registration method into a single composite image. A weighted approach is applied to the registered images to fuse the information from both RGB and NIR images. The weights are determined based on factors such as camera configuration, lighting conditions, and the relative importance of each modality for pain estimation. This fused image enables the system to analyze the pain indicators more effectively.

By incorporating heterogeneous visual and audio sensors with various parameters and specifications, the computing platform facilitates a comprehensive and accurate analysis of pain indicators. The communication component utilizes a wireless channel to transmit the results of pain estimation to a centralized location. Figure 3 shows the sensing, analysis, and transmission of pain estimation results to a centralized location.

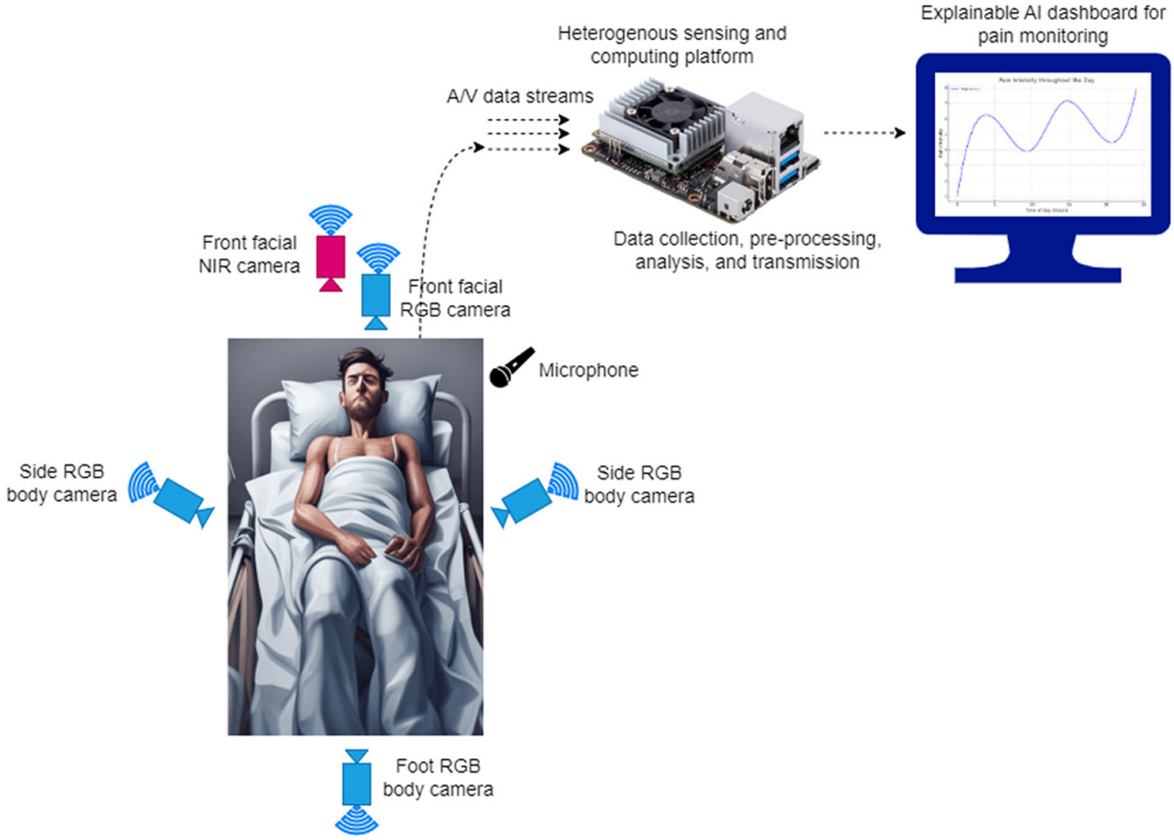

Fig. 3. A depiction of contactless sensing, analysis, and transmission of pain estimation to a centralized location

4.5 Data collection and management

This step is crucial to the development of accurate models for pain estimation, as it aims to capture a wide range of pain indicators and ensures the precision of the pain estimation models. To achieve this, data is collected from various clinical and hospital settings, including different patient populations, medical conditions, and pain intensities. The collected data encompasses all the indicators of the selected pain assessment scale. These indicators are captured using the developed sensing and processing platform. The auditory indicators, such as compliance with the ventilator, are captured through sensitive microphones and sound analysis, as changes in breathing patterns can indicate discomfort or pain. Muscle tension is inferred from changes in posture and movement patterns, providing a more complete picture of the patient's pain experience.

All the behavioral pain assessment scales described in Table 3 utilize a diverse range of modalities that can be captured through a contactless setup of heterogeneous sensors (audio, visual). Some of the indicators in PACSLAC and DOLOPLUS-2 scales may require long-term data collection and analysis for pain estimation, e.g., changes in activity patterns, sleep disorders, social interactions, etc. For the demonstration of our concept, we select one pain scale from each group. Automating these observer-rated pain assessment scales entails collecting the same data related to each pain indicator as acquired by a human observer. However, in a contactless automated system, this data has to be collected by relevant acoustic and visual sensing devices. Table 4 describes the audio-visual pertaining to each pain indicator. The cues mentioned in the table have been mentioned according to the audio-visual data collection. That is, they specifically mention what specific audio-visual features can be analyzed for each pain indicator.

Table 4. Audio-visual data collection for behavior pain scales

Pain Indicator	Pain Behavior	Pain Scale	Data to be Collected	Cues to be Analyzed
Facial expression	Relaxed/neutral	CPOT, NIPS	Face video capture	Smooth and unwrinkled skin, neutral eyes, and lips in a neutral position [133]
	Tense	CPOT, NIPS	Face video capture	A furrowed brow, tightened lips, clenched jaw, frowning, brow lowering, orbit tightening, and little levator contraction [134][135]
	Grimacing	CPOT, NIPS, BPS	Face video capture	Lowering of the eyebrows, squeezing of the eyes, wrinkling of the nose, raising of the upper lip, and opening of the mouth [136]
Body movements	Normal position	CPOT	Capturing video of body posture	Absence of movements, absence of protective, restless, or guarding behavior [137]
	Protection	CPOT	Capturing video of body posture	Guarding the painful area, slow & cautious movements, touching or rubbing the pain site [137]
	Restlessness	CPOT	Capturing video of body posture	Constant shifting, inability to remain still, attempting to sit up, moving limbs/thrashing [137]
Compliance with ventilation	Tolerating ventilator	CPOT, BPS	Capturing video of the chest and abdomen	Chest and abdomen movement synchrony with ventilator, no coughing, no alarms [137]
	Coughing but tolerating	CPOT, BPS	Collecting audio data using a microphone	Audio: detection of brief coughing and alarm sounds; Visual: occasional chest and abdomen movement desynchronization [138]
	Fighting ventilator	CPOT, BPS	Capturing video of the chest and abdomen	frequent coughing and alarm sounds, chest and abdomen movement desynchronization, agitation signs, blocking ventilation [137]
	Unable to control ventilation	BPS	Capturing video of the chest and abdomen	Chest and abdomen movement desynchronization, severe agitation, inability to synchronize with ventilator [137]
Vocalization	No vocalization	COPT	Collecting audio data using a microphone	Absence of vocalization, no audible sounds related to pain
	Sighing, moaning	COPT	Collecting audio data using a microphone	Low-pitched vocalizations, audible exhales, deep breaths [139]
	Crying out	COPT	Collecting audio data using a microphone	Acoustic characteristics of the cry, such as pitch, duration, and intensity [140]
Breathing patterns	Relaxed/normal	NIPS	Face video capture	Capturing the changes in blood flow and skin color through rPPG [53]
	Irregular	NIPS	Face video capture	Capturing the changes in blood flow and skin color through rPPG [53]
Arm movements	Relaxed/neutral	NIPS	Capturing video of the upper body, focusing on arms and shoulders	Detecting arms, analyzing arm movement, muscle tension, and positioning consistent with relaxed or neutral posture
	Tense or flexed	NIPS	Capturing video of the upper body, focusing on arms and shoulders	Detecting arms, analyzing arm movement, muscle tension, and positioning showing tension

(Continued)

Table 4. Audio-visual data collection for behavior pain scales *(Continued)*

Pain Indicator	Pain Behavior	Pain Scale	Data to be Collected	Data to be Collected
Leg movements	Relaxed/neutral	NIPS	Capturing video of the lower body, focusing on the legs and feet	Detecting leg, analyzing leg movement, muscle tension, and positioning consistent with relaxed or neutral posture
	Tense or flexed	NIPS	Capturing video of the lower body, focusing on the legs and feet	Detecting legs, analyzing leg movement, muscle tension, and positioning showing tension or flexing (e.g., kicking, legs held tightly)
State of arousal	Calm or sleeping	NIPS	Collecting audio data using a microphone; Face video capture	Audio: no significant change in vocal patterns; Visual: facial landmarks consistent with a calm or sleeping state
	Agitated or awake	NIPS	Collecting audio data using a microphone; Face video capture	Audio: changes in vocal patterns; Visual: facial landmarks and expressions indicating agitation or alertness
Upper limb movements	No movements	BPS	Capturing video of upper limb posture	Absence of movements, relaxed positions
	Partially bent	BPS	Capturing video of upper limb posture	Partially bent positions (e.g., slight flexion of fingers or wrists)
	Fully bent with finger flexion	BPS	Capturing video of upper limb posture	Fully bent positions with finger flexion (e.g., clenched fists, flexed elbows)
	Permanently retracted	BPS	Capturing video of upper limb posture	Permanently retracted positions (e.g., arms held close to the body, limited movement)
Muscle tension	Relaxed	CPOT	Capturing video of upper limb posture	Smooth, easy movements during passive flexion/extension, relaxed muscle tone when at rest and being turned.
	Tense, rigid	CPOT	Capturing video of upper limb posture	Resistance to passive flexion/extension, visibly strained muscle tone, tightened muscles when at rest and being turned.
	Very tense, or rigid	CPOT	Capturing video of upper limb posture	Strong resistance to passive flexion/extension, visibly rigid muscle tone, severely tightened muscles when at rest and being turned.

The data collection process starts by setting up data annotation protocols which involve consultations with clinical and pain management experts, physicians, and nurses having extensive experience in pain management. A detailed set of guidelines outlining the expected outcomes for each pain indicator are developed. The guidelines also include examples of correctly annotating data and a description of the factors to be analyzed for each pain indicator.

In the next step, requisites for data collection are established which involve setting up the necessary equipment, such as the cameras, microphones, and computing platform, to collect and process the audio-visual data. After collecting the data, it is pre-processed to ensure its compatibility with annotation tools and techniques. Video data is processed to extract visual features such as facial landmarks, body postures, limb movements, etc. Whereas, audio data is processed to extract vocalizations, coughing, and crying sounds. The processed data is stored securely to ensure privacy and compliance with relevant regulations.

Subsequently, the data is annotated by pain management experts, physicians, and other relevantly trained professionals using the established protocols. It is essential to maintain the quality during the annotation process by monitoring the consistency and accuracy of the annotators. Inter-rater agreement measures are also implemented to assess the consistency of annotations among multiple annotators.

4.6 Developing machine learning models for pain estimation

The objective of this stage is the development of machine learning models tailored for pain estimation. This is accomplished by developing and training multimodal models, which use audio and visual cues to predict pain levels, based on a diverse array of pain indicators. Each pain scale encompasses different indicators, each of which comprises several classes and associated scores. The aim is to accurately predict a specific class for each pain indicator, and then aggregate these individual scores to arrive at a comprehensive pain score. This can be achieved through the deployment of a singular, integrated model composed of multiple sub-networks (models), each tailored to address a specific pain indicator.

In simpler terms, the integrated model could be a combination of several individual pain indicator models, each addressing a multi-class problem. For instance, in the case of the CPOT scale, the integrated model will incorporate four separate sub-networks, each of which is dedicated to predicting different states of facial expressions, body movements, muscle tension, and vocalization. The scores associated with each state are then compiled to provide the final overall pain score.

An alternative to the combined models' approach is the development of a unified, multimodal model. Leveraging efficient fusion techniques for integrating data from multiple modalities, such a model can provide effective pain score estimation [141]. Recent advances in multimodal transformer models, capable of encoding raw input data concurrently across a broader array of modalities [142], open up new possibilities. The potential of these models for developing a comprehensive multimodal pain estimation system is certainly worth exploring.

4.7 Data protection and privacy

Data protection and privacy compliance with GDPR must be ensured. Robust mechanisms for data anonymization and protection for the contactless sensing system must be developed [143]. All the identifiable information, such as patient names or medical records, is removed from the data before it is used for training the models. Differential privacy techniques are applied during model training to withhold information about individual patients [144]. To ensure that the data cannot be linked back to specific individuals, pseudonymization techniques, such as using unique identifiers for patients, are used [145]. In addition to that, access to the data is restricted to authorized personnel only. Protection from unauthorized access is provided by implementing security protocols such as encryption and secure data storage. It is also essential to conduct regular audits and reviews to ensure adherence to GDPR [146]. Any necessary updates or changes to the data protection and privacy measures need to be made promptly to ensure continued compliance.

4.8 Generating narrative and visual explanations of the results

Generating clear and informative explanations of the results generated by the real-time pain estimation system is essential. The explanations can be provided either in narrative or visual form (or both) which can further help enhance the transparency and trust in the system. At the same time, explanations also provide valuable information for healthcare providers to make informed decisions about patient care.

Narrative explanations are helpful to give an insight into the system's performance as well as its accuracy and precision in pain prediction. The explanations about the decisions made by the AI system provide an overview of how the various pain indicators are combined to generate the pain intensity score, and what the influence of each indicator on the pain prediction is. The narrative explanations, written in clear and concise language, are made accessible to both healthcare providers and patients. An automated narrative can be generated by fine-tuning a large language model.

Narrative explanations are further complemented by visual explanations which comprise interactive graphs, charts, and diagrams that can help healthcare providers and patients understand the system's performance and the factors that contribute to pain intensity scores. Due to their user-friendly and easy-to-understand presentation, visual explanations make it easier for healthcare providers to communicate the results to their patients in a simple form.

The narrative as well as visual explanations are further made available to medical experts and researchers through a user-friendly and intuitive interface, allowing medical experts to easily access and evaluate the explanations, and facilitating the medical researchers to gain insight into AI decisions to find the influencing factors.

4.9 Pain estimation sandbox

Pain estimation sandbox operates as a secure, controlled environment, facilitating the seamless ingestion and preprocessing of multiple modalities pertaining to pain indicators in hospitals or research centers while adhering to data protection regulations, as shown in Figure 4. The data is then preprocessed within the sandbox, including steps like image resizing, normalization, and data augmentation, to improve model training. Based on the evaluation results, the model is refined by adjusting hyperparameters, incorporating additional data, or employing advanced techniques like transfer learning [147]. Feedback from medical professionals, such as pain management experts, is also gathered, ensuring the model meets real-world requirements and expectations.

The models for pain indicators recognition and pain estimation are integrated into a simulated healthcare environment within the AI sandbox to test their performance under realistic conditions. For instance, these models might be put to the test in a virtual patient monitoring setup to assess their proficiency in accurately identifying and scoring levels of pain based on a patient's visual and auditory cues. This step helps identify potential issues that might arise during deployment and ensures seamless integration with existing healthcare systems.

Once the models and the algorithms have been thoroughly tested and validated within the sandbox, they are deployed in a real-world healthcare setting, an intensive care unit or a postoperative recovery room. Continuous monitoring and feedback collection from end-users, such as nurses, clinicians, and pain experts, ensure the model remains accurate and effective over time. Any necessary updates or improvements are made within the AI sandbox before being deployed to the production environment.

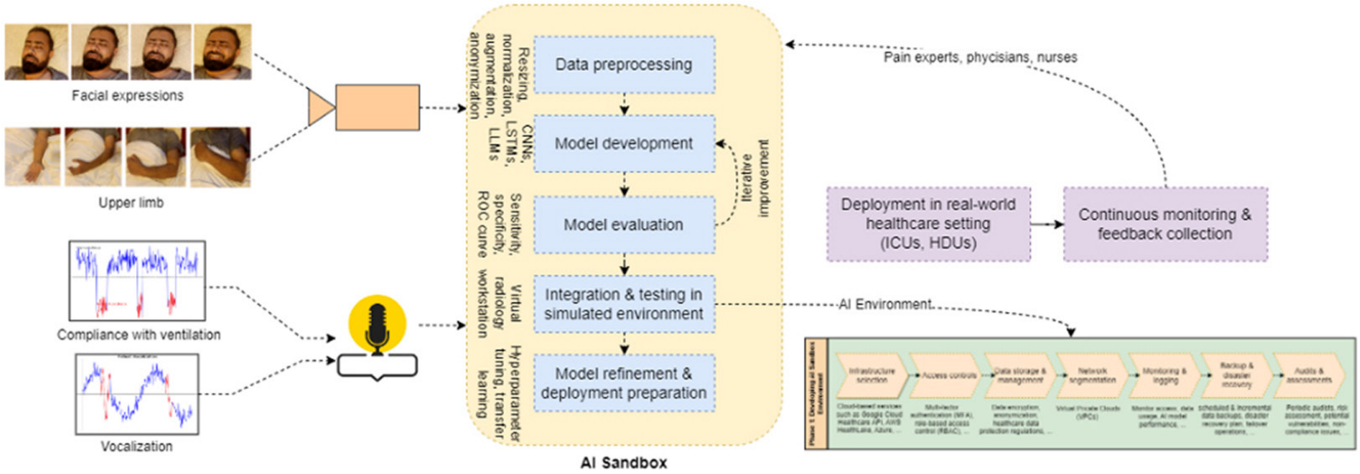

Fig. 4. Pain estimation sandbox

5 EVALUATION AND VALIDATION OF THE PAIN ESTIMATION SANDBOX

Conducting a clinical evaluation of the developed real-time pain prediction system is essential before deploying it in real scenarios. The evaluation needs to be carried out in various clinical and hospital settings to test the system's performance in real-world scenarios. The evaluation is primarily focused on assessing the accuracy and reliability of the system, as well as its usability and user acceptance. The evaluation involves testing the system's effectiveness in detecting and managing pain for patients with dementia and other cognitive disabilities. The results of the clinical evaluation are used to refine and improve the system and ensure that it meets the needs of both patients and healthcare providers. The findings of the evaluation must be documented in a report, which can be made available to stakeholders and medical experts.

Engaging medical practitioners directly in the evaluation process can add significant depth to the validation of the AI system. Hence, to strengthen the evaluation mechanism and ensure that the AI system aligns more closely with clinical interpretations, a user-friendly interface could be integrated. This interface will allow medical technicians and physicians to effortlessly input annotations, share comments, and rate the perceived pain levels based on their expertise and observations. By integrating these professional insights into the system's learning loop, the AI system can be provided with enriched datasets and additional reference points. This dynamic feedback mechanism will further fine-tune the system's accuracy, bridging the gap between automated AI interpretation and human clinical expertise. This symbiotic relationship, wherein the AI learns from clinical observations while supporting medical professionals with its predictions, will be pivotal in enhancing the credibility and precision of our pain estimation system.

We underscore the significance of implementing robust testing frameworks for AI systems, especially within the realm of contactless healthcare. It is of paramount importance to establish test beds with diverse datasets to fully grasp the capabilities and boundaries of AI algorithms. Such diversity ensures the simulation of various real-world scenarios, pushing the boundaries of AI and confirming its adaptability. Particularly in pain estimation, challenges often arise from sparse datasets, or even initial datasets that might be limited or heavily anonymized [148]. This underscores the necessity of utilizing a blend of datasets. While expansive datasets enable the system to discern overarching patterns, smaller, specific datasets improve the AI's performance in rare or less frequent cases. The overarching goal is to subject the system to a comprehensive spectrum of pain manifestations, ranging from the most prevalent to the most atypical.

Simulated patient cases, rooted in genuine clinical experiences and medical literature, should be seamlessly incorporated. They serve as an evaluative tool, examining the AI's performance under realistic conditions and spotlighting areas ripe for enhancement.

Holzinger's elucidation of the interactive machine learning paradigm for healthcare solutions [149] offers a blueprint that resonates with our stance. Holzinger describes it as a system where "*algorithms interact with agents, optimizing their learning behavior through these interactions, where agents can also be humans*" [149]. Building on this foundation, we advocate a human-in-the-loop methodology. This interactive framework, which combines algorithmic computations with human insight, promises a depth of understanding that traditional methods might overlook.

6 ETHICAL CONSIDERATIONS

Pain is the most common reason why patients begin to seek medical attention and care [150]. Ethical considerations in pain management usually relate to two main issues: i) pain management as a human right, and ii) patient-physician relationship [151]. Since pain management as a human right is ethically important to provide for patients, all new technological devices and tools to support this initiative are recommended. In addition, new technological innovations are also able to support the positive development of patient-physician relationships in all phases of care processes. Although the intention to provide technological support for those ethically important needs would be well justified, the developers should put special focus on data protection and privacy issues.

It is important to draw attention to patients' privacy concerns in designing pain management systems. Privacy concern means a situation where a person feels that his personal space is threatened, and it influences his behavior [152]. Reducing privacy concerns while persons adopt new e-health services and technologies is important for successful adoption [153]. For example, an organization's ability to use a person's sensitive data reduces trust in that organization [154]. Health and medical organization can increase the trust of patients and their willingness to provide personal data to the use of organizations by providing benefits to them [155]. Thus, trade-offs between patients' personal data and personal benefits are recommended as patients feel that they will also receive personal value if they provide consent to use their data in medical research and care processes. Prior health research [153], [156], [157] points out that demographics, information type, situational factors, and patient's preferences towards the opinions of organizations impact their privacy concerns. In addition, the authors in [153] show that females and healthy adults have more security and privacy concerns than males and the ailing elderly. Health status also affects patients' attitudes toward organizations that collect and use their personal information [158]. Persons' experiences with genetics also affect their willingness to participate in medical gene studies [159].

World Health Organization's guidance [160] for ethics and governance of artificial intelligence for health states that the key ethical principles for the use of artificial intelligence for health are protecting patients' autonomy, promoting human well-being, human safety and the public interest, ensuring transparency, explainability, and intelligibility, fostering responsibility and accountability, ensuring inclusiveness and equity and promoting AI solutions that are socially responsible and sustainable. Adapting those key principles in designing AI-based healthcare and medical services and technologies is expected to increase human autonomy, trust, transparency, and explainability while using those AI solutions. The lack of transparency and explainability of AI solutions is a key challenge in healthcare [161]. Similarly, unwanted biases, discrimination and misleading and inconclusive evidence cause several challenges from the ethical perspective [162].

Pain estimation systems using an AI sandbox in medical and healthcare contexts should increase patients' autonomy, safety, and well-being. That means that the AI sandbox may not limit patients' ability to choose measurement systems that promote ethical risks and decrease their safety and well-being during the medical care processes. An essential question is whether an AI sandbox as a closed system potentially creates new ethical or privacy challenges compared to AI systems that have secured data access or integration to Internet-based services. Although the closed system is evidently more secure from vulnerabilities and attacks, it does not have real-time data integration and sharing with other medical or healthcare systems. This might limit its user experience, remote use, and multimodality. Transparency and explainability are not dependent on external data integration if they are embedded software features that function as part of the AI system. Accountability, responsibility, and sustainability are typically related to the adaptation and usage processes, not software features and functionalities or data integration. A pain management system running in the closed AI sandbox operates with data, algorithms and other software resources that AI solutions can use within the sandbox without any direct external integration and real-time access. Thus, its ability to perform real-time analytics by integrating external data sources and the ability to use external infrastructure resources for calculation and computing processes is partly blocked. This might potentially weaken its usability, performance, and intelligence but simultaneously, practitioners and users can trust its privacy, security, and ethical capability.

The challenge of protecting patient data spans various phases of healthcare [163]. Before the care process, patients must grant informed consent regarding data collection and its subsequent use. Often, patients exhibit a greater willingness to share their data when aware of the potential benefits [155]. During the care process, data transmission and processing from devices to cloud-based computing and storage is crucial from privacy and security perspectives. Although privacy protection still lacks widely accepted technical standards, it should be implemented with general technical standards from the whole system perspective [164]. Analyzing highly anonymized data in healthcare challenges the capabilities of machine learning algorithms due to the difficulty to learn the internal connections and meanings of information cues from the lean information of anonymized data sets [165], [166]. In addition to anonymization, encryption of patients' data is important for privacy and medical data protection in healthcare devices. Especially systems that include several sensor devices that transmit data to cloud servers require high-level security features. In this connection, the studies such as [167] describe an IoT-based healthcare system where plain text is encrypted to cyphertext by using a secret key with an initial vector i.e., a random number for each counter to safeguard the plain text data even from potential internal threats.

7 IMPLEMENTATION AND ADOPTION BARRIERS

While designing a secure and ethical pain estimation system using an AI sandbox for contactless pain detection, certain challenges related to data uploading and updating, data anonymization, and consent management must be addressed.

7.1 Data uploading and updating

Uploading and updating data from external databases to the AI sandbox system is a critical step that requires careful consideration of potential vulnerabilities and malicious attacks. This process is a potential entry point for attacks, and hence, ensuring a secure data transfer mechanism is crucial.

One approach to mitigate these risks is the use of secure and encrypted data transfer protocols, such as Secure File Transfer Protocol (SFTP) or Secure Copy Protocol (SCP), which provide strong authentication and secure communications over networks. Data integrity checks should also be employed during the data transfer process. Checksums or hash values can be computed for the data before and after the transfer. If these values match, the data integrity is confirmed. If not, it suggests the data may have been tampered with during the transfer.

Furthermore, a dedicated intrusion detection system (IDS) could be employed to monitor the data transfer process and system activities, detect possible malicious activities, and alert system administrators. Regular audits and updates of security policies and practices are also essential to ensure the continued security of the data transfer process.

7.2 Data anonymization

Regarding the anonymization of personal data, it is most secure to perform this process within the AI sandbox system. This approach minimizes the exposure of personal data during transfer and storage. The anonymization process should employ techniques such as data masking, pseudonymization, and generalization to ensure that personal identifiers are sufficiently altered or removed.

If the anonymization process needs to be performed outside of the AI sandbox, additional security measures should be implemented. This could include the use of secure and encrypted connections for data transfer, restricting access to the data to authorized personnel only, and employing strong data anonymization techniques.

7.3 Consent management

When data is saved, shared, and used outside of the AI sandbox, appropriate consent management strategies need to be implemented. Clear and explicit consent should be obtained from patients or their legal guardians before their personal data is used. This includes informing them about how their data will be used, who will have access to it, and the measures in place to protect their data.

In situations where patients may be too sick or old to provide consent, alternative consent mechanisms should be employed. This could involve obtaining consent from a legal guardian or a designated health proxy. In all cases, the principle of minimal data usage should be applied—only the data necessary for the intended purpose should be used. Additionally, a robust data governance framework should be implemented to ensure ongoing oversight of data use. This includes monitoring and auditing data usage, implementing mechanisms for data subjects to withdraw consent or request data deletion, and ensuring compliance with applicable data protection laws and regulations.

7.4 Promoting acceptability and user trust

The successful implementation and adoption of the AI sandbox for contactless pain detection hinge on user acceptability and trust. Earning this trust requires transparency about the AI system's workings, decision-making processes, and potential risks and benefits. Clear, understandable explanations about these aspects can foster this transparency. Robust data security and privacy measures are crucial for establishing user trust. The system needs to demonstrate a strong ability to safeguard sensitive health data and maintain user privacy. Regular audits and transparent reporting about these measures can bolster this trust.

The AI system must be user-centric, designed to cater to users' needs and preferences with intuitive, easy-to-use features. Actively seeking and incorporating user feedback into system enhancements can ensure the system aligns with users' expectations. In addition, continuous engagement with users and stakeholders can cultivate a sense of ownership and involvement, further enhancing user trust and acceptability. Regular communication, training, and opportunities for user feedback and involvement in system development can facilitate this engagement.

8 DISCUSSION

As we traverse further into the realm of technological progress, remarkable advancements in both sensing technologies and machine learning have paved the way for contactless data acquisition. This revolutionary development mitigates the necessity for invasive or contact-based sensors, expanding the potential for research in a plethora of healthcare applications.

Our exploration serves as a practical case study demonstrating how AI sandbox technologies can be harnessed effectively in healthcare. This scenario illustrates the potential for these technologies to address existing challenges in healthcare, while also emphasizing the critical need to uphold ethical considerations and security in the design and implementation of AI-based solutions. Through this lens, our research offers a new perspective on the role of AI within healthcare, specifically in refining and enhancing pain estimation procedures.

While the domain of automated pain estimation has been explored extensively, there is a notable lack of focus on the automation of established, clinically validated pain tools. These tools, underpinned by empirical evidence, hold the potential to offer a more intricate understanding of pain levels. The widely used, unimodal method of pain estimation leveraging facial expression recognition, either through automated methods or observer-based tools is prone to inter-subject variability, facial paralysis, as well as cultural and personal differences. Therefore, it must be augmented with other modalities. Furthermore, physiological signals—while often used as indicators—can be influenced by other emotions like stress, fear, and anxiety, adding an additional layer of complexity to the pain estimation process.

Moreover, these signals have not been emphasized in traditional pain assessment tools. Therefore, our research underscores the need for considering additional modalities, including contactless behavioral cues, for more effective pain estimation.

In particular, our work highlights the under-recognized role of vocalization in pain estimation. Despite its significance in various pain scales, the existing literature has not fully acknowledged its contribution to accurate pain estimation. Our proposal emphasizes the automation of standard pain scales, suggesting that this approach could enhance the precision of pain assessments, particularly for patients with communication difficulties.

In practical terms, our work provides a detailed plan for a contactless, multimodal pain estimation system within a secure AI sandbox, forming a blueprint for real-world implementations. It focuses on automating standard pain scales, improving pain understanding, and addressing the limitations of current methods through the inclusion of various modalities. This enhances pain estimation accuracy and contributes to better pain management strategies. The application of AI sandbox for this purpose presents an opportunity to address several practical challenges in the field of healthcare. It offers a controlled environment for rigorous system testing, evaluation, and improvement. It also ensures security, data privacy, and reliability during operation. Our practical contributions extend to data collection and management. We identify specific cues for each pain indicator across pain scales, enabling comprehensive data gathering. When paired with advanced machine learning, this data can yield highly accurate and reliable pain prediction models.

The wealth of existing literature corroborates the potential of contactless monitoring methods in healthcare. Progress in computer vision, speech processing, and machine learning has created a dynamic pathway for gathering and analyzing cues from various pain indicators for efficient pain estimation. The facial expression analysis, a well-researched area, could be exploited further, in combination with other modalities, for the automation of standard pain scales. Additionally, the Facial Action Coding System [168] could be employed to further interpret the cues listed in Table 4. There is a good potential for augmenting facial expression recognition with other cues as discussed in this paper. Several other pertinent techniques, such as vision-based vital sign monitoring [169], adaptive breath monitoring [170], upper limb tension detection [171], infant cry detection [172], and posture monitoring of bedridden patients [173], among others, could be fruitfully applied to automate the discussed pain scales.

However, the adoption of a closed pain management system poses several challenges, including issues related to usability, intelligence, and real-time analytics. This is primarily because closed systems cannot directly access external databases, Internet-based cloud computing, and machine learning resources. Thus, our study underscores the necessity for further research to strike the right balance between security measures, user settings, and seamless integration with other systems such as patient and care process information.

9 CONCLUSION

In this study, we have advanced the concept of automating standard pain scales, particularly for patients having cognitive impairments or communication challenges. To that end, we have offered a meticulously devised roadmap for creating a contactless, multimodal pain estimation system in a secure AI sandbox environment. While detailing a comprehensive systematic approach for data collection and analysis of each pain indicator falls outside the purview of this study, our work brings forth significant insights and valuable contributions. These contributions encompass the delineation of multimodal cues linked with standard pain scales, the establishment of a systematic framework for generating a contactless pain estimation system within an AI sandbox, and a thorough investigation of pertinent ethical and privacy issues, all of which are based on robust theoretical foundations. This comprehensive approach seeks to assist researchers as they chart their course through the expanding territory of secure, automated, and contactless healthcare systems.

As we look to the future, we anticipate that our study can act as the foundation for future investigations in this realm. There are substantial opportunities for advancing this research in multiple directions, such as improving the trustworthiness of pain recognition, expanding the dataset to include a wider range of pain indicators, and further refining the models for more accurate pain estimation. Additionally, more emphasis can be placed on integrating these systems into real-world healthcare environments and assessing their performance and impact in these settings.

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