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PII: S0277-9536(25)00014-0

DOI: https://doi.org/10.1016/j.socscimed.2025.117685

Reference: SSM 117685

To appear in: *Social Science & Medicine*

Received Date: 1 August 2024

Revised Date: 25 November 2024

Accepted Date: 6 January 2025

Please cite this article as: Capulli, E., Druda, Y., Palmese, F., Butt, A.H., Domenicali, M., Macchiarelli, A.G., Silvani, A., Bedogni, G., Ingravallo, F., Ethical and Legal Implications of Health Monitoring Wearable Devices: A Scoping Review, *Social Science & Medicine*, https://doi.org/10.1016/j.socscimed.2025.117685.

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Ethical and Legal Implications of Health Monitoring Wearable Devices: A Scoping Review

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Acknowledgements

The authors would like to thank the expert college librarian, Claudia Cavicchi, for her invaluable assistance in developing the search strategy and performing the systematic literature search.

Declaration of Interest statement

There is no potential conflict of interest by any of the authors.

Funding

NRPP Enlarged Partnership 8, project "Age-IT: A novel public-private alliance to generate socioeconomic, biomedical and technological solutions for an inclusive Italian ageing society".

Ethical and Legal Implications of Health Monitoring Wearable Devices: A Scoping Review

Abstract

Background: health monitoring wearable devices (HMWDs) are increasingly implemented for personalized and preventive care. This review aims to summarize the existing literature on the ethical and legal implications of HMWDs in healthcare.

Methods: the study design is a scoping review and narrative synthesis of scientific literature. The literature search was conducted in May 2023, and updated on March 15th, 2024, from the following databases: PubMed, CINHAL, PsycInfo, Engineering Village, Index to Legal Periodicals & Books, Philosopher's Index, HeinOnline, and Nexis Uni. Pairs of blinded authors independently screened articles using Ryyan software, and manually checked reference lists of included articles. Peer-reviewed articles in English discussing ethical and/or legal implications of HMWDs in healthcare were included. A thematic synthesis approach was used to identify and summarize ethical and legal issues and recommendations. Protocol registration: https://osf.io/kfuh4/.

Findings: Overall, out of 7767 records retrieved, 405 full texts were assessed, and 12 articles, published between 2017 and 2024, were included. We identified 6 main themes: the use of HMWDs may adversely affect and reshape care relationships and the healthcare system; the use of HMWDs raises a variety of justice-related concerns; there are ethical issues related to personal data; HMWDs present several risks but the benefits are still uncertain; there are ethical issues regarding clinical research on HMWDs; and the current regulatory framework is inadequate.

Interpretation: the use of HMWDs in clinical and research settings raises several ethical and legal concerns, ranging from patient safety to autonomy, justice, and data protection. Implementing HMWDs without addressing these concerns may lead to dehumanization and datafication of care relationships and further marginalization of vulnerable populations.

Keywords

sensors; digital health; telemedicine; ethics; law; research; older adults

1. Introduction

The history of wearable technologies can be traced back to pocket watches and wristwatches from the 16th century (Amft and Lukowicz, 2009). Nonetheless, it was the advancements in informatics and digital communication during the 1990s that facilitated the swift advancement of wearable technologies. Today, wearable devices are devices that are designed to be worn or attached to the body and capable of performing various computer-like functions. Numerous classifications of wearable devices have been proposed in the scholarly literature (Iqbal et al., 2016; Seneviratne et al., 2017). In recent times, wearable devices have been utilized in diverse domains such as education (Liang et al., 2019), sports (Olsen et al., 2024), workplaces (Stepanovic and Mettler, 2022), and military settings (Scheit, 2021), and they are increasingly being incorporated into daily life (Lu et al., 2020). Notwithstanding this, one of their primary fields of application is healthcare, both in clinical practice and research settings.

Health monitoring wearable devices (HMWDs) are increasingly recognized as important tools for telemedicine as well as for personalized and preventive care. Despite technical limitations, such as sensor performance and reliability, HMWDs have shown promise in identifying potential health risks early on, facilitating faster diagnosis and treatment (Chen M. et al., 2022, Masoumian Hosseini et al., 2023).

In an aging society, there is an increasing number of people with chronic diseases and without in-home support; these people often have care needs that are challenging to address for healthcare systems and informal caregivers (Sundgren et al., 2020; Ji and Kim, 2022; Piau et al., 2023). In this context it was argued that HMWDs may be used to improve care and assistance for older people (Farivar et al., 2020; Lu et al., 2020; Chandrasekaran et al. 2021; Schicktanz and Schweda, 2021; Teixeira et al., 2021; Ji and Kim, 2022). These technologies, in fact, can permit continuous and remote monitoring of the health status of older adults, allowing the development of their chronic conditions to be tracked (Chen C. et al., 2023), providing detailed information on disease trends (Fowe and Boot, 2022), and enabling the outcome of treatments to be observed. Moreover, HMWDs can generate alarms and activate intervention in case of emergencies (Fowe and Boot, 2022; Chen C. et al., 2023). This kind of support has the potential to improve the autonomy and quality of life of older adults. In fact, they can be remotely monitored without leaving their homes, thereby delaying institutionalization and reducing readmission rates (Farivar et al., 2020; Chen C. et al., 2023). In doing so, HMWDs may also help healthcare providers and families in their care activities (Sundgren et al., 2020).

Although HMWDs are revolutionizing healthcare, their implementation presents ethical and legal challenges. Privacy and data sharing are among the most frequently discussed topics, given the continuous transfer of health data over extended periods. It is essential to ensure the security of devices and data storage systems to mitigate the risks of cybersecurity threats and data breaches, as well as issues related to data access and ownership. Additionally, even if HMWDs are expected to improve access to healthcare services, for example, by reaching rural areas (Martinez-Martin et al., 2021; Chen M. et al., 2022), they may add new burdens for people with low digital literacy and few socio-economic resources, exacerbating inequalities in benefit access (Canali et al., 2022).

Although ethical and legal issues of HMWDs have been discussed in the literature, it is difficult to identify which aspects are associated with the use of HMWDs in healthcare, because HMWDs are often considered with reference to fitness or together with other emerging technologies (Martinez-Martin et al., 2021; Predel and Steger, 2021). Importantly, non-technological challenges remain unexplored (Habibipour, 2019), with the majority of reviews on HMWDs focusing on technical aspects and medical applications (Lu et al., 2020; Masoumian Hosseini et al., 2023; Chow et al. 2024). On the other hand, it is essential to understand the ethical and legal implications of the use of HMWDs in healthcare in order to enable their fair implementation in this sector. Indeed, even if recommendations for medical devices developed by organizations and agencies such as the World Health Organization (WHO) (2017; 2020a; 2020b) and the United States Food and Drug Administration (US-FDA) (2022; 2023), as well as regulations such as the EU Medical Device Regulation (MDR 2017/745) (Regulation [EU] 2017/745) emphasize user protection, device reliability, and data security issues, most of these documents are not specific for HMWDs or focus on the phases of product development and legal framework design, rather than offering comprehensive guidance for the fair use of HMWDs.

This scoping review aims to map and summarize existing literature on the ethical and legal implications of HMWDs in healthcare. This work has the potential to assist healthcare professionals in addressing ethical and legal concerns that are emerging in both clinical practice and research of these technologies. It may assist policymakers in formulating more informed strategies and interventions. It may also provide insight for bioethicists and lawyers in areas in which ethics and laws require revision and updating due to the novelty of the issues posed by HMWDs. Finally, everyone involved in research and patients should be aware of the ethical and legal issues surrounding these devices.

2. Methods

2.1 Design

Scoping review and narrative synthesis of scientific literature following the PRISMA-ScR (PRISMA for Scoping Reviews) guidelines (Tricco et al. 2018) along with the RESERVE (REporting of SystEmatic ReViews in Ethics) guidelines (Kahrass et al., 2023). The protocol of this review has been made publicly available on the Open Science Framework website (https://osf.io/kfuh4/).

2.2 Research question

The main research question was: "What are the ethical and legal issues of the use of HMWDs in healthcare?"

We reviewed documents that addressed ethical or legal issues related to HMWDs recording signals from the human body, such as Holter electrocardiography monitors, ambulatory blood pressure monitors, or altigraphs. Devices that serve solely as position trackers were excluded.

The term "ethical issue" is used to encompass a diverse range of terms, such as "moral dilemmas" or "ethical challenges", which are commonly employed by authors from diverse backgrounds to denote facts or situations that necessitate ethical reflection (i.e., an argument-based reflection that adopts the tools of ethical analysis and follows a reasoned and logical argumentation, as stated in Howes and Gastmans 2021). With regard to legal issues, we aimed to identify the issues that were generally relevant (i.e., not strictly pertaining to a particular legal system) such as concerns for which there is no clear legal solution or potential legal conflicts that could arise.

We also looked into what recommendations have been made and summarized them.

Finally, due to the importance of HMWDs for the aging population, we investigated whether there are ethical or legal issues that, according to the current literature, are specific to older people, i.e., people aged 65 and above.

2.3 Data sources and search strategy

Given the interdisciplinary nature of the project, we searched databases from four different disciplinary areas: biomedical (PubMed, CINHAL and PsycInfo), engineering (Engineering Village), philosophical (Index to Legal Periodicals & Books and Philosopher's Index), and legal (HeinOnline and Nexis Uni). Electronic databases were searched from May 24, 2023, to May 29, 2023. On March 15th, 2024, an updated search was performed to evaluate any relevant literature published since the initial search.

The selection of the research terms and the final search strategy were developed through collaboration between a multidisciplinary team and an experienced college librarian. Our multidisciplinary team includes expertise in internal medicine, geriatrics, research methodology, psychology, physiology, computer engineering, anthropology, legal medicine, bioethics and law.

The full search strategy for each database is available in Appendix 1.

We included all articles that: (1) were peer-reviewed, (2) were written in English, (3) addressed the ethical or legal implications of HMWDs as a relevant topic, and (4) focused on the utilization of HMWDs in healthcare, i.e., under the guidance of healthcare providers.

We excluded articles that (1) corresponded to the following types of documents: dissertations, theses, books, abstracts, laws, court decisions, notes to court decisions, and conference proceedings; documents on conference proceedings were only considered in the Engineering Village database, as these are a common dissemination modality for structured research findings in the engineering community. Moreover, we excluded articles (2) focusing on specific legislation/regulation, and (3) consisting in empirical studies only (e.g., questionnaires, focus groups, interviews).

There were no restrictions based on publication date.

2.4 Study selection

Pairs of authors independently screened the retrieved articles against eligibility criteria using Rayyan software (https://www.rayyan.ai/). First, after removing duplicate entries, the reviewers independently screened the title and abstract of the articles (only titles in the case of articles retrieved from HeinOnline) ranking them as relevant, irrelevant, or unsure. Articles ranked as irrelevant by both reviewers were excluded, while in case of disagreement, and when at least one author ranked the record as unsure, there was an open discussion. Articles ranked as relevant were obtained in full text version and screened for inclusion. The reference list of each included article was checked in order to identify any other relevant reference. Disagreements were resolved through discussion with one of the senior authors. Following the PRISMA-ScR, there was no quality assessment of the included studies.

2.5 Data extraction and synthesis

The following information was double extracted independently by pairs of authors: first author, year of publication, country(es) of authors' affiliations, relevant topic (ethical, legal, or both), ethical framework, population and setting, objectives of the study, terminologies employed to denote the

technologies, types of devices mentioned, and recorded body variables mentioned. Disagreement between extractors was resolved by consensus between them.

A thematic synthesis approach was used to identify and summarize ethical and legal issues. First, for validity purposes, two authors independently read four of the included articles; they marked all ethical and legal issues in the text, labelling them as codes and sub-codes that were then gathered into categories following an inductive approach, without relying on pre-defined categories.

This was an iterative process, in which themes, categories, codes, and sub-codes were constantly adjusted as new information was added. To ensure accuracy and consistency, this process involved multiple readings of the articles and discussions between the authors regarding emerging categories and themes organization. After developing a preliminary codebook, one author coded the remaining 8 articles. The same inductive approach was followed for the extraction and synthesis of ethical and legal recommendations. The implementation of the coding framework was aided by the utilization of the software NVivo (https://lumivero.com/products/nvivo/), into which all the articles were imported. The findings are presented in a descriptive manner through tables and a narrative summary clarifies the outcomes. The findings are discussed from a multidisciplinary perspective and their implications for clinical and research practice, ethical reflection, and future research are considered.

3. Results

3.1 Results of the search

Figure 1 shows a PRISMA flow diagram of the selection procedure. In overall, the search produced 7767 records and, after 1425 duplicates were removed, a total of 6342 were screened. After the first round of screening, 5925 records were excluded based on the title and the abstract and 417 were sought for retrieval. Excluding 12 documents that were not retrievable, 405 of these studies were assessed for eligibility and 12 met all inclusion criteria. The screening of references of the included articles did not provide for further relevant articles.

3.2 Study Characteristics

The studies' characteristics are described in Table 1.

The included studies were published between 2017 and 2024. Authors' affiliations belong to United States (Ulrich et al., 2020; Tu and Gao, 2021; DeClue, 2023; Psihogios et al., 2024), followed by Italy (Canali et al., 2022; Canali et al. 2023) and other European Countries (Lucivero and Jongsma, 2018;

Ott et al., 2023), Australia (Segura Anaya et al., 2017), Canada (Grigorovich et al., 2020), China (Qu and Gao, 2020), and Japan (Nakazawa et al., 2021). Among the selected studies, 7 exclusively addressed ethical concerns (Segura Anaya et al., 2017; Lucivero and Jongsma, 2018; Tu and Gao, 2021; Canali et al., 2022; Canali et al. 2023; Ott et al., 2023; Psihogios et al., 2024), 1 exclusively addressed legal concerns (DeClue, 2023), and 4 addressed both (Grigorovich et al., 2020; Qu and Gao, 2020; Ulrich et al., 2020; Nakazawa et al., 2021). Among the articles analyzed, only 2 utilized a distinct and explicitly stated ethical framework, namely Principlism and Belmont or Principles framework (Canali et al. 2023; Psihogios et al., 2024). With regard to the population considered, 6 studies focused on patients in general (Lucivero and Jongsma, 2018; Qu and Gao, 2020; Ulrich et al., 2020; Tu and Gao, 2021; Canali et al., 2022; DeClue, 2023), 2 focused on specific populations of patients (Ott et al., 2023; Psihogios et al., 2024), 2 studies targeted older adults (Grigorovich et al., 2020; Nakazawa et al., 2021) and 2 considered both patients and the general population (Segura Anaya et al., 2017; Canali et al. 2023). Seven studies addressed concerns related to clinical practice (Segura Anaya et al., 2017; Lucivero and Jongsma, 2018; Grigorovich et al., 2020; Qu and Gao, 2020; Nakazawa et al., 2021; DeClue, 2023; Ott et al., 2023), 2 related to clinical research (Ulrich et al., 2020; Tu and Gao, 2021), and 3 related to both (Canali et al., 2022; Canali et al. 2023; Psihogios et al., 2024). 3 studies mentioned home (Ulrich et al., 2020; Nakazawa et al., 2021; Ott et al., 2023), 2 examined public institutions/institutional care settings (Grigorovich et al., 2020; Ott et al., 2023), and the remaining 7 did not mention any specific setting.

Table 2 presents the terminology used to refer to HMWDs, while Supplementary Table 1 shows the type of device mentioned and the recorded body variables as reported by the included articles. The terminology and related definitions were sometimes broader or more general than the ones specifically related to HMWDs used in our review. The term “wearable devices”, which was utilized in 4 articles (Segura Anaya et al., 2017; Nakazawa et al., 2021; Canali et al., 2022; Canali et al. 2023), was followed by “wearable technology/technologies”, which was employed in 3 articles (Tu and Gao, 2021; Canali et al. 2023; DeClue, 2023). Other terms were used once.

Table 1: Selected characteristics of the included articles

First Author year	Country	Relevant Topic	Ethical Framework	Population and setting	Aim(s) of the study
Segura Anaya, 2017	Australia	Ethical	Not reported	Patients and general population	To review ethical issues regarding privacy and security of wearable devices in the health sector, collect information on users' and patients' perceptions, and propose an ethical framework incorporating privacy and informed consent.
Lucivero, 2018	United Kingdom Netherlands	Ethical	Not reported	Patients	To provide an overview of bioethical issues raised by mobile health technology.
Grigorovich, 2020	Canada	Ethical and legal	Not reported	Older adults in institutional settings	To review the ethical, social, and policy implications of monitoring technologies, and guidance regarding their implementation.
Qu, 2020	China	Ethical and legal	Not reported	Patients	To identify ethical problems in the whole process of health medical wearable equipment serving human beings and to suggest countermeasures and suggestions.
Ulrich, 2020	United States	Ethical and legal	Not reported	Patients in their homes	To discuss ethical concerns regarding sensor-based technologies that arise in research and to outline ethical considerations.
Nakazawa, 2021	Japan	Ethical and legal	Not reported	Older adults living at home alone under conditions of social isolation	«To examine ethical issues surrounding the application of wearable devices and cloud-based information processing systems to prevent solitary death».
Tu, 2021	United States	Ethical	Not reported	Patients	«To briefly discuss ethical considerations and challenges specific to the wearable research community, with close reference to the current technological advances and their potential applications».
Canali, 2022	Italy	Ethical	Not reported	Patients	To identify the ethical challenges and provide recommendations for the use of wearable devices in digital health.
Canali, 2023	Italy	Ethical	Principlism	Patients and general population	To discuss the hypothesis that the use of wearable devices for continuous stress measurement is beneficial from an ethical viewpoint.
DeClue, 2023	United States	Legal	Not applicable	Patients	To discuss legal issues connected to «the effects of wearables in cases of medical malpractice and the scope of liability of doctors, the effects on the standard of care and the traditional doctor-patient relationship, and privacy and confidentiality concerns from utilizing third-party wearables to collect patient data».
Ott, 2023	Germany	Ethical	Not reported	Patients receiving palliative care at home/ healthcare facilities	To identify changes and challenges related to the use of smart sensor technologies in palliative care, and to develop normative guiding criteria for their use.
Psihogios, 2024	United States	Ethical	Belmont Report	Pediatric populations	To «discuss ethical challenges and recommendations for implementing health based, human-enabled sensors in pediatric populations».

Table 2: Terminology and definitions used to refer to the wearable technology

First Author, year	Terminology and definitions
Segura Anaya, 2017	Wearable Devices: «wearable devices used in the health sector called "medical care devices"».
Lucivero, 2018	mHealth (mobile health): «a broad label for a variety of services and technologies supported by mobile devices, such as smartphones, patient monitoring devices, personal digital assistants and other wireless devices to improve healthy behaviors, quality of life and well-being of individuals».
Grigorovich, 2020	Monitoring Technologies (used in institutional care settings) «include smartphones, wearables, and sensors embedded in everyday institutional objects (e.g., mattress, bed) that can continuously and passively collect, transmit, and process data regarding the movements, activities, and physiological outcomes».
Qu, 2020	Health Medical Wearable Devices «can be directly worn on the body or implanted into the human body and can be perceived, recorded, analyzed, regulated, or intervened through software support and data interaction, and even treat diseases and maintain health status».
Ulrich, 2020	Sensor Technologies «encompass a broad range of technical platforms and data sources, some of which are new to care delivery, such as global positioning systems, physiological sensors capturing vital signs and brain activity, and social media».
Nakazawa, 2021	Wearable Devices – Definition not given
Tu, 2021	Wearable Technology – Definition not given
Canali, 2022	Wearable Devices: «devices that can be worn on our bodies and track several activities and parameters».
Canali, 2023	Wearable Technologies, including wearable devices «that can be worn directly on the body and collect large volumes of data on different types of biomedical metrics and physiological signals».
DeClue, 2023	Wearable Technology «or "wearables" are devices are devices that can be worn or mated with human skin to continuously and closely monitor an individual's activities, without interrupting or limiting the user's motions».
Ott, 2023	Smart sensor technologies (SST) «include all non- or minimally invasive sensor technology aimed at the comprehensive collection of physical data – e.g., sweat, blood pressure, movements, and heart / respiratory rate».
Psihogios, 2023	Accelerometer-based devices «refer to actigraphs and other sensors that measure accelerations to infer body movement and estimate sleep and physical activity patterns».

3.3 Ethical and legal issues

The thematic analysis led to the identification of 6 themes and several categories, that are reported in Table 3 along with codes and subcodes. Each theme is explained in the sections below.

Finally, our review aimed not only to share findings with the bioethics community, but also to provide guideline developers with strategies and suggestions to adequately deal with ethical and legal issues. To this aim, recommendations reported in the included articles are summarized in Supplementary Table 2.

Table 3: Summary of ethical and legal issues

Category	Code	Subcode
Theme 1. The use of HMWDs may adversely affect and reshape care relationships and the healthcare system		
1.1 Shift of responsibility and workload from healthcare system to patient and family	Transfer tasks carried out by healthcare professionals to patients or family	
	HMWD use may cause a burden on users	Device demands and impact on daily routine
		Intrusiveness (privacy intrusion and discomfort)
1.2 Rethink medical roles and expectations, and those of patients and family	Patients and caregivers are no longer the only source of information	
	Families may rely on data from HMWDs rather than seeking support	
	Need to rethink roles and responsibilities in data interpretation	
1.3 Potential hazards of datafication	Physicians may focus on somatic parameters while neglecting psychosocial, relational, and spiritual aspects and patient-reported data	
	Physicians may overrely on HMWD data or ignore the fact that HMWDs are fallible	
1.4 HMWDs may compromise patients' autonomy	Patients may not fully understand the technology	Patients may be unaware of the impact of HMWDs on their future health, which data are collected, and for which purposes
	Patients may be induced to perform tasks and comply to a medical quantified regimen	
Theme 2. The use of HMWDs raises a variety of justice-related concerns		
2.1 Unfair access to technology	HMWDs favor users who are younger, more educated, wealthier, and of higher socioeconomic status	Older people are less likely to use technological devices and may need support
		For data to be accurate it requires users to have a higher level of health literacy
		Cost may be prohibitive for socially disadvantaged communities
	HMWDs' characteristics may have varying impacts on certain populations	Efficacy may vary based on skin tone
		Sensor acceptability may differ for children with neurodevelopmental conditions
2.2 Risk of discrimination and marginalization	Users with limited resources may be more affected in case of low-quality data	
	Privacy disclosure may lead to unequal treatment of vulnerable populations	People with disabilities
		Patients with special diseases
		Socioeconomically disadvantaged people
	Concerns about surveillance for marginalized groups without clear benefits	Populations that are already discriminated against and that have experienced «medical mistrust»
2.3 Benefits and resources may be not equally distributed	Risks related to excluding some users	Biased and under-representative datasets
		Discriminatory health policy
	Benefits and tools disproportionately available to consumer technology companies	Providers and manufacturers do not share information on collection, classification, interpretation of HMWDs data
	Inaccurate detection or prediction may divert resources from genuinely problematic situations	
Theme 3. There are ethical issues related to personal data		
3.1 Risks related to data security	Risks of personal data breaches	Data leakage or unintentional disclosure
		Unauthorized access, theft, or

		interception by third parties
	Factors that may challenge data security	Data obtained, shared, disclosed, or used without full patient consent Ambiguity between commercial and medical domains Limitations in the efficacy of data anonymization and inefficiencies in encryption Inadequate user awareness and control over privacy Challenging interaction among different stakeholders Fragmentation and big data of medical information
3.2 Risk of data commercialization, exploitation, and misuse	Data may be sold Data may be used for data mining and creation of customer profiles Discriminatory policies regarding employment, credit, and health insurance	Targeted advertising without user knowledge or consent
Theme 4. HMWDs present several risks but the benefits are still uncertain		
4.1 Risks related to device safety	Biological risks	Infection
	Chemical risks	Chemical exposure, skin irritation, ingestion of toxic metals
	Physical risks	Electrical shock; electromagnetic, radiofrequency, and geomagnetic radiation
	Health risks associated with cyber-attacks	Attacks can jeopardize patients' health and safety
4.2 Risks related to device reliability and validity	False negatives	Unfoundedly reassure the user
	False positives	Escalate discomfort, anxiety, emotional distress, and confusion Degrade efficacy Cause the loss of faith in the signal by stakeholders Trigger unintended interventions
	Inaccurate data result in inaccurate diagnoses, prescriptions, medical advice	Subjectivity in selecting and applying scoring algorithms Inadequate technology Interference/unanticipated factors Difficult to assess data quality
	Alarm systems are ineffective without a service that manages the alarm and provides a prompt response	
4.3 Risk of excessive emotional distress	Lack of contextual information may create doubt and anxiety for the users Patients may feel abandoned Awareness of one's own stress levels could potentially exacerbate stress	
4.4 Limited evidence of benefits	Few studies on the impact of HMWDs in real-life settings	
	Research limitations	Atheoretical evaluations Small sample
Theme 5. There are ethical issues regarding clinical research on HMWDs		
5.1 Participants may encounter difficulties in comprehending the utilization, hazards, and advantages of HMWDs	Therapeutic-diagnostic misconception	Overestimation of benefits Unrealistic expectations about safety
	Privacy risks are difficult to explain	
	Users might be unfamiliar with HMWDs or be confused by other technologies	
	Data literacy may affect understanding	
	Obtaining proxy consent may differ from other types of research	Patients/minors and proxies may have diverse literacy levels and privacy

		concerns
5.2 Ethical oversight over HMWD research is weak	Difficult to establish a specific set of ethical guidelines	Ethical considerations differ for fitness tracking and medical-grade wearable technology
	Internal Review Board members may lack experience and expertise with HMWDs	
5.3 Other ethical issues of research with HMWDs	Issues of data ownership and storage when researchers collaborate with hardware or software vendors	
	Most studies are first-in-human or early-stage human trials	
	Study design may unfairly exclude people based on their ethnic, socioeconomic, and health status	Enrollment may be non-inclusive relying on participant resources
		Overlook children with neurodevelopmental impairments
		Studies may be influenced by biases and assumptions about the user
Theme 6. The current regulatory framework is inadequate		
6.1 Limitation of current regulatory framework	Laws do not adequately safeguard individuals	Contractual obligations favor more advantaged parties
		Individuals are not protected from discrimination based on predictions of their future health issues
	Lack of specific legal regulation	Lack of legal supervision of current market environment
		No clear regulation of the use of wearable technology across countries with different jurisdictions
6.2 Medical malpractice and liability	HMWDs may raise malpractice claims and make it more difficult to prove them	
	Uncertainties about liability may lead to blame-shifting situations	Doctors may claim that patients changed data
		Doctors may claim that technology is not reliable

Theme 1: The use of HMWDs may adversely affect and reshape care relationships and the healthcare system

Many articles underline the potential undesirable impact of HMWDs on care relationships and the healthcare system (Lucivero and Jongsma, 2018; Segura Anaya et al., 2018; Grigorovich et al., 2020; Qu and Gao, 2020; Ulrich et al., 2020; Nakazawa er al., 2021; Tu and Gao, 2021; Canali et al, 2023; DeClue, 2023; Ott et al., 2023; Psihogios et al., 2024).

Shift of responsibility and workload from healthcare system to patient and family

The first issue observed was the shifting of responsibility and workload from healthcare providers and systems to patients and family. This shift, which has been interpreted in the context of neoliberalism by one article (Lucivero and Jongsma, 2018), primarily involves the transfer of certain tasks traditionally performed by healthcare professionals, such as monitoring vital signals, to patients or their families (Lucivero and Jongsma, 2018; Segura Anaya et al., 2018). This shift may be associated with a high technology burden due to the demands of the device and the impact on daily

routine, such as the need to recharge batteries or connect to the Internet, which may prevent some patients from leaving home (Ulrich et al., 2020). It may also be associated with intrusiveness, such as the invasion of personal privacy and the discomfort of cumbersome devices (Segura Anaya et al., 2018; Ulrich et al., 2020; Nakazawa er al., 2021; Tu and Gao, 2021; Canali et al, 2023; DeClue, 2023).

Rethink medical roles and expectations, and those of patients and family

Consistently, the use of HMWDs may lead to a reassessment of medical, patient, and family roles and expectations, as well as a reassessment of the health data itself. The use of HMWDs may lead to a rethinking of the role of doctors, patients, and families and the health data itself, as patients and caregivers are no longer the only source of information (Ott et al., 2023), and families might rely on data from their personal wearable devices instead of seeking support from doctors (Psihogios et al., 2024). Furthermore, the use of HMWDs may require a rethinking of roles and responsibilities in data interpretation, for example, healthcare providers may assume new data management responsibilities (Lucivero and Jongsma, 2018; Grigorovich et al., 2020).

Potential hazards of datafication

The utilization of HMWDs is associated with the potential hazards of datafication, i.e., the transformation of qualitative aspects of life into quantified data (Ruckenstein et al., 2017). In detail, it has been suggested that physicians may focus on somatic parameters while neglecting psychosocial, relational, and spiritual aspects of a patient's condition, which are crucial for a comprehensive approach (Ulrich et al., 2020; DeClue, 2023; Ott et al., 2023). Furthermore, physicians and researchers may overrely on HMWD data by giving priority to device-driven over patient-reported data, or by ignoring the fallibility of HMWDs (DeClue, 2023; Psihogios et al., 2024).

HMWDs may compromise patients' autonomy

Another concern is the potential for HMWDs to compromise patients' autonomy. Patients may be unaware of the impact of HMWDs on their future health and of which data are collected and for which purposes (Lucivero and Jongsma, 2018; Qu and Gao, 2020). Additionally, it is argued that the use of HMWDs may affect autonomy by inducing patients to perform tasks and comply to a medical quantified regimen, e.g., taking medication (Lucivero and Jongsma, 2018; Canali et al, 2023), or labeling older patients who refuse this technology as being non-compliant (Grigorovich et al., 2020).

Theme 2: The use of HMWDs raises a variety of justice-related concerns

Several articles underline the issue that access to HMWDs and the consequences of their implementation may be unequal and unfair (Canali, 2022; Qu and Gao, 2020; Ulrich et al., 2020; Nakazawa et al., 2021; Tu and Gao, 2021; Canali et al, 2023; DeClue, 2023; Psihogios et al., 2024).

Unfair access to technology

It is argued that HMWDs favor users who are younger, more educated, wealthier, and of higher socioeconomic status; older people are less likely to use them, and they need social support (Ulrich et al., 2020; Nakazawa et al., 2021; Canali, 2022; Canali et al, 2023). In order for data to be accurate, a higher level of health literacy is required on the part of users, especially in the case of deviation from data collection in a special environment (Qu and Gao, 2020; Nakazawa et al., 2021). The cost of HMWDs may be prohibitive for socioeconomically disadvantaged communities (Qu and Gao, 2020; Ulrich et al., 2020; Canali et al., 2022; Canali et al, 2023; DeClue, 2023; Psihogios et al., 2024). Furthermore, it should be noted that the characteristics of HMWDs may have varying impacts on certain populations (Tu and Gao, 2021), for instance, efficacy may vary based on skin tone (Nakazawa et al., 2021), and sensor acceptability may differ for children with a neurodevelopmental condition (Psihogios et al., 2024).

Risk of discrimination and marginalization

The implementation of devices may present risks of discrimination and marginalization in various ways. First of all, if HMWDs become the main health service available to users with limited financial resources, and if data quality is not constantly checked and ensured, they would be the most affected by the low quality data (Canali et al., 2022). Second, privacy disclosure, such as the disclosure of a disease without user consent, may lead to unequal treatment of people with disabilities, patients with special diseases, and those who are socioeconomically disadvantaged (Qu and Gao, 2020). Monitoring in the context of public health raises concerns regarding surveillance that may target marginalized social groups without clear benefits (Canali et al., 2022). In this context, concerns about monitoring without consent may be increased for populations that have suffered discrimination in healthcare settings and experience «medical mistrust» (Psihogios et al., 2024).

Benefits and resources may be not equally distributed

Finally, benefits and resources may not be equally distributed. Furthermore, excluding some users may lead to biased and under-representative datasets, and focusing health policy on selected members of the population (Canali et al., 2022). In addition, the benefits and tools are disproportionately available to consumer technology companies, with data providers and manufacturers not sharing

information on the collection, classification, and interpretation of wearable data (Canali et al., 2022). Inaccuracies in wearable devices, moreover, can result in the overestimation of health concerns by erroneously identifying and predicting non-problematic conditions as critical, thus diverting resources from genuinely problematic situations (Nakazawa et al., 2021; Canali et al., 2022).

Theme 3: There are ethical issues related to personal data

Several authors highlight the ethical issues raised by the use of HMWDs in relation to personal data, pointing out the need to address data governance in this sector (Lucivero and Jongsma, 2018; Segura Anaya et al., 2018; Grigorovich et al., 2020; Qu and Gao, 2020; Ulrich et al., 2020; Tu and Gao, 2021; DeClue, 2023; Psihogios et al., 2024).

Risks related to data security

First, articles identify risks for personal data security, such as personal data breaches, including data leakage or unintentional disclosure (Qu and Gao, 2020; Ulrich et al., 2020), unauthorized access, theft, or interception by third parties (Lucivero and Jongsma, 2018; Segura Anaya et al., 2018; Grigorovich et al., 2020; Qu and Gao, 2020; Ulrich et al., 2020; DeClue, 2023) and data being obtained, shared, disclosed, or used without full patient consent (Lucivero and Jongsma, 2018; Grigorovich et al., 2020; Qu and Gao, 2020; DeClue, 2023; Psihogios et al., 2024). Numerous factors may pose a challenge to data security, including the ambiguity between commercial and medical domains (Lucivero and Jongsma, 2018; Ulrich et al., 2020), limitations in the efficacy of data anonymization against privacy violations (Ulrich et al., 2020: Tu and Gao, 2021; DeClue, 2023), inefficiencies in data encryption (Qu and Gao, 2020), inadequate user awareness and control over privacy (Lucivero and Jongsma, 2018; Qu and Gao, 2020; Psihogios et al., 2024), challenging interaction among stakeholders with diverse competence and objectives (Segura Anaya et al., 2018; Ulrich et al., 2020) and the potential for blurred data protection due to fragmentation and big data of personal health and medical information (Qu and Gao, 2020).

Risk of data commercialization, exploitation, and misuse

Other significant concerns pertain to data commercialization, exploitation, and misuse. Data may be sold or utilized for data mining and for the creation of customer profiles, which may be utilized for targeted advertising without user knowledge or consent (Lucivero and Jongsma, 2018; DeClue, 2023). Furthermore, users' data may be used for discriminatory policies regarding employment, credit, and health insurance (Lucivero and Jongsma, 2018; Segura Anaya et al., 2018; Qu and Gao, 2020; DeClue, 2023).

Theme 4: HMWDs present several risks but the benefits are still uncertain

Many authors mention issues related to the possibility that the use of HWMD devices could cause risks for those who use them, while evidence of benefits is still scarce (Lucivero and Jongsma, 2018; Segura Anaya et al., 2018; Grigorovich et al., 2020; Qu and Gao, 2020; Ulrich et al., 2020; Nakazawa er al., 2021; Tu and Gao, 2021; Canali 2022; Canali et al, 2023; DeClue, 2023 Psihogios et al., 2024).

Risks related to device safety

The first category is that of risks related to device safety that can be biological, such as infection (Tu and Gao, 2021) chemical, such as skin irritation or accidental ingestion of toxic heavy metals (Qu and Gao, 2020; Tu and Gao, 2021), or physical, such as electrical shock (Tu and Gao, 2021). Cyber-attacks may also pose risks to patients' health and safety, compromising the proper functioning of the device (Segura Anaya et al., 2018; Qu and Gao, 2020; Tu and Gao, 2021; Canali et al, 2023).

Risks related to device reliability and validity

Another category of risks pertains to the reliability and validity of technology, including the risks associated with the occurrence of false negatives, false positives, inaccurate data, and an inadequate response in the event of an alarm or emergency. False negatives may unfoundedly reassure the user (Lucivero and Jongsma, 2018; Ulrich et al., 2020), while false positives may escalate discomfort, anxiety, emotional distress, and confusion (Canali et al., 2022; Ulrich et al., 2020), degrading efficacy (Nakazawa et al., 2021), causing stakeholders to lose faith in the signal (Grigorovich et al., 2020 Nakazawa et al., 2021), and triggering unintended interventions (Tu and Gao, 2021). Data that is inaccurate due to inadequate technology (Segura Anaya et al., 2018; Nakazawa et al., 2021; Canali et al, 2023), interference, and unanticipated factors (Qu and Gao, 2020; Tu and Gao, 2021), difficulty in evaluating data quality (Canali et al., 2022), and subjectivity in selecting and applying scoring algorithms (Psihogios et al., 2024) may result in inaccurate diagnoses, prescriptions, or medical advice (DeClue, 2023). Lastly, alarm systems are ineffective without a service that manages the alarm and provides a prompt response (Nakazawa et al., 2021).

Risk of excessive emotional distress

A third category of risk pertains to the possibility of HMWDs causing excessive emotional distress to users: lack of contextual information regarding reliability of data and their interpretation may create doubts and cause anxiety in the users (Canali et al. 2022), or patients may feel abandoned, which can

cause stressful awareness (Lucivero and Jongsma, 2018), and awareness of one's own stress levels could potentially exacerbate the stress itself (Canali et al., 2023).

Limited evidence of benefits

Finally, few articles have underlined the limited evidence of benefits for HMWDs as an ethical issue (Lucivero and Jongsma, 2018; Grigorovich et al., 2020; Canali et al., 2023), due to both a scarcity of studies on the impact on individual health and the healthcare system in the real-life setting, and research limitations, such as the frequent small sample size and atheoretical evaluations. One article highlighted the inadequate evidence regarding the perceptions and experiences of patients, healthcare providers, older adults, and family members (Grigorovich et al., 2020).

Theme 5: There are ethical issues regarding clinical research on HMWDs

Few articles address ethical concerns related to research in the field (Lucivero and Jongsma, 2018; Ulrich et al., 2020; Tu and Gao, 2021; Psihogios et al., 2024).

Participants may encounter difficulties in comprehending the utilization, hazards, and advantages of HMWDs

The initial concern is that study participants may encounter difficulties in comprehending the utilization, hazards, and advantages of HMWDs. One article emphasized the risk of a therapeutic-diagnostic misconception. The therapeutic misconception is that participants may not fully understand that the research may not benefit them. Diagnostic misconception refers to the erroneous belief that HMWDs provide additional safety. For example, it is incorrect to believe that HMWDs provide supplementary safety measures, as if healthcare providers were providing real-time monitoring during the night (Ulrich et al., 2020). Furthermore, elucidating privacy hazards may prove challenging, certain technologies may be unfamiliar to users or misinterpreted in relation to other similar technologies, and data literacy may affect their understanding of the research (Ulrich et al., 2020; Psihogios et al., 2024). Lastly, some articles have highlighted that requirements and preferences, technological and health literacy, and apprehensions regarding data privacy and security may differ among individuals with cognitive limitations and their proxies as well as between minors and their parents (Ulrich et al., 2020; Psihogios et al., 2024).

Ethical oversight over HMWDs research is weak

There is consensus that ethical oversight of HMWDs research is weak. It is difficult to establish a specific set of ethical guidelines for this field (Lucivero and Jongsma, 2018; Ulrich et al., 2020; Tu

and Gao, 2021), considering that ethical considerations regarding wearable technology for generic fitness tracking may differ from those concerning medical-grade wearable technology (Tu and Gao, 2021). Furthermore, members of the internal review board may lack experience and expertise in handling HMWDs (Tu and Gao, 2021).

Other ethical issues of research with HMWDs

Other ethical concerns associated with research involving HMWDs comprise potential concerns regarding data ownership and storage when researchers collaborate with hardware or software vendors (Ulrich et al., 2020; Tu and Gao, 2021), as well as the fact that numerous studies involve first-in-human or early-stage human trials (Tu and Gao, 2021). One article notes that study design may unfairly exclude people based on their ethnic, socioeconomic, and health status. Indeed, studies have predominantly focused on non-Hispanic Latinx white families with higher socioeconomic status and in good health. For instance, studies that rely on family resources, such as smartphones, may result in non-inclusive enrollment practices, and children with neurodevelopmental impairments are frequently overlooked (Psihogios et al., 2024). Furthermore, studies may be influenced by biases and assumptions about the user. For example, studies on infant sleep often do not consider the impact of bedsharing, which is common in Africa, Asia, and among US Black and Latinx families (Psihogios et al., 2024).

Theme 6: The current regulatory framework is inadequate

Only one article addressed ethical issues related to the use of HMWDs (DeClue, 2023), while four other papers addressed legal issues (Grigorovich et al., 2020; Qu and Gao, 2020; Ulrich et al., 2020; Nakazawa er al., 2021).

Limitation of current regulatory framework

There is consensus regarding the limitations of the present regulatory framework: laws do not adequately safeguard individuals, since contractual obligations favor more advantaged parties (Nakazawa et al., 2021), and individuals are not protected from discrimination based on predictions of their future health issues (Grigorovich et al., 2020). There is a lack of specific legal regulation related to the supervision of the current market environment (Qu and Gao, 2020) and the use of wearable technology across countries with different jurisdictions (DeClue, 2023).

Medical malpractice and liability

A second question relates to medical malpractice and liability issues (Ulrich et al., 2020; DeClue, 2023). Wearable technology could increase malpractice claims and make it more difficult to prove them. For instance, when HMWDs are employed for telemedicine, the absence of a distinct standard of care may pose a challenge in determining whether a physician has breached it. Furthermore, uncertainty regarding liability may lead to blame-shifting situations, as doctors may say that patients changed data or that the HMWDs technology is not reliable.

Ethical and legal implications of HMWDs regarding older adults

There were two articles that address the population of older adults. A first issue concerns older individuals greater difficulties in utilizing technology and accessing it. Typically, digital devices are projected toward young people. Older adults are less likely to use them and may require assistance in using and properly maintaining them. Many older adults may lack the necessary skills and knowledge to utilize wearable technologies as a result of the digital divide. However, it is possible to improve their use by improving the devices design, comfort, and aesthetic (Nakazawa et al., 2021). A second main issue concerns autonomy. The refusal to use technology expressed by older people with cognitive impairment may be considered to be a non-compliance with technology rather than a genuinely self-determined choice (Grigorovich et al., 2020). Family carers and providers may «influence or coerce» older adults into accepting monitoring technologies, especially if they are seen as essential for survival, health, and hygiene. Moreover, given that monitoring technologies are frequently intended to substitute or alleviate the burden of supervision borne by family carers or providers, these caregivers may possess a greater enthusiasm for these technologies than the older adults themselves, sometimes surpassing their preferences (Grigorovich et al., 2020).

4. Discussion

The purpose of this study was to examine the ethical and legal issues surrounding the use of HMWDs under the supervision of health care professionals, which have been addressed in the medical, engineering, philosophical, and legal literature. Because the novelty of the topic results in fragmented and scattered literature, we chose a scoping review methodology that allowed us to formulate broader research questions, which seem more suitable for research involving a heterogeneous body of knowledge and an interdisciplinary research field.

In recent times, significant emphasis has been placed on the advantages these technologies can afford in terms of patient empowerment, prevention and monitoring of diseases, and improved management of healthcare resources. These technologies have the potential to enhance accessibility and reduce some healthcare expenses. However, this review raised several ethical concerns regarding the use of

HMWDs in clinical and research settings, ranging from patient safety to autonomy, justice and data protection. Few generalizable legal issues were found. The main issue that emerged was how HMWDs could contribute to a paradigm shift affecting the healthcare system and care relationships. The articles reviewed were all recent, with the oldest article dating back to 2017, indicating a recent interest in the ethical and legal implications of HMWDs, despite their long history in healthcare. In spite of their limited number, the selected articles are from diverse geographic locations, suggesting a widespread interest in this emerging topic. Nonetheless, only 2 out of the 11 articles addressing ethical concerns are framed within a distinct ethical framework. This may indicate that authors are unaware of the significance of a theoretical framework, or that established ethical frameworks may be perceived as insufficient to address the ethical challenges presented by HMWDs. The heterogeneity of HMWDs and vagueness in their classification complicate research in this field and present challenges for ethical analysis, as different technologies raise specific moral questions (Lucivero and Jongsma, 2018). Therefore, a more precise ethical reflection requires greater specificity and clarity regarding the HMWD technologies under consideration and their functions.

The included articles highlight how the use of HMWDs could help shift responsibility and workload from healthcare providers and systems to patients and their families. According to Lucivero and Jogsma (2018), this shift in responsibility is consistent with the wider neoliberal trend of transferring responsibility and management of care from the state to citizens. In the most economically advanced countries, this trend emphasizes personal accountability for personal actions, and expects people to be competent and actively involved in the promotion of their own health. However, national health services are also facing budget reduction, decentralization, and privatization (McGregor 2001; Lupton 2013; Lupton 2015; Schicktanz and Schweda, 2021).

This suggests that ethical reflections regarding the use of HMWDs should consider not only the technological tools themselves, but also the socio-economic context in which they are implemented. The rhetoric of empowerment may be supporting this neoliberal shift (Schicktanz and Schweda, 2021). HMWDs have the potential to empower patients and to enhance their autonomy by facilitating self-management and providing access to health-related data (Lucivero and Jongsma, 2018; Canali et al. 2022; Canali et al. 2023). This could improve patients' knowledge, autonomy in decision-making, and ability to better plan one's care (Ott et al. 2023). Our results show the limitation of autonomy understood only as receiving quantified information and the consequent performing of tasks. In this context, further ethical reflection is necessary to better understand how the increasing availability of information can be used to truly enhance patients' autonomy and empowerment. It is crucial to ensure that the presumed neutrality of data does not undermine the significance of individuals' knowledge

of their own bodies (Lupton, 2015). Moreover, it is imperative to consider individuals' values, requirements, and objectives in relation to their health and life projects (Schermer, 2009).

Studies with patient-oriented outcomes could address the burden of HMWDs on patients and their needs regarding these technologies. Furthermore, it is important to consider the incorporation of HMWDs into infrastructures capable of providing supplementary services, such as staff capable of monitoring and intervening when aid is required. Otherwise, there is a clear risk that patients will be abandoned instead of receiving support.

These concerns regarding personal autonomy are consistent with the risk of patient dehumanization and datafication. The extensive availability of data and the excessive reliance on HMWDs have the potential to undermine the information reported to healthcare professionals by patients and family members, resulting in a reification of the disease and an underestimation of the psychosocial, relational, and spiritual aspects of individuals. These concerns may be particularly pertinent in light of the interaction between the utilization of HMWDs and telemedicine, which increases the physical distance between physicians and patients (DeClue, 2023). Communication, a thorough understanding of the patients and their past, as well as the caliber of personal interactions, are crucial factors for the foundation of the relationship's trust (Chandra, 2018). Recent research has also highlighted the importance of physical contact, which results in a sense of relaxation, trust, and cooperation. The loss of that contact might impact the patient-physician relationship by undermining trust and standards of care (Mangione et al., 2024). These considerations also prompt inquiries regarding a prospective scenario wherein the responsibilities of healthcare professionals may be largely delegated to artificial intelligence (Dalton-Brown, 2020).

There were no defined principles or clear indications with which to address these risks in the included articles, although some recommendations have been formulated, as reported in Supplementary Table 2. As suggested by Ott, «the use of SST [smart sensor technologies], often referred to as "high tech" and the human corporeality, their dependence on relationality in care settings, often referred to as "high touch", is not mutually exclusive but can enrich each other» (Ott et al. 2023).

Another important issue identified in this review is the unequal and unjust outcomes resulting from the implementation of HMWDs, i.e., risks of discrimination and marginalization, unequal distribution of benefits and resources, and unfair access to HMWDs. As previously discussed, genuine patient empowerment necessitates efforts that address structural inequalities rather than solely providing tools at the individual level (Schicktanz and Schweda, 2021). The effectiveness and real benefit of these tools, such as HMWDs, are too dependent on intersectional vulnerabilities. Even if the literature has identified the possibility of making healthcare more accessible as an expected benefit of HMWD use, permitting the monitoring of people who would not otherwise access healthcare services, failure

to address structural challenges may, on the contrary, exacerbate marginalization of certain populations (Lucivero and Jongsma, 2018). In fact, the risks highlighted in our review disproportionately affect disadvantaged populations, who may have less awareness of the dangers associated with HMWDs and fewer tools to mitigate the adverse impacts of this technology.

The main concern regarding justice was access to HMWDs. Three articles mention the problem of the digital divide (Nakazawa et al. 2021; Canali et al. 2022; Psihogios et al. 2024). Such a concept was initially developed to refer to inequitable access to computers and the internet, and later extended to include differences in digital skills and digital usage (Lythreatis et al. 2022). It is of great importance to address the digital divide and understand how it intersects with existing inequalities to ensure health rights and benefits across different populations (Saeed and Masters, 2021).

It should be noted that this review did not uncover any discussions regarding the ecological aspect, including the energy consumption associated with these devices or the necessity to cater for battery life cycle and global warming concerns (Habibipour et al., 2019). This theme deserves further exploration, especially considering how the burden of care may extend to non-human entities and the environment.

All the included articles emphasized the importance of privacy protection, but we found little thorough elaboration on this point. The articles discussed risks such as data breaches and commercial exploitation, and identified factors that may challenge data security. Nevertheless, there was limited discussion regarding the ethical or legal implications of these risks. The ambiguity between the commercial and healthcare domains is important, but has received little attention. The public research sector could benefit from the private sector's infrastructure and expertise. At the same time, collaboration with public research institutes may encourage people to trust and share data with private companies (Predel and Steger, 2021). Nonetheless, conflicts may arise regarding data ownership and usage, which may result in reduced transparency and accessibility (Breslin et al. 2019; Sui et al. 2023). It has been argued that private companies may utilize data for non-health-related purposes, disseminate it to third parties, and if private companies own data sets, public research may become dependent on them (Predel and Steger, 2021; Tu and Gao 2021; Sui et al. 2023). This is why it is crucial to both raise companies' awareness of their social responsibilities (Predel and Steger, 2021) and inform patients on how their data will be used (Predel and Steger, 2021).

Our review has also revealed certain risks associated with the utilization of HMWDs that are frequently overlooked. The emotional distress risk of HMWD users may be underappreciated, but physicians should at least conduct an informal risk-benefit assessment. In addition to the physical, biological, and chemical hazards, a significant concern is the potential unreliability of HMWD technology, which could potentially cause harm to users. This concern requires more rigorous and

large-scale studies to evaluate the true benefits of HMWDs in terms of individual health outcomes and healthcare systems, including research into their impact in real-world settings (Qu and Gao, 2020; Ulrich et al., 2020; Tu and Gao 2021; Canali et al. 2022).

The main ethical issues in the research context concern the informed consent process. It is plausible that individuals may lack comprehension regarding the functioning of HMWDs and the consequences of their utilization in terms of protection and benefits. Furthermore, people may not be aware of the privacy risks associated with HMWDs (Lucivero and Jongsma, 2018; Psihogios et al. 2024), which suggests that a dynamic and personalized approach should be adopted (Ulrich et al. 2020). These considerations align with concerns regarding potential risks to autonomy discussed previously, suggesting that some effort is needed to foster user awareness of the implications of HMWD use both in clinical and research settings. Finally, our review highlights the need for ethical guidelines for research in the field of HMWDs and the necessity to improve the experience and expertise of the institutional review board (IRB) regarding privacy risks.

It is important for IRBs to be able to cope with the evolution of research methodologies and emerging technologies in a new field where there are no clear standards or best practices (Torous and Weiss Roberts, 2017). From this perspective, the literature highlights the importance of sharing knowledge, improving the standardization of review practices, enhancing training for IRB members with accreditation of review boards, and investing resources to improve the IRB system (Torous and Weiss Roberts, 2017; Peute et al., 2020).

The legal aspects that emerged from our scoping review were limited, but they concerned some important topics. Our review identified the need to update the current legal framework to address the challenges posed by these new technologies, especially regarding the adoption of measures that protect users from discrimination, inequalities in contractual relationships, and privacy violations (Grigorovich et al. 2020; Ulrich et al. 2020; Nakazawa et al. 2021; DeClue 2023). Furthermore, the utilization of HMWDs renders the matter of liability more intricate, rendering it imperative to establish precise legal provisions defining the parameters and standards utilized to determine liability in this particular domain.

Limitations regarding legal and regulatory frameworks may reflect the fact that most recommendations were developed for medical devices in general and do not account for the specificities of HMWDs. Beyond the aforementioned WHO and U.S. FDA guidelines, regulatory frameworks that may apply to the manufacturing and use of HMWDs among other medical devices are present in several other countries, such as Australia (TGA, 1989; 2002), Brazil (ANVISA, 1976; 2022), China (NMPA, 2021a; 2021b), India (CDSCO, 2017), and Russia (Roszdravnadzor, 2011; 2012). Currently, the African Union Development Agency (AUDA-NEPAD) is promoting

harmonized standards for medicines, including medical devices, across Africa via the African Medicines Regulatory Harmonization (AMRH) initiative. Finally, the EU MDR 2017/745 has established strict standards for medical devices, requiring evidence of safety, efficacy, and data management in order for CE marking to be granted, with a focus on data protection and cybersecurity, in conjunction with the General Data Protection Regulation (GDPR) and recent Data Act and AI Act (Ravizza et al., 2019; Bouderhem, 2023). Considering this overview and the widespread adoption of HMWDs, we deem it essential to promote global efforts toward the standardization of specific regulatory policies. Finally, despite the literature highlighting the potential benefits of these tools, especially for older adults, this review revealed scarce attention toward this population and few, albeit significant, concerns. Fostering wide accessibility of HMWDs to older adults should not become a form of pressure to use them (Sundgren et al., 2020), even when they are considered a desirable solution by healthcare providers or family caregivers. Few studies have considered older adults' perspectives on smart/wearable technology, including ethical issues that they may experience as users (Ji and Kim, 2022) and their attitudes and willingness toward the healthcare providers collecting and using their digital data (Chandrasekaran et al., 2021; Fowe and Boot, 2022). For better implementation of HMWDs that respects both the autonomy and the access to health of older adults, a deeper understanding of their perspective is needed, and studies adopting qualitative research designs and ethnographic approaches from different cultures and countries should be encouraged.

Limitations and strengths

The present review has some limitations. A global ethical perspective led us to exclude articles referring to local regulations, thus excluding almost all legal documents. Additionally, we searched only two legal databases. These restrictions might have caused some important information to be missed. Therefore, our review of the legal implications of HMWDs should be considered as a preliminary outline and should be further explored in future studies. The exclusion of books, dissertations, theses, and conference proceedings, as well as non-peer reviewed sources and literature not written in English, may have resulted in the exclusion of pertinent information and in a limitation of the diversity of viewpoints on ethical concerns regarding the use of HMWDs. We included only English written texts both because of resource constraints and to ensure the broadest replicability and accessibility of the reviewed materials. Our search strategy provided articles written by authors from 4 continents and at least nine different countries, including non-English-speaking nations such as China, Germany, Italy, Japan, and the Netherlands. Nonetheless, we recognize that our analysis lacks viewpoints from Africa and large regions such as South America, which may limit the global comprehensiveness of our findings. Additionally, our review focused on argument-based literature,

excluding empirical studies. This may have resulted in the disregard of ethical and legal implications of HMWDs that are derived from patients, caregivers, and policymakers. Finally, it is possible that the background, competence, and subjectivity of the researchers may have influenced data extraction, potentially influencing the interpretation of findings. As a measure of mitigation, the review team comprised authors from diverse backgrounds who frequently engaged in dialogue.

The strengths of our study were the rigorous methodological approach, the simultaneous utilization of multiple databases from diverse disciplines, the multidisciplinary research team, and the precise definition of HMWDs addressed by the review.

Future perspectives

The results of this review highlight that most of the articles addressing the ethical implications of HMWDs lack a clear theoretical perspective, with the consequence that recommendations and strategies to address the ethical concerns outlined are sparse or lack a consistent ethical framework. Therefore, we wondered which of the most widely recognized ethical theories better address the ethical issues raised in our review.

Utilitarianism could provide an initial approach to evaluate the consequences of adopting HMWDs, focusing on the potential overall benefits for the greatest number of people. Within this framework, HMWDs can be seen as tools to enhance global well-being, facilitating the prevention and management of diseases. However, it does not adequately consider the duration or distribution of the benefits. Limits of this approach include failing to account for both minorities and individuals who do not fall within the benefited majority, and overlooking long-term effects, considering that the potential to predict consequences is inherently limited. Moreover, applying a utilitarian approach to global contexts can be problematic, as what constitutes overall benefits varies across cultures.

On the other hand, addressing issues related to individual freedom and data protection might encourage the adoption of an individualistic, rights-based theoretical approach in addressing the ethical issues posed by the use of HMWDs. However, a focus merely on data-related rights might present the risk of underestimating the broader impact of datafication in healthcare, as well as certain of privacy and commercial concerns (e.g., profiling), issues which are difficult to address within a strictly individualistic framework. Moreover, an ethical approach such as this often overlooks the relational and collective implications associated with the use of HMWDs, and cannot be applied to many cultural contexts. HMWDs are increasingly being used in both developed and developing countries, necessitating a discussion of the specific ethical concerns in different application contexts, since the target population of HMWDs varies from country to country and from context to context. In this regard, our results show that the impact of HMWDs on a population does not depend only on

the economic means to access technology, but also on the surveillance concerns and mistrust that marginalized and stigmatized populations may experience. Recognizing these layered vulnerabilities suggest that it is necessary to adopt an ethical framework that considers resource distribution as well as the broader socio-political forces shaping access, experiences, and consequences regarding the implementation of digital health technologies.

It was recently suggested that discussions on technology-mediated care could greatly benefit from a cohesive ethics of care framework (Ramvi et al., 2021). With regard to HMWDs, the ethics of care may be useful to address the risk of dehumanization and datafication of the patient, by adopting a holistic conception of care that does not overlook the socio-emotional aspects of the patient. Moreover, this approach recognises the burdens and vulnerabilities that may be borne by healthcare personnel (Ramvi et al., 2021). However, the ethics of care framework may be less suitable to address some of the important issues raised in this work concerning the protection of personal data or justice. On the other hand, principlism could serve as a general guide framework, since most of the issues emerging from the review can be subsumed in the four principles of autonomy, beneficence, non-maleficence, and justice. For example, it provides tools with which to address the possible criticisms concerning the older adult-caregiver relationship that emerged from our review. Our results highlight the issue that family caregivers, especially those supporting older adults with dementia or cognitive impairments, may rely on HMWDs to reduce the burden of supervision. This can lead to caregivers pressuring older adults to accept these devices or making decisions on their behalf (Boyle, 2014). The multifaceted implications concerning the respect for and promotion of autonomy in relation to HMWD use are one of the central topics of this review. Principlism addresses such scenarios by first defining criteria to assess a person's decision-making capacity, including empirical tests. When a patient loses capacity, if they previously left advanced directives or designated someone to decide for them, the autonomy-based standard applies, ensuring that the patient's previously stated wishes are respected. In the absence of such directives, the best interest standard is used, requiring decisions aimed at maximizing the patient's well-being based on objective assessments, including physical suffering and medical diagnosis. In all cases, family members may assist in interpreting the patient's values and preferences (Beauchamp and Childress, 1999). A different situation involves older adults who are heavily dependent on family caregivers but still competent. Here, personal autonomy should prevail, even if the older adult refuses HMWDs that family caregivers or healthcare providers consider beneficial. However, capacity is a binary (all-or-nothing) condition in few situations. In many cases, a relational account for autonomy recognizes that autonomy is a dynamic and graded process and that decision-making encompasses not only rational capacity, but also emotions, bodily experiences, and relationships (Gómez-Vírseda et al., 2020). From this perspective, the older adult-

caregiver relationship should be viewed as a partnership that supports the older adult's preferences throughout the illness, including their decisions about HMWDs.

Finally, similarly to other western ethical frameworks, principlism may require adaptation to local moralities and cultural values through a dialectical process that balances universal demands with cultural specificity (Gordon, 2011). For instance, in several countries a notion of family/community autonomy may be more suitable than that of individual autonomy. In another context, such as in an Asian Confucian-influenced society, it is the family members who ordinarily decide whether a medical act will be performed or whether to reveal unfortunate news to the patient. Even if moderated during the past few years, this "family autonomy" is still valid, especially in the case of older patients (Zhao et al., 2015; Raposo, 2019). Similarly, in African communities, autonomy is deeply rooted in relational dynamics and communal values. Here collective interests take precedence, and decisions are made collectively, sometimes requiring authorization from the community leader (Tindana et al., 2006; Akpa-Inyang and Chima, 2021).

With this caveat, and considering its widespread knowledge and application, principlism seems to be the most suitable ethical approach with which to address this issue at the moment. Adopting this ethical approach, and following the outlined framework as well as the review results, in Table 4 we summarize measures to address the ethical concerns of HMWDs. In particular, we propose some key goals for each principle, along with the suggested actions each relevant actor(s) should take to implement them. Indeed, our results highlight evidence that responsible use of HMWDs requires cooperation among all relevant stakeholders to maximize health benefits while minimizing the risks connected with HMWDs.

Table 4: Summary of measures to address the ethical concerns of HMWDs.

Key goals	Relevant actor(s)	Suggested actions/implementation steps
Autonomy		
Ensure understandable, transparent, dynamic, and context-specific informed consent and privacy policy	Device developers and manufacturers	Develop user-friendly interface designs Disclose potential for commercial profit deriving from exploitation of user data
	Healthcare providers	Offer explanations regarding functioning, scope, and data collection and use Adopt a dynamic consent approach Promote shared decision making in HMWD use
	Policymakers	Establish guidelines for informed consent and privacy policy
Ensure comprehensive transparency and awareness regarding data and self-monitoring practices	Device developers and manufacturers	Develop tools that allow users to track data use for both clinical and commercial purposes
	Healthcare providers	Provide patient and caregivers with education on the correct use of HMWDs for self-monitoring Offer support in health data interpretation

	Policymakers and educational institutions	Promote digital literacy among users (e.g., public awareness campaigns; digital literacy programs) Establish regulatory standards that guarantee that the users have control over their data circulation
Ensure privacy and personal data protection	Device developers and manufacturers	Ensure robust security features and minimize risk of cyber-attacks
	Legislators	Develop data protection regulation ad hoc for HMWDs
Beneficence		
Ensure health benefits and patient-oriented outcomes in research	Researchers, Device developers	Prioritize evidence of benefits and patient-oriented outcomes Investigate perceptions and preferences of patients, caregivers, and clinicians
Integrate HMWDs into a well-informed healthcare system	Policymakers	Integrate HMWDs into a supportive healthcare network, ensuring timely and appropriate responses
Account for contextual and user-specific adaptation needs	Device developers	Ensure feasibility for the user to personalize HMWD functions and user interfaces Ensure HMWD support for ecological momentary assessments and interventions
	Healthcare providers	Interpret HMWD data in conjunction with patients' and caregivers' reports and clinical findings (when needed)
Non maleficence		
Prevent hazards for users	Device developers and manufacturers	Ensure post-market monitoring, periodic compliance checks, regular updates, and user-friendly maintenance protocols to enhance safety and optimize performance
Prevent risk for datafication and self-surveillance behaviors	Healthcare providers	Avoid undervaluing information provided by patients and family Assess the risk of emotional distress (e.g., social isolation) and monitor for signs of excessive surveillance
Justice		
Ensure equitable and inclusive access, sustainability, and supply	Policymakers, Healthcare Systems, Vendors	Ensure devices, replacement parts, and software updates are affordable and accessible Address cultural specificities and intersectional vulnerabilities
	Device developers	Ensure effectiveness and usability across diverse demographics, and cultural, economic, and geographic differences
Prevent discriminatory data use	Policymakers, Legislators	Implement strict policies and laws to ensure data is not used for discriminatory practices or profiling
Minimize environmental impact and promote sustainability across the lifecycle of HMWDs	Policymakers, Legislators, Device Developers and Manufacturers,	Adopt environmentally responsible materials and sustainable design principles to reduce waste, ensure components are recyclable, and extend product lifecycle

Conclusions

This scoping review highlights the fact that the use of HMWDs raises several complex ethical questions, while revealing scarce investigations into legal questions and a general lack of clear theoretical bases for conducting such analyses. Although we narrowed the review focus to devices used for medical purposes under the supervision of healthcare providers, we revealed a wide

variability in how HMWDs are defined and a trend to consider devices that are very different and have different implications, e.g., ECG Holters and position trackers.

Hence, it is imperative to establish a consensus on a taxonomy for HMWDs and enhance the theoretical foundation in the domain of ethics applicable to these medical technologies, both through a more rigorous implementation of existing theories and concepts and through the development of novel reflections. Furthermore, this examination emphasizes the necessity to build legal provisions to cater to the peculiarities of these novel technologies, as the present regulatory frameworks may be partially inadequate.

If the implementation of HMWDs continues without addressing these emerging concerns, it could result in a dehumanization and datafication of care relationships and further marginalization of more vulnerable populations. It is important to consider the risks of these technologies at every stage of design, development, and use. It is also crucial to involve patients and citizens in order to understand how to maximize the benefits of HMWDs while addressing their limitations.

This scoping review provides material to promote further reflection on the topic and to serve as a reference for researchers and guideline developers.

References

1. African Union Development Agency (AUDA-NEPAD), African Medicines Regulatory Harmonization (AMRH) initiative.
2. Agência Nacional de Vigilância Sanitária (ANVISA), Brazil, March 30, 2022, RDC No. 665.
3. Agência Nacional de Vigilância Sanitária (ANVISA), Brazil, September 23, 1976, Federal Law No. 6.360.
4. Akpa-Inyang, F., Chima, S. C., 2021. South African traditional values and beliefs regarding informed consent and limitations of the principle of respect for autonomy in African communities: A cross-cultural qualitative study. BMC Medical Ethics, 22(111). https://doi.org/10.1186/s12910-021-00678-4.
5. Amft, O., Lukowicz, P., 2009. From backpacks to smartphones: Past, present, and future of wearable computers. IEEE Pervasive Comput. 8, 8–13. https://doi.org/10.1109/MPRV.2009.82.
6. Beauchamp, T.L, Childress, J.F., 1989. Principles of biomedical ethics, 4th edition, Oxford.
7. Bouderhem, R., 2023. Privacy and Regulatory Issues in Wearable Health Technology. Engineering Proceedings, 58(1), 87. https://doi.org/10.3390/ecsa-10-16206.

8. Boyle, G., 2014. Recognising the agency of people with dementia. Disability & Society, 29:7, 1130-1144. https://doi.org/10.1080/09687599.2014.910108.
9. Brannon, G.E., Mitchell, S., Liao, Y., 2022. Addressing privacy concerns for mobile and wearable devices sensors: Small-group interviews with healthy adults and cancer survivors. PEC Innovation 1, 100012. https://doi.org/10.1016/j.pecinn.2022.100012.
10. Breslin, S., Shareck, M., Fuller, D., 2019. Research ethics for mobile sensing device use by vulnerable populations. Soc. Sci. Med. 232, 50–57. https://doi.org/10.1016/j.socscimed.2019.04.035.
11. Canali, S., De Marchi, B., Aliverti, A., 2023. Wearable Technologies and Stress: Toward an Ethically Grounded Approach. Int. J. Environ. Res. Public Health 20, 4077. https://doi.org/10.3390/ijerph20054077.
12. Canali, S., Schiaffonati, V., Aliverti, A., 2022. Challenges and recommendations for wearable devices in digital health: Data quality, interoperability, health equity, fairness. PLOS Digit. Health 1, e0000104. https://doi.org/10.1371/journal.pdig.0000104.
13. Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Government of India, 2017, Medical Device Rules.
14. Chandra, S., Mohammadnezhad, M., Ward, P., 2018. Trust and Communication in a Doctor-Patient Relationship: A Literature Review. J. Healthc. Commun. 3, 36. https://doi.org/10.4172/2472-1654.100136.
15. Chandrasekaran, R., Katthula, V., Moustakas, E., 2021. Too old for technology? Use of wearable healthcare devices by older adults and their willingness to share health data with providers. Health Inform. J. 27, 14604582211058073. https://doi.org/10.1177/14604582211058073.
16. Chen, C., Ding, S., Wang, J., 2023. Digital health for aging populations. Nat. Med. 29, 1623–1630. https://doi.org/10.1038/s41591-023-02391-8.
17. Chen, M., Wang, H., Yu, L., Yeung, E.H.K., Luo, J., Tsui, K.L., & Zhao, Y., 2022. A Systematic Review of Wearable Sensor-Based Technologies for Fall Risk Assessment in Older Adults. Sensors 22, 6752. https://doi.org/10.3390/s22186752.
18. Chow, R., Drkulec, H., Im, J. H. B., Tsai, J., Nafees, A., Kumar, S., Hou, T., Fazelzad, R., Leighl, N. B., Krzyzanowska, M., Wong, P., & Raman, S., 2024. The Use of Wearable Devices in Oncology Patients: A Systematic Review. Oncologist 29, e419–e430. https://doi.org/10.1093/oncolo/oyad305.
19. Dalton-Brown, S., 2020. The Ethics of Medical AI and the Physician-Patient Relationship. Camb. Q. Healthc. Ethics 29, 115–121. https://doi.org/10.1017/S0963180119000847.

20. DeClue, P., 2023. Health Monitoring From Home: Legal Considerations of Wearable Technology in Telemedicine. SMU Sci. Technol. Law Rev. 26, 111.
21. Farivar, S., Abouzahra, M., Ghasemaghaei, M., 2020. Wearable device adoption among older adults: A mixed-methods study. Int. J. Inf. Manage. 55, 102209. https://doi.org/10.1016/j.ijinfomgt.2020.102209.
22. Fowe, I.E., Boot, W.R., 2022. Understanding older adults' attitudes toward mobile and wearable technologies to support health and cognition. Front. Psychol. 13, 1036092. https://doi.org/10.3389/fpsyg.2022.1036092.
23. Gómez-Vírseda, C., de Maeseneer, Y., Gastmans, C., 2020. Relational autonomy in end-of-life care ethics: A contextualized approach to real-life complexities. BMC Medical Ethics, 21(50). https://doi.org/10.1186/s12910-020-00495-1.
24. Gordon, J.S., 2011. Global ethics and Principlism. Kennedy Institute of Ethics Journal, 21(3), 251-276.
25. Grigorovich, A., Kontos, P., Meeks, S., 2020. Towards Responsible Implementation of Monitoring Technologies in Institutional Care. Gerontologist 60, 1194–1201. https://doi.org/10.1093/geront/gnaa014.
26. Habibipour, A., Padyab, A., Ståhlbröst, A., 2019. Social, Ethical and Ecological Issues in Wearable Technologies. Twenty-fifth Americas Conference on Information Systems, Cancun, 2019.
27. Howes, J., Gastmans, C., 2021. Electronic tracking devices in dementia care: A systematic review of argument-based ethics literature. Arch. Gerontol. Geriatr. 95, 104419. https://doi.org/10.1016/j.archger.2021.104419.
28. Iqbal, M.H., Aydin, A., Brunckhorst, O., Dasgupta, P., Ahmed, K., 2016. A review of wearable technology in medicine. J. R. Soc. Med. 109, 372–380. https://doi.org/10.1177/0141076816663560.
29. Ji, Y.A., Kim, H.S., 2022. Scoping Review of the Literature on Smart Healthcare for Older Adults. Yonsei Med. J. 63, S14–S21. https://doi.org/10.3349/ymj.2022.63.S14.
30. Kahrass, H., Borry, P., Gastmans, C., Ives, J., van der Graaf, R., Strech, D., Mertz, M., 2023. RESERVE - REporting of SystEmatic ReViews in Ethics: development, explanations and examples. Bioethics Open Res. 1, 4. https://doi.org/10.12688/bioethicsopenres.13421.2.
31. Liang, J.M., Su, W.C., Chen, Y.L., Wu, S.L., Chen, J.J., 2019. Smart interactive education system based on wearable devices. Sensors 19, 2042. https://doi.org/10.3390/s19092042.

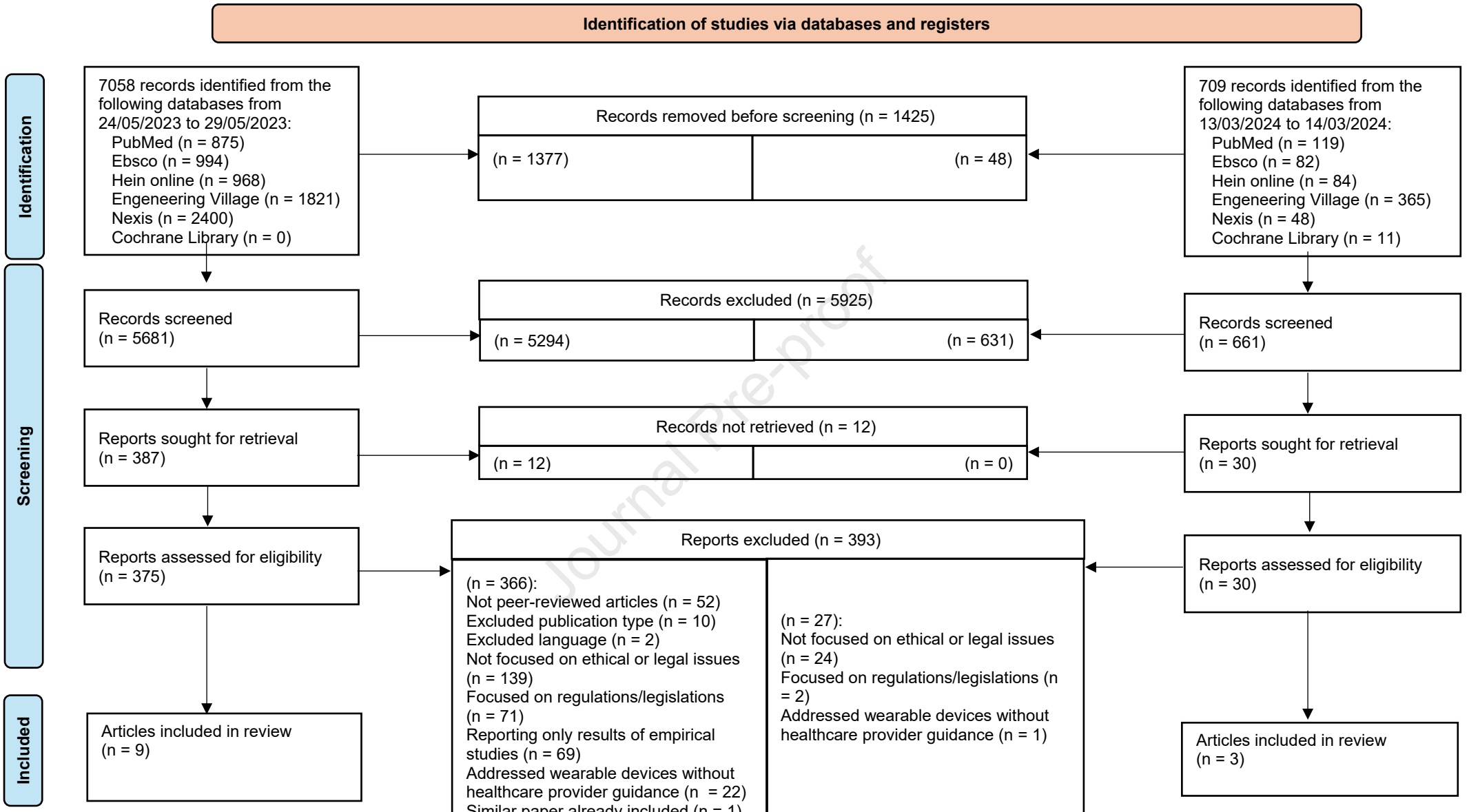
32. Lu, L., Zhang, J., Xie, Y., Gao, F., Xu, S., Wu, X., Ye, Z., 2020. Wearable health devices in health care: Narrative systematic review. JMIR Mhealth Uhealth 8, e18907. https://doi.org/10.2196/18907.
33. Lucivero, F., Jongsma, K.R., 2018. A mobile revolution for healthcare? Setting the agenda for bioethics. J. Med. Ethics 44, 685–689. https://doi.org/10.1136/medethics-2017-104741.
34. Lupton, D., 2013. The digitally engaged patient: Self-monitoring and self-care in the digital health era. Soc. Theory Health 11, 256–270. https://doi.org/10.1057/sth.2013.10.
35. Lupton, D., 2015. Quantified sex: a critical analysis of sexual and reproductive self-tracking using apps. Cult. Health Sex. 17, 440–453. https://doi.org/10.1080/13691058.2014.920528.
36. Lupton, D., 2020. A more-than-human approach to bioethics: The example of digital health. Bioethics 34, 969–976. https://doi.org/10.1111/bioe.12764.
37. Lythreatis, S., Singh, S.K., El-Kassar, A.N., 2022. The digital divide: A review and future research agenda. Technol. Forecast. Soc. Change 175, 121348. https://doi.org/10.1016/j.techfore.2021.121348.
38. Mangione, S., Basile, M., Post, S.G., 2024. Out of Touch. JAMA 331, 729–730. https://doi.org/10.1001/jama.2024.0888.
39. Martinez-Martin, N., Luo, Z., Kaushal, A., Adeli, E., Haque, A., Kelly, S. S., Wieten, S., Cho, M. K., Magnus, D., Fei-Fei, L., Schulman, K., Milstein, A., 2021. Ethical issues in using ambient intelligence in health-care settings. Lancet Digit. Health 3, e115–e123. https://doi.org/10.1016/S2589-7500(20)30275-2.
40. Masoumian Hosseini, M., Masoumian Hosseini, S.T., Qayumi, K., Hosseinzadeh, S., Sajadi Tabar, S.S., 2023. Smartwatches in healthcare medicine: assistance and monitoring; a scoping review. BMC Med. Inform. Decis. Mak. 23, 2. https://doi.org/10.1186/s12911-022-02103-8.
41. McGregor, S., 2001. Neoliberalism and health care. Int. J. Consum. Stud. 25, 82–89. https://doi.org/10.1111/j.1470-6431.2001.00183.x.
42. Nakazawa, E., Yamamoto, K., London, A.J., Akabayashi, A., 2022. Informed Consent for the Use of Wearable Devices for Personal Health Data Collection: Considerations from an Ethics and Policy Perspective. J. Gen. Intern. Med. 37, 2477–2482. https://doi.org/10.1007/s11606-022-07652-y.
43. National Medical Products Administration (NMPA), China, 2021a, Provisions for Medical Device Registration and Filing.
44. National Medical Products Administration (NMPA), China, 2021b, Regulations on Supervision and Administration of Medical Devices.

45. Olsen, R.J., Hasan, S.S., Woo, J.J., Nawabi, D.H., Ramkumar, P.N., 2024. The Fundamentals and Applications of Wearable Sensor Devices in Sports Medicine: A Scoping Review. Arthroscopy 40, 51–67. https://doi.org/10.1016/j.arthro.2024.01.042.
46. Ott, T., Heckel, M., Öhl, N., Steigleder, T., Albrecht, N.C., Ostgathe, C., Dabrock, P., 2023. Palliative care and new technologies. The use of smart sensor technologies and its impact on the Total Care principle. BMC Palliative Care 22, 101–115. https://doi.org/10.1186/s12904-023-01174-9.
47. Peute, L.W., Lichtner, V., Baysari, M. T., Hägglund, M., Homco, J., Jansen-Kosterink, S., Jauregui, I., Kaipio, J., Kuziemsky, C. E., Lehnbom, E. C., Leite, F., Lesselroth, B., Luna, D., Otero, C., Pedersen, R., Pelayo, S., Santos, R., Silva, N. A., Tyllinen, M., Van Velsen, L., Marcilly, R., 2020. Challenges and Best Practices in Ethical Review of Human and Organizational Factors Studies in Health Technology: A Synthesis of Testimonies. Yearbook of Medical Informatics 29, 58–70. https://doi.org/10.1055/s-0040-1701979.
48. Piau, A., Steinmeyer, Z., Mattek, N., Lindauer, A., Sharma, N., Bouranis, N., Wild, K., & Kaye, J., 2023. Caregiving in Older Adults; Experiences and Attitudes toward Smart Technologies. Journal of Clinical Medicine 12, 1789. https://doi.org/10.3390/jcm12051789.
49. Predel, C., Steger, F., 2021. Ethical Challenges With Smartwatch-Based Screening for Atrial Fibrillation: Putting Users at Risk for Marketing Purposes? Frontiers in Cardiovascular Medicine 7, 63–75.
50. Psihogios, A.M., King-Dowling, S., Mitchell, J.A., McGrady, M.E., Williamson, A.A., 2024. Ethical Considerations in Using Sensors to Remotely Assess Pediatric Health Behaviors. American Psychologist 79, 39–51.
51. Qu, S., Gao, X., 2020. Analysis of Ethical Issues Involved in Wearable Equipment for Health Care. In: Proceedings - 2020 International Conference on Public Health and Data Science, ICPHDS 2020, pp. 406–410. Institute of Electrical and Electronics Engineers Inc. https://doi.org/10.1109/ICPHDS51617.2020.00087.
52. Ramvi, E., Gripsurd, B.H., Hellstrand, I., Gjerstad, B., Vagli, A.E., 2021. CARING FUTURES: a study protocol for transdisciplinary qualitative research on technology-mediated care practices and theory development for ethics of care. BMJ Open, 11. https://doi.org/10.1136/bmjopen-2021-054458.
53. Raposo, V. L., 2019. Lost in 'culturation': Medical informed consent in China (from a Western perspective). Medicine, Health Care and Philosophy, 22(1), 17–30. https://doi.org/10.1007/s11019-018-9835-0.

54. Ravizza, A., De Maria, C., Di Pietro, L., Sternini, F., Audenino, A.L., Bignardi, C., 2019. Comprehensive Review on Current and Future Regulatory Requirements on Wearable Sensors in Preclinical and Clinical Testing. Frontiers in Bioengineering and Biotechnology, 7, 313. https://doi.org/10.3389/fbioe.2019.00313.
55. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance).
56. Roszdravnadzor - Federal Service for Surveillance in Healthcare, Russia, November 21, 2011, Federal Law No. 323-FZ.
57. Roszdravnadzor - Federal Service for Surveillance in Healthcare, Russia, December 27, 2012, Government Decree No. 1416.
58. Ruckenstein, M., Dow, N., Schüll, S.S., 2017. The Datafication of Health. Annual Review of Anthropology 46, 261–278.
59. Saeed, S.A., Masters, R.M., 2021. Disparities in Health Care and the Digital Divide. Psychiatry in the Digital Age. https://doi.org/10.1007/s11920-021-01274-4/Published.
60. Scheit, L., 2021. Optimizing the Introduction of Wearable Sensors into the German Armed Forces for Military Medical Applications. Military Medicine 186, 962–968.
61. Schermer, M., 2009. Telecare and self-management: Opportunity to change the paradigm? Journal of Medical Ethics 35, 688–691.
62. Schicktanz, S., Schweda, M., 2021. Aging 4.0? Rethinking the ethical framing of technology-assisted eldercare. History and Philosophy of Life Sciences 43, 1–13.
63. Segura Anaya, L.H., Alsadoon, A., Costadopoulos, N., Prasad, P.W.C., 2018. Ethical Implications of User Perceptions of Wearable Devices. Science and Engineering Ethics 24, 643–664. https://doi.org/10.1007/s11948-017-9872-8.
64. Seneviratne, S., et al., 2017. A Survey of Wearable Devices and Challenges. IEEE Communications Surveys and Tutorials 19, 2573–2620. https://doi.org/10.1109/COMST.2017.2731979.
65. South African Health Products Regulatory Authority (SAHPRA), 1965, Medicines and Related Substances Act (Act 101).
66. South African Health Products Regulatory Authority (SAHPRA), December 9, 2016, Government Gazette No. 40480, Regulations Relating to Medical Devices and In Vitro Diagnostic Medical Devices (December 9, 2016).

67. Stepanovic, S., Mettler, T., 2022. Safe return to the workplace: Perceived opportunities and threats in the use of health surveillance technologies in public administrations. In: ACM International Conference Proceeding Series, pp. 328–335. Association for Computing Machinery. https://doi.org/10.1145/3543434.3543435.
68. Sui, A., Sui, W., Liu, S., Rhodes, R., 2023. Ethical considerations for the use of consumer wearables in health research. Digital Health 9, 20552076231153740. https://doi.org/10.1177/20552076231153740.
69. Sundgren, S., Stolt, M., Suhonen, R., 2020. Ethical issues related to the use of gerontechnology in older people care: A scoping review. Nursing Ethics 27, 88–103. https://doi.org/10.1177/0969733019845132.
70. Teixeira, E., Fonseca, H., Diniz-Sousa, F., Veras, L., Boppre, G., Oliveira, J., Pinto, D., Alves, A. J., Barbosa, A., Mendes, R., Marques-Aleixo, I., 2021. Wearable Devices for Physical Activity and Healthcare Monitoring in Elderly People: A Critical Review. Geriatrics (Basel, Switzerland) 6, 38. https://doi.org/10.3390/geriatrics6020038.
71. Therapeutic Goods Administration, Department of Health (TGA), Government of Australia, 1989, Therapeutic Goods Act.
72. Therapeutic Goods Administration, Department of Health (TGA), Government of Australia, 2002, Therapeutic Goods Regulations.
73. Tindana, P. O., Kass, N., & Akweongo, P., 2006. The informed consent process in a rural African setting: A case study of the Kassena-Nankana District of Northern Ghana. IRB: Ethics & Human Research, 28(3), 1–6.
74. Torous, J., Roberts, L.W., 2017. The Ethical Use of Mobile Health Technology in Clinical Psychiatry. The Journal of Nervous and Mental Disease 205, 4–8. https://doi.org/10.1097/NMD.0000000000000596.
75. Tricco, A.C., Lillie, E., Zarin, W., O'Brien, K., Colquhoun, H., Levac, D., Moher, D., Peters, M.D.J., Horsley, T., Weeks, L., Hempel, S., Akl, E.A., Chang, C., McGowan, J., Stewart, L., Hartling, L., Aldcroft, A., Wilson, M.G., Garritty, C., Lewin, S., Godfrey, C., Macdonald, M.T., Langlois, E.V., Soares-Weiser, K., Moriarty, J., Clifford, T.; Tuncalp, O., Straus, S.E., 2018. PRISMA extension for scoping reviews (PRISMA-ScR): Checklist and explanation. Annals of Internal Medicine 169, 467–473. https://doi.org/10.7326/M18-0850.
76. Tu, J., Gao, W., 2021. Ethical Considerations of Wearable Technologies in Human Research. Advanced Healthcare Materials 10, 2000852.
77. U.S. Food and Drug Administration (US-FDA), 2022. Policy for Device Software Functions and Mobile Medical Applications. FDA, September 28.

78. U.S. Food and Drug Administration (US-FDA), 2023. Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring. FDA, October 19.
79. U.S. Food and Drug Administration (US-FDA), 2024. Guidance for Industry: Use of Data Monitoring Committees in Clinical Trials. FDA, February.
80. Ulrich, C.M., Demiris, G., Kennedy, R., Rothwell, E., 2020. The ethics of sensor technology use in clinical research. Nursing Outlook 68, 720–726.
81. World Health Organization (WHO), 2017. WHO Global Model Regulatory Framework for Medical Devices Including In Vitro Diagnostic Medical Devices (WHO Medical Device Technical Series). Geneva: World Health Organization.
82. World Health Organization (WHO), 2020a. Guidance for Post-Market Surveillance and Market Surveillance of Medical Devices, Including In Vitro Diagnostics. Geneva: World Health Organization.
83. World Health Organization (WHO), 2020b. WHO Technical Guidance and Specifications of Medical Devices for Screening and Treatment of Precancerous Lesions in the Prevention of Cervical Cancer. Geneva: World Health Organization.
84. Zhang, C., Shahriar, H., 2020. The Adoption, Issues, and Challenges of Wearable Healthcare Technology for the Elderly. In: SIGITE 2020 - Proceedings of the 21st Annual Conference on Information Technology Education, pp. 50–53. Association for Computing Machinery, Inc. https://doi.org/10.1145/3368308.3415454.
85. Zhao, W., 2015. A Confucian worldview and family-based informed consent: A case of concealing illness from the patient in China. In: R. Fan (Ed.), Family-Oriented Informed Consent, pp. 231–251. Springer.



Highlights

- The use of health monitoring wearable devices raises several complex ethical issues
- These devices could deeply modify health systems and care relationships
- These issues should be considered by researchers and devices developers
- Clear theoretical bases and specific legal provisions are needed
- Patient and public involvement should be promoted